UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A
Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant ☒

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

☒ Definitive Proxy Statement

☐ Definitive Additional Materials

☐ Soliciting Material under §240.14a-12

Silverback Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Payment of Filing Fee (Check the appropriate box)

☐ No fee required

☒ Fee paid previously with preliminary materials

☐ Fee computed on table in exhibit required by Item 25(b) per Exchange Act Rules 14a-6(i)(1) and 0-11

PROPOSED MERGER
YOUR VOTE IS VERY IMPORTANT

To the Stockholders of Silverback Therapeutics, Inc.:

You are cordially invited to attend a virtual special meeting of the stockholders of Silverback Therapeutics, Inc., a Delaware corporation, which we refer to as "we", "Silverback", or the "Company", which will be held exclusively online via live audio-only webcast on November 4, 2022, at 10:00 a.m. Pacific Time, unless postponed or adjourned to a later date. This is an important meeting that affects your investment in Silverback.

Silverback and ARS Pharmaceuticals, Inc. ("ARS Pharma") have entered into an Agreement and Plan of Merger and Reorganization, dated July 21, 2022, as amended on August 11, 2022 (as it may be further amended from time to time, the "Merger Agreement"), pursuant to which a wholly owned subsidiary of Silverback will merge with and into ARS Pharma, with ARS Pharma surviving as a wholly owned subsidiary of Silverback (the "Merger"). The Merger will result in a biopharmaceutical company focused on the development and potential commercialization of a novel, potentially first-in-class product candidate, *neffy*, a no needle, no injection nasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis.

At the effective time of the Merger (the "Effective Time"), each outstanding share of common stock of ARS Pharma, $0.01 par value per share ("ARS Pharma Common Stock"), (after giving effect to the automatic conversion of all shares of preferred stock of ARS Pharma into shares of ARS Pharma Common Stock immediately prior to the Effective Time (the "Preferred Stock Conversion")) will be converted into the right to receive approximately 1.2441 shares of common stock of Silverback, $0.0001 par value per share ("Silverback Common Stock") based on an assumed exchange ratio of 1.2441, which is subject to certain adjustments, including based on Silverback's net cash at the closing of the Merger (the "Closing") (which net cash has been assumed to be $240 million for the purposes of calculating the assumed exchange ratio). Silverback will assume outstanding and unexercised options to purchase shares of ARS Pharma Common Stock, and in connection with the Merger they will be converted into options to purchase shares of Silverback Common Stock. Each warrant to purchase ARS Pharma Common Stock outstanding and unexercised immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion) will be assumed by Silverback and will become a warrant to purchase shares of Silverback Common Stock. At the Effective Time, Silverback's stockholders will continue to own and hold their then existing shares of Silverback Common Stock. All outstanding and unexercised options to purchase shares of Silverback Common Stock and all outstanding and unvested restricted stock units will remain outstanding to the extent they are not otherwise forfeited or, for restricted stock units, accelerated (and settled) in connection with the Merger.

Immediately after the Merger, assuming Silverback holds $240 million of net cash at Closing, the pre-Merger equity holders of ARS Pharma are expected to hold approximately 63% of the outstanding shares of Silverback Common Stock and the pre-Merger equity holders of Silverback are expected to hold approximately 37% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method. If Silverback holds less than $240 million of net cash at Closing, the pre-Merger equity holders of Silverback are expected to hold between 34% and 36% of the outstanding shares of Silverback Common Stock, and if Silverback holds more than $240 million of net cash at Closing, the pre-Merger equity holders of Silverback are expected to hold between 37% and 38% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method.

Shares of Silverback Common Stock are currently listed on The Nasdaq Global Market under the symbol "SBTX." Silverback has filed an initial listing application with The Nasdaq Stock Market LLC ("Nasdaq") pursuant to Nasdaq's "reverse merger" rules for the purposes of listing the shares of Silverback Common Stock issuable pursuant to the Merger. Substantially concurrent with the completion of the Merger, Silverback will be renamed "ARS Pharmaceuticals, Inc." and expects to trade on The Nasdaq Global Market under the symbol "SPRY". On October 5, 2022, the last trading day before the date of the attached proxy statement, the closing sale price of the Silverback Common Stock was $5.10 per share.

Silverback is holding a virtual special meeting of its stockholders (the "Silverback virtual special meeting") in order to obtain the stockholder approvals necessary to complete the Merger and related matters. In light of the continuing public health concerns regarding the COVID-19 pandemic, Silverback has chosen to hold an exclusively virtual special meeting rather than an in-person meeting to minimize the health and safety risks of holding an in-person meeting and to allow for greater access to those who may want to attend. Any stockholder entitled to attend and vote at the Silverback virtual special meeting is entitled to appoint a proxy to attend and vote on such stockholder's behalf. Such proxy need not be a holder of Silverback Common Stock. At the Silverback virtual special meeting, unless postponed or adjourned to a later date, Silverback will ask its holders of Silverback Common Stock to, among other things:

1. approve (i) the issuance of shares of Silverback Common Stock or other securities of Silverback pursuant to the Merger, which will represent (or are convertible into) more than 20% of the shares of Silverback Common Stock outstanding immediately prior to the Merger, and (ii) the change of control resulting from the Merger, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), respectively (the "Merger Proposal" or "Proposal No. 1"); and

2. approve a postponement or adjournment of the Silverback virtual special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal No. 1 (the "Adjournment Proposal" or "Proposal No. 2").

Please refer to the attached proxy statement for further information with respect to the business to be transacted at the Silverback virtual special meeting. As described in the accompanying proxy statement, certain of Silverback's stockholders who in the aggregate own approximately 31% of the shares of Silverback Common Stock outstanding as of immediately prior to the date of the Merger Agreement are parties to support agreements with ARS Pharma, whereby such stockholders have agreed to vote their shares in favor of the adoption or approval, among other things, of the Merger Agreement and the approval of the transactions contemplated therein, including the Merger and the Merger Proposal, subject to the terms of the support agreements.

After careful consideration, Silverback's board of directors has unanimously (i) determined that the Merger and the other transactions and actions contemplated by the Merger Agreement (the "Contemplated Transactions") are fair to, advisable and in the best interests of Silverback and its stockholders; (ii) approved and declared advisable the Merger Agreement and the Contemplated Transactions, including the issuance of shares of Silverback common stock to the stockholders of ARS Pharma and the change of control of Silverback; and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that the stockholders of Silverback vote "**FOR**" Proposal Nos. 1 and 2. More information about Silverback, ARS Pharma and the proposed transaction is contained in the accompanying proxy statement. Silverback urges you to read the accompanying proxy statement carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER "*RISK FACTORS*" BEGINNING ON PAGE 25.

Silverback is excited about the opportunities the Merger brings to its stockholders, and thanks you for your consideration and continued support.

Sincerely,

Jeffrey Pepe, Ph.D., J.D.
Interim Chief Executive Officer
Silverback Therapeutics, Inc.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved the Merger described in this proxy statement or the Silverback Common Stock to be issued in connection with the Merger or passed upon the adequacy or accuracy of this proxy statement. Any representation to the contrary is a criminal offense.

The accompanying proxy statement is dated October 6, 2022, and, together with the enclosed form of proxy card, is first being mailed to Silverback stockholders on or about October 7, 2022.

SILVERBACK THERAPEUTICS, INC.

500 Fairview Ave. N, Suite 600
Seattle, Washington 98109
(206) 456-2900

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS
TO BE HELD ON NOVEMBER 4, 2022

Dear Stockholder of Silverback:

On behalf of the board of directors of Silverback Therapeutics, Inc., a Delaware corporation ("Silverback"), we are pleased to deliver this proxy statement for a virtual special meeting of stockholders of Silverback (the "Silverback virtual special meeting"), for the proposed merger between Silverback and ARS Pharmaceuticals, Inc., a Delaware corporation ("ARS Pharma"), pursuant to which Sabre Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Silverback, will merge with and into ARS Pharma, with ARS Pharma surviving as a wholly owned subsidiary of Silverback (the "Merger").

Notice is hereby given that the Silverback virtual special meeting will be held on November 4, 2022, at 10:00 a.m. Pacific Time. In light of the continuing public health concerns regarding the COVID-19 pandemic, to protect the health and safety of our stockholders and employees and facilitate stockholder participation in the Silverback virtual special meeting, we have determined that the Silverback virtual special meeting will be held in a virtual meeting format only, via the internet, with no physical in-person meeting. You will be able to attend and participate in the Silverback virtual special meeting online by visiting www.proxydocs.com/SBTX to register for the meeting, where you will be able to listen to the meeting live, submit questions, and vote. To participate, vote or submit questions during the Silverback virtual special meeting via live webcast, you must register in advance at www.proxydocs.com/SBTX prior to the meeting. Please note that you will not be able to attend the Silverback virtual special meeting in person. Silverback is holding the Silverback virtual special meeting to consider the following proposals:

1. approve (i) the issuance of shares of common stock of Silverback, $0.0001 par value per share ("Silverback Common Stock"), or other securities of Silverback pursuant to the Merger, which will represent (or are convertible into) more than 20% of the shares of Silverback Common Stock outstanding immediately prior to the Merger, and (ii) the change of control resulting from the Merger, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), respectively (the "Merger Proposal" or "Proposal No. 1"); and

2. approve a postponement or adjournment of the Silverback virtual special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal No. 1 (the "Adjournment Proposal" or "Proposal No. 2").

Please refer to the attached proxy statement for further information with respect to the business to be transacted at the Silverback virtual special meeting. The board of directors of Silverback (the "Silverback Board") has fixed September 19, 2022, as the record date for the determination of stockholders entitled to notice of, and to vote at, the Silverback virtual special meeting and any adjournment or postponement thereof. Only holders of record of shares of Silverback Common Stock at the close of business on the record date are entitled to notice of, and to vote at, the Silverback virtual special meeting. At the close of business on the record date, Silverback had 35,798,117 shares of Silverback Common Stock outstanding and entitled to vote. A complete list of such stockholders

entitled to vote at the Silverback virtual special meeting will be available for examination at the Silverback offices in Seattle, Washington during normal business hours for a period of ten days prior to the Silverback virtual special meeting.

Your vote is important. Approval of Proposal Nos. 1 and 2 requires the affirmative vote of a majority of the votes cast virtually or by proxy at the virtual special meeting. Proposal No. 1 is a condition to the consummation of the Merger. Therefore, the Merger cannot be consummated without the approval of Proposal No. 1.

You are cordially invited to attend the Silverback virtual special meeting. Whether or not you expect to attend the meeting, you are urged to cast your vote as soon as possible. You may vote your shares via the internet or via a toll-free telephone number by following the instructions on the enclosed proxy card. In addition, if you received paper copies of the proxy materials by mail, you can also vote by mail by following the instructions on the enclosed proxy card. Submitting a proxy card will not prevent you from attending the Silverback virtual special meeting and voting at the Silverback virtual special meeting if you so desire. Please note, however, that if your shares are held of record by a broker, bank, or other nominee and you wish to vote at the meeting, you must obtain from the record holder a proxy issued in your name.

If you own shares in street name through an account with a bank, broker or other nominee and you decide to attend the Silverback virtual special meeting, you cannot vote at the Silverback virtual special meeting unless you present a “legal proxy”, issued in your name from your bank, broker or other nominee.

THE SILVERBACK BOARD HAS UNANIMOUSLY DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS ADVISABLE TO, AND IN THE BEST INTERESTS OF, SILVERBACK AND ITS STOCKHOLDERS AND HAS UNANIMOUSLY APPROVED EACH SUCH PROPOSAL. THE SILVERBACK BOARD UNANIMOUSLY RECOMMENDS THAT SILVERBACK’S STOCKHOLDERS VOTE “FOR” EACH SUCH PROPOSAL.

By Order of the Silverback Board of Directors,

Jeffrey Pepe, Ph.D., J.D.
Interim Chief Executive Officer
Seattle, Washington

October 6, 2022

REFERENCES TO ADDITIONAL INFORMATION

This proxy statement incorporates information by reference that is not included in or delivered with this document. You may obtain this information without charge through the Securities and Exchange Commission website (www.sec.gov) or upon your written or oral request by contacting Silverback Therapeutics, Inc., Attention: Investor Relations, 500 Fairview Ave. N, Suite 600, Seattle, Washington 98109, by calling (206) 736-7946 or by email at IR@silverbacktx.com.

You may also request information from MacKenzie Partners, Inc., Silverback's proxy solicitor, at the following address and telephone number:

MacKenzie Partners, Inc.
1407 Broadway, 27th Floor
New York, NY 10018
(800) 322-2885
proxy@mackenziepartners.com

To ensure timely delivery of these documents, any request should be made no later than October 24, 2022 to receive them before the Silverback virtual special meeting.

For additional details about where you can find information about Silverback, please see the section titled "*Where You Can Find More Information*" beginning on page 261 of this proxy statement.

ABOUT THIS DOCUMENT

Silverback Therapeutics, Inc., which we refer to herein as the "Company," "Silverback," "we," "our," or "us" (unless otherwise indicated), is providing these proxy materials in connection with the solicitation by our board of directors of proxies to be voted at our virtual special meeting to be held be held exclusively online via live audio-only webcast on November 4, 2022, at 10:00 a.m. Pacific Time, or at any adjournment or postponement thereof. This proxy statement and the enclosed proxy card will be mailed to each stockholder entitled to notice of, and to vote at, the virtual special meeting of stockholders commencing on or about October 7, 2022.

You are cautioned not to rely on any information other than the information contained in or incorporated by reference into this proxy statement. No one has been authorized to provide you with information that is different from that contained in or incorporated by reference into this proxy statement. This proxy statement is dated October 6, 2022. You should not assume that the information contained in this proxy statement is accurate as of any other date, nor should you assume that the information incorporated by reference into this proxy statement is accurate as of any date other than the date of such incorporated document. The mailing of this proxy statement to our stockholders will not create any implication to the contrary.

This proxy statement does not constitute an offer to sell, or a solicitation of an offer to buy, any securities, or the solicitation of a proxy, in any jurisdiction in which or from any person to whom it is unlawful to make any such offer or solicitation in such jurisdiction.

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QUESTIONS AND ANSWERS ABOUT THE SPECIAL MEETING AND THE MERGER

The following section provides answers to frequently asked questions about the proposed merger transaction and the Silverback Therapeutics, Inc. ("Silverback") virtual special meeting of its stockholders (the "Silverback virtual special meeting"). This section, however, provides only summary information. For a more complete response to these questions and for additional information, please refer to the cross-referenced sections.

Q: What is the Merger?

A: Silverback, Sabre Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Silverback ("Merger Sub"), and ARS Pharmaceuticals, Inc., a Delaware corporation ("ARS Pharma"), entered into the Agreement and Plan of Merger and Reorganization on July 21, 2022, as amended on August 11, 2022 (as it may be further amended from time to time, the "Merger Agreement"). The Merger Agreement, as it may be further amended from time to time, contains the terms and conditions of the proposed transaction among Silverback, Merger Sub and ARS Pharma. Under the Merger Agreement, Merger Sub will merge with and into ARS Pharma, with ARS Pharma surviving as a wholly owned subsidiary of Silverback (the "Merger").

At the effective time of the Merger (the "Effective Time"): (a) each share of ARS Pharma's common stock (the "ARS Pharma Common Stock") outstanding immediately prior to the Effective Time, after giving effect to the automatic conversion of all shares of preferred stock of ARS Pharma ("ARS Pharma Preferred Stock" and, together with the ARS Pharma Common Stock, the "ARS Pharma Capital Stock") into shares of ARS Pharma Common Stock immediately prior to the Effective Time (the "Preferred Stock Conversion"), excluding shares held as treasury stock by ARS Pharma or held or owned by Silverback, Merger Sub or any subsidiary of Silverback or ARS Pharma and shares held by stockholders who have exercised and perfected appraisal rights (as more fully described in the section titled "*The Merger—Appraisal Rights and Dissenters' Rights*"), will automatically be converted into the right to receive a number of shares of Silverback's common stock ("Silverback Common Stock") calculated using an exchange ratio formula described in the Merger Agreement (the "Exchange Ratio").

Under the Exchange Ratio formula described in the Merger Agreement and assuming the Silverback Net Cash (as defined below) at the closing of the Merger (the "Closing") is $240 million, immediately following the Merger, the pre-Merger equity holders of ARS Pharma are expected to hold approximately 63% of the outstanding shares of Silverback Common Stock and the pre-Merger equity holders of Silverback are expected to hold approximately 37% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method. The Exchange Ratio formula is based upon an ARS Pharma fixed valuation of $435 million and a Silverback equity value of $255 million, which is subject to certain adjustments, including based upon the Silverback Net Cash at Closing, as more fully described in the section titled "*The Merger Agreement—Merger Consideration and Exchange Ratio.*" As a condition to Closing, Silverback Net Cash must be no less than $210 million nor greater than $255 million (the "Net Cash Condition"); provided that Silverback may declare a dividend to its stockholders for any amount of Silverback Net Cash that exceeds $255 million or ARS Pharma may waive such condition.

If the Silverback Net Cash at Closing is less than $240 million, the pre-Merger equity holders of Silverback are expected to hold between 34% and 36% of the outstanding shares of Silverback Common Stock immediately following the Merger, and if the Silverback Net Cash at Closing is more than $240 million, the pre-Merger equity holders of Silverback are expected to hold between 37% and 38% of the outstanding shares of Silverback Common Stock immediately following the Merger, in each case, on a fully diluted basis using the treasury stock method.

At the Effective Time, Silverback's stockholders will continue to own and hold their existing shares of Silverback Common Stock. All outstanding and unexercised options to purchase shares of Silverback Common Stock and all outstanding and unvested restricted stock units will remain outstanding to the extent they are not forfeited or, for restricted stock units, accelerated (and settled) in connection with the Merger. Each option to purchase shares of ARS Pharma Common Stock that is outstanding and unexercised immediately prior to the Effective Time, whether or not vested, will be assumed by Silverback and converted into an option to purchase shares of Silverback Common Stock. Each warrant to purchase ARS Pharma Common Stock outstanding immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion) will be assumed by Silverback and will become a warrant to purchase shares of Silverback Common Stock. Substantially concurrent with the completion of the Merger, Silverback will change its corporate name to "ARS Pharmaceuticals, Inc." as required by the Merger Agreement.

Q: When will the Exchange Ratio be final?

A: At least 10 calendar days prior to the Silverback virtual special meeting, Silverback and ARS Pharma will agree upon the anticipated date for Closing (the "Anticipated Closing Date"). At least five calendar days prior to the Anticipated Closing Date, Silverback shall deliver to ARS Pharma a schedule setting forth the estimated calculation of Silverback Net Cash as of the Anticipated Closing Date. Following the final determination of the Silverback Net Cash as of the Anticipated Closing Date, Silverback and ARS Pharma will issue a press release setting forth the anticipated Exchange Ratio, which the parties have agreed to publicly disclose as early as practicable prior to the Silverback virtual special meeting (provided that in no event shall the press release delay, or cause the postponement of, the Silverback virtual special meeting).

Q: What will happen to Silverback if, for any reason, the Merger does not close?

A: If, for any reason, the Merger does not close, the board of directors of Silverback (the "Silverback Board") may elect to, among other things, attempt to complete another strategic transaction similar to the Merger, attempt to sell or otherwise dispose of the various assets of Silverback, continue to operate the business of Silverback or liquidate and distribute available cash. Under certain circumstances, Silverback may be obligated to pay ARS Pharma a termination fee of $10 million or $6 million and reimburse certain expenses of ARS Pharma up to $1.5 million, as more fully described in the section titled "*The Merger Agreement—Termination and Termination Fees.*" If Silverback decides to dissolve and liquidate its assets, Silverback would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims. There can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying the debts and other obligations of Silverback and setting aside funds for reserves.

Q: Why are the two companies proposing to merge?

A: The Merger will result in a biopharmaceutical company focused on the development and potential commercialization of a novel, potentially first-in-class product candidate, *neffy*, a no needle, no injection nasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis. For a discussion of Silverback's reasons for the Merger, please see the section titled "*The Merger—Silverback Reasons for the Merger.*"

Q: Why am I receiving this proxy statement?

A: You are receiving this proxy statement because you have been identified as a holder of Silverback Common Stock as of the record date, and you are entitled to vote at the Silverback virtual special meeting to approve the matters described in this proxy statement. This proxy statement

contains important information about the Silverback virtual special meeting, the Merger, the Merger Agreement and the other business to be considered by Silverback stockholders at the Silverback virtual special meeting and you should read it carefully and in its entirety. The enclosed voting materials allow you to authorize a proxy to vote your shares of Silverback Common Stock without attending the Silverback virtual special meeting. As promptly as practicable, please complete, sign, date and mail your proxy card in the pre-addressed postage-paid envelope provided or call the toll-free telephone number listed on your proxy card or access the internet website described in the instructions on the enclosed proxy card.

Q: What am I voting on?

A: Holders of Silverback Common Stock as of the record date are entitled to vote at the Silverback virtual special meeting on each of the following proposals:

1. the approval of (i) the issuance of shares of Silverback Common Stock or other securities of Silverback pursuant to the Merger, which will represent (or are convertible into) more than 20% of the shares of Silverback Common Stock outstanding immediately prior to the Merger, and (ii) the change of control resulting from the Merger, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), respectively (the "Merger Proposal" or "Proposal No. 1"); and
2. the approval of a postponement or adjournment of the Silverback virtual special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal No. 1 (the "Adjournment Proposal" or "Proposal No. 2").

We do not expect that any matter other than Proposal Nos. 1 and 2 will be brought before the Silverback virtual special meeting.

Q: What is required to consummate the Merger?

A: To consummate the Merger, the holders of Silverback Common Stock must approve the Merger Proposal. Proposal No. 2 is not a closing condition for the consummation of the Merger.

Certain of Silverback's officers, directors and stockholders who in the aggregate own approximately 31% of the shares of Silverback Common Stock outstanding as of immediately prior to the date of the Merger Agreement, are parties to Silverback Support Agreements (as defined below) with ARS Pharma, whereby such stockholders have agreed, subject to the terms of the Silverback Support Agreements, to vote all of their shares of Silverback Common Stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the Merger Proposal, and the other transactions and actions contemplated by the Merger Agreement (collectively, the "Contemplated Transactions"), (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any acquisition proposal involving a third party.

In addition to the requirement of obtaining stockholder approval of the Merger Proposal, each of the other closing conditions set forth in the Merger Agreement must be satisfied or, unless not waivable as a matter of law, waived. For a complete description of the closing conditions under the Merger Agreement, we urge you to read the section titled "*The Merger Agreement—Conditions to the Completion of the Merger.*"

Q: How can I find out the results of the voting at the Silverback virtual special meeting?

A: Final voting results will be published in a current report on Form 8-K that we expect to file within four business days after the Silverback virtual special meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the Silverback virtual special meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an additional Form 8-K to publish the final results.

Q: Will Silverback monetize any of its legacy programs in connection with the Merger?

A: Silverback is entitled, but under no obligation, to separate into a new company or sell, transfer, assign or otherwise divest its legacy programs and other preclinical assets to a third party in one or a series of transactions prior to, concurrently with, or immediately following the Closing (the "Asset Dispositions"). If the Asset Dispositions are not completed prior to, concurrently with, or immediately following the Closing, Silverback's legacy programs and other preclinical assets will be retained by Silverback and the value of such assets will have no impact on the calculation of the Exchange Ratio. For a more complete description of the Asset Dispositions, please see the section titled "*The Merger Agreement—Potential Asset Disposition*." While Silverback is currently exploring third party interest in partnering or acquiring the Silverback's legacy programs or other preclinical assets, Silverback may be unable to partner or divest the program assets in a timely manner, or at all, and therefore may not receive any return on Silverback's investment in the program assets. Please see the section titled "*Risk Factors—Risks Related to the Merger—Silverback may not be able to divest its legacy programs within the timeframe under the Merger Agreement, on favorable terms or at all, which may result in the value of such assets not being included in the calculation of the Exchange Ratio*."

Q: What will ARS Pharma's stockholders, option holders and warrant holders receive in the Merger?

A: Each outstanding share of ARS Pharma Common Stock (after giving effect to the Preferred Stock Conversion) will be converted into the right to receive a number of shares of Silverback Common Stock calculated using the Exchange Ratio. Silverback will assume outstanding and unexercised options to purchase shares of ARS Pharma Common Stock, and in connection with the Merger such options will be converted into options to purchase shares of Silverback Common Stock. Each warrant to purchase ARS Pharma Common Stock outstanding and unexercised immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion) will be assumed by Silverback and will become a warrant to purchase shares of Silverback Common Stock. For a more complete description of what ARS Pharma's equity holders will receive in the Merger, please see the section titled "*The Merger Agreement—Merger Consideration and Exchange Ratio.*"

Q: Will holders of the Silverback Common Stock issued in the Merger be able to sell those shares without restriction?

A: The shares of Silverback Common Stock issued as consideration in the Merger will be issued in transactions exempt from registration under the Securities Act of 1933, as amended (the "Securities Act") in reliance on Section 4(a)(2) of the Securities Act and may not be offered or sold by the holders of those shares absent registration or an applicable exemption from the registration requirements. As a general matter, holders of such shares will not be able to transfer any of their shares until at least six months after receiving shares of Silverback Common Stock, which is when the shares would first be eligible to be sold under Rule 144 promulgated under the Securities Act, assuming the conditions thereof are otherwise satisfied.

Certain officers, directors and stockholders of ARS Pharma representing approximately 84% of the outstanding shares of ARS Pharma Capital Stock immediately prior to the date of the Merger Agreement have agreed to certain transfer restrictions on the shares of common stock to be issued to them in the Merger, for a period of 180 days following the Effective Time. For a more complete description of the lock-up agreements, please see the section titled "*Agreements Related to the Merger — Lock-Up Agreements.*"

Q: What will Silverback's stockholders receive in the Merger?

A: At the Effective Time, Silverback's stockholders will continue to own and hold their existing shares of Silverback Common Stock.

Q: What will happen to Silverback's options and restricted stock units in the Merger?

A: Silverback stock options and Silverback restricted stock units will remain outstanding to the extent they are not forfeited or, for restricted stock units, accelerated (and settled) in connection with the Merger. For a more detailed description of the treatment of Silverback equity awards, please see the section titled "*The Merger Agreement—Treatment of Silverback Stock Options and Restricted Stock Units*."

Q: Who will be the directors of Silverback following the Merger?

A: At the Effective Time, the combined company is expected to initially have an eleven member board of directors, comprised of (a) Richard Lowenthal, M.S., MSEL, Pratik Shah, Ph.D., Peter Kolchinsky, Ph.D., Rajeev Dadoo, Ph.D., Brenton L. Saunders, Phillip Schneider, Michael Kelly and Jonathan Leff, each as an ARS Pharma designee, and (b) Laura Shawver, Ph.D., Peter A. Thompson, M.D. and Saqib Islam, J.D., each as a Silverback designee, until their respective successors are duly elected or appointed and qualified or their earlier death, resignation or removal.

The aforementioned board of directors will have an audit committee, a compensation committee and a nominating and corporate governance committee, in accordance with the rules of The Nasdaq Stock Market LLC ("Nasdaq"). All of Silverback's current directors other than Dr. Shawver, Dr. Thompson and Mr. Islam are expected to resign from their positions as directors of Silverback, effective upon the Effective Time.

Q: Who will be the executive officers of Silverback following the Merger?

A: Immediately following the Merger, the executive management team of the combined company is expected to be comprised of the following individuals with such additional officers as may be added by ARS Pharma or the combined company:

Name	Position with the Combined Company	Current Position
Richard Lowenthal, M.S., MSEL	President and Chief Executive Officer	President and Chief Executive Officer of ARS Pharma
Kathleen Scott	Chief Financial Officer	Chief Financial Officer of ARS Pharma
Sarina Tanimoto, M.D.	Chief Medical Officer	Chief Medical Officer of ARS Pharma
Eric Karas	Chief Commercial Officer	Chief Commercial Officer of ARS Pharma
Justin Chakma	Chief Business Officer	Chief Business Officer of ARS Pharma

Q: As a stockholder of Silverback, how does the Silverback Board recommend that I vote?

A: After careful consideration, the Silverback Board unanimously recommends that the holders of Silverback Common Stock as of the record date vote:

- "**FOR**" the Merger Proposal; and
- "**FOR**" the Adjournment Proposal.

For more information on each proposal and the Silverback Board's recommendations, please see the section entitled "*Matters Being Submitted to a Vote of Silverback's Stockholders.*"

Q: How many votes are needed to approve each proposal?

A: Approval of the proposals requires the affirmative vote of a majority of the votes cast virtually or by proxy at the Silverback virtual special meeting.

Q: What risks should I consider in deciding whether to vote in favor of Proposal Nos. 1 and 2?

A: You should carefully review the section of the proxy statement titled "*Risk Factors*," which sets forth certain risks and uncertainties related to the Merger, risks and uncertainties to which the combined company's business will be subject, and risks and uncertainties to which each of Silverback and ARS Pharma, as an independent company, is subject.

Q: When do you expect the Merger to be consummated?

A: We anticipate that the Merger will be consummated during the fourth quarter of 2022, soon after the Silverback virtual special meeting to be held on November 4, 2022, but we cannot predict the exact timing. For more information, please see the section titled "*The Merger Agreement—Conditions to the Completion of the Merger.*"

Q: What are the material U.S. federal income tax consequences of the Merger to U.S. Holders of ARS Pharma shares?

A: Silverback and ARS Pharma intend the Merger to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code"), as described in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger.*"

The tax consequences to each ARS Pharma stockholder will depend on that stockholder's particular circumstances. Each ARS Pharma stockholder should consult with his, her or its tax advisor for a full understanding of the tax consequences of the Merger to that stockholder.

Q: What do I need to do now?

A: Silverback and ARS Pharma urge you to read this proxy statement carefully, including its annexes and information incorporated herein, and to consider how the Merger affects you.

If you are a holder of Silverback Common Stock as of the record date, please vote your shares as soon as possible so that your shares will be represented at the Silverback virtual special meeting. Please follow the instructions set forth on the enclosed proxy card or on the voting instruction form provided by the record holder of your shares if your shares are held in the name of your bank, broker or other nominee.

Q: When and where is the Silverback virtual special meeting?

A: The Silverback virtual special meeting will be held exclusively online via live audio-only webcast on November 4, 2022 at 10:00 a.m. Pacific Time. Please note that you will not be able to attend the Silverback virtual special meeting in person.

Q: How do I vote and what must I do to attend the Silverback virtual special meeting?

You will be able to vote your shares and submit questions during the Silverback virtual special meeting webcast by logging in to the website listed below using the control number included in your proxy card on November 4, 2022. Stockholders may begin to log in 15 minutes prior to the Silverback virtual special meeting. The Silverback virtual special meeting will begin promptly at 10:00 a.m. Pacific Time.

We will have technicians ready to assist you with any technical difficulties you may have accessing the Silverback virtual special meeting. If you encounter any difficulties accessing the Silverback virtual special meeting platform, including any difficulties voting or submitting questions, you may call the technical support number that will be posted in your instructional email.

If you wish to submit a question during the Silverback virtual special meeting, log into the Silverback virtual special meeting registration platform at www.proxydocs.com/SBTX, type your question into the "Questions for Management" field, and click "Submit." Silverback will respond to as many properly submitted questions during the relevant portion of the Silverback virtual special meeting agenda as time allows. The procedures for voting are as follows:

Shares Registered in Your Name

If you are a stockholder of record, you may vote online at the Silverback virtual special meeting, vote by proxy over the telephone, vote by proxy through the internet, or vote by proxy by mail using the enclosed proxy card. Whether or not you plan to attend the Silverback virtual special meeting, we urge you to vote by proxy to ensure your vote is counted. You may still attend the Silverback virtual special meeting and vote even if you have already voted by proxy.

- To vote online during the Silverback virtual special meeting, follow the instructions posted at www.proxydocs.com/SBTX. You must register in advance at www.proxydocs.com/SBTX to be able to vote during the Silverback virtual special meeting.
- To vote over the telephone, dial toll-free (866) 355-8664 using a touch-tone phone and follow the recorded instructions. You will be asked to provide the company number and control number from the enclosed proxy card.
- To vote through the internet, go to www.proxypush.com/SBTX to complete an electronic proxy card. You will be asked to provide the company number and control number from the enclosed proxy card.
- To vote by mail, simply complete, sign and date the enclosed proxy card and return it promptly in the envelope provided. If you return your signed proxy card to us before the Silverback virtual special meeting, we will vote your shares as you direct.

If your shares are registered in your name with Silverback's stock registrar and transfer agent, American Stock Transfer & Trust Company, LLC, no proof of ownership is necessary because Silverback can verify your ownership.

Shares Registered in the Name of a Broker, Bank or Other Nominee

If you are a beneficial owner of shares registered in the name of your broker, bank, or other nominee, you should have received voting instructions from that organization rather than from Silverback. Simply follow the voting instructions provided by your broker, bank or other nominee to ensure that your vote is counted. Alternatively, you may vote by telephone or over the internet as instructed by your broker, bank, or other nominee. To vote online at the Silverback virtual special

meeting, you must obtain a valid proxy from your broker, bank, or other nominee. Follow the instructions from your broker, bank, or other nominee included with these proxy materials, or contact that organization to request a proxy form.

If you own shares in street name through an account with a bank, broker or other nominee, please send proof of your Silverback share ownership as of the Silverback record date (for example, a brokerage firm account statement or a "legal proxy" from your intermediary) along with your registration request. If you are not sure what proof to send, check with your intermediary.

We provide internet proxy voting to allow you to vote your shares online, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your internet access, such as usage charges from internet access providers and telephone companies.

If Silverback experiences technical difficulties during the Silverback virtual special meeting (e.g., a temporary or prolonged power outage), Silverback will determine whether the Silverback virtual special meeting can be promptly reconvened (if the technical difficulty is temporary) or whether the Silverback virtual special meeting will need to be reconvened on a later day (if the technical difficulty is more prolonged). In any situation, Silverback will promptly notify stockholders of the decision via www.proxydocs.com/SBTX. Silverback will have technicians ready to assist you with any technical difficulties you may have accessing the Silverback virtual special meeting website. If you encounter any difficulties accessing the Silverback virtual special meeting website during the check-in or meeting time, please call the technical support number that will be posted on the Silverback virtual special meeting website log-in page at www.proxydocs.com/SBTX.

Q: How are votes counted?

A: Votes will be counted by the inspector of elections appointed for the meeting, who will separately count votes "**FOR**" and "**AGAINST**," abstentions and, if applicable, broker non-votes.

We do not expect that any matter other than Proposal Nos. 1 and 2 will be brought before the Silverback virtual special meeting.

Q: What are "broker non-votes"?

A: Brokers who hold shares in street name for customers have the authority to vote on "routine" proposals when they have not received instructions from beneficial owners. However, brokers are precluded from exercising their voting discretion with respect to approval of non-routine matters, such as Proposal No. 1, and, as a result, absent specific instructions from the beneficial owner of such shares, brokers are not empowered to vote those shares, referred to generally as "broker non-votes." Broker non-votes, if any, will be treated as shares that are present at the virtual special meeting for purposes of determining whether a quorum exists but will not be counted or deemed present virtually or by proxy for the purpose of voting on Proposal No. 1.

Q: What will happen if I return my proxy or voting instruction form without indicating how to vote?

A: If you submit your proxy or voting instruction form without indicating how to vote your shares on any particular proposal, the shares of Silverback Common Stock represented by your proxy will be voted as recommended by the Silverback Board with respect to that proposal.

Q: May I change my vote after I have submitted a proxy or voting instruction form?

A: Silverback's stockholders of record, other than those Silverback stockholders who are parties to Silverback Support Agreements, except as otherwise provided therein, may change their vote at any time before their proxy is voted at the Silverback virtual special meeting in one of following ways:

- by sending a written notice to the Secretary of Silverback stating that you would like to revoke your proxy.
- by duly executing a subsequently dated proxy relating to the same shares of Silverback Common Stock and returning it in the postage-paid envelope provided, which subsequent proxy is received before the prior proxy is exercised at the Silverback virtual special meeting;
- by duly submitting a subsequently dated proxy relating to the same shares of Silverback Common Stock by telephone or via the internet (i.e., your most recent duly submitted voting instructions will be followed); and/or
- by attending the Silverback virtual special meeting and voting such shares of Silverback Common Stock during the Silverback virtual special meeting.

If a stockholder who owns shares of Silverback Common Stock in "street name" has instructed a broker, bank or other nominee to vote its shares of Silverback Common Stock, the stockholder must follow directions received from its broker to change those instructions.

Q: Who is paying for this proxy solicitation?

A: Silverback and ARS Pharma will equally share the cost of printing and filing of this proxy statement and the proxy card, including fees paid to the U.S. Securities and Exchange Commission ("SEC") in connection with filing the proxy statement, and any amendments and supplements thereto, with the SEC. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Silverback Common Stock for the forwarding of solicitation materials to the beneficial owners of Silverback Common Stock. Silverback will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. In addition to these proxy materials, Silverback's directors and employees, and Silverback's proxy solicitor, MacKenzie Partners, Inc., may also solicit proxies in person, by telephone or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. MacKenzie Partners, Inc. will be paid its customary fee of approximately $12,500, plus out-of-pocket expenses if it solicits proxies.

Q: What is the quorum requirement?

A: A quorum of stockholders is necessary to hold a valid meeting. The presence at the Silverback virtual special meeting, virtually or by proxy, of the holders of a majority of the voting power of the stock issued, outstanding and entitled to vote thereat, as of the record date, will constitute a quorum for the transaction of business at the Silverback virtual special meeting.

Your shares will be counted towards the quorum if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other nominee) or if you attend the Silverback virtual special meeting and vote your shares during the Silverback virtual special meeting. Abstentions and broker non-votes, if applicable, will also be counted towards the quorum requirement. If there is no quorum, the holders of a majority of shares present at the Silverback virtual special meeting or represented by proxy may postpone or adjourn the meeting to another date.

Q: Am I entitled to dissenters' rights?

A: No, Silverback's stockholders are not entitled to dissenters' rights in connection with the Merger.

Q: Have ARS Pharma's stockholders agreed to adopt the Merger Agreement?

A: Yes. On July 21, 2022, ARS Pharma's stockholders adopted the Merger Agreement and approved the Merger and the other Contemplated Transactions via the ARS Pharma Stockholder Written Consent (as defined below). For more information on the matters approved by the stockholders of ARS Pharma please see the sections titled "*The Merger Agreement—Conditions to the Completion of the Merger*" and "*The Merger Agreement—ARS Pharma Stockholder Action by Written Consent.*"

Q: Who can help answer my questions?

A: If you are a holder of Silverback Common Stock as of the record date and would like additional copies, without charge, of this proxy statement or if you have questions about the Merger, including the procedures for voting your shares, you should contact our proxy solicitor:

MacKenzie Partners, Inc.
1407 Broadway, 27th Floor
New York, NY 10018
(800) 322-2885
proxy@mackenziepartners.com

SUMMARY

This summary highlights selected information from this proxy statement and may not contain all of the information that is important to you. To better understand the Merger, the proposals being considered at the Silverback virtual special meeting, you should read this entire proxy statement carefully, including the Merger Agreement attached as Annex A and the fairness opinion of SVB Securities LLC attached as Annex B. For more information, please see the section titled "Where You Can Find More Information" beginning on page 261 of this proxy statement.

The Companies

Silverback Therapeutics, Inc.
500 Fairview Ave N, Suite 600
Seattle, Washington 98109
(206) 456-2900

Silverback is a biopharmaceutical company focused on leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of cancer, chronic viral infections and other serious diseases. Silverback's platform enables it to strategically pair proprietary linker-payloads that modulate key disease-modifying pathways with monoclonal antibodies directed to specific disease sites.

In July 2020, Silverback initiated clinical development of its first ImmunoTAC product candidate, a TLR8 agonist conjugated to a HER2 antibody, SBT6050. Preclinical data suggested that Silverback would be able to demonstrate a therapeutic window and advance SBT6050 through clinical development as a monotherapy and in combination with standard-of-care agents that had a complementary mechanism-of-action. Silverback's Phase 1/1b program was designed to measure safety and tolerability, pharmacokinetic, pharmacodynamic and anti-tumor activity as monotherapy and in combination with pembrolizumab. On March 28, 2022, Silverback made the decision to discontinue its clinical development program for SBT6050 due to limited monotherapy activity and the adverse event profile when used in combination with pembrolizumab. SBT6290, comprised of the same linker payload conjugated to a Nectin4 antibody was expected to show a similar clinical profile and, therefore, Silverback also terminated this program prior to dosing patients. Following the decision on March 28, 2022, Silverback prioritized its resources to focus on the development of SBT8230 for the treatment of chronic Hepatitis B virus ("cHBV") infection and early-stage discovery programs.

In connection with the discontinuation of the SBT6050 and SBT6290 programs, Silverback announced a work force reduction of 27% to focus on the development of SBT8230 and early-stage discovery programs while evaluating strategic alternatives. Strategic alternatives were evaluated with a goal to identify the opportunity that would, in the opinion of the Silverback Board, create the most value for Silverback stockholders, including strategic mergers and acquisitions, asset acquisitions and sales, remaining a standalone company pursuing a limited pipeline focusing on SBT8230 and preclinical programs, and liquidation to distribute available cash. On July 21, 2022, Silverback announced that it entered into the Merger Agreement with ARS Pharma. In connection with the Merger, Silverback started to winddown its research and development activities and focus on exploring opportunities to divest its legacy programs, including SBT8230 for cHBV, next-generation linker technologies, and our preclinical GC conjugate program, and committed to reducing its workforce by approximately 75% by September 2, 2022 and the remaining 25% at Closing in order to preserve cash resources.

On August 10, 2022, the Silverback Board approved the termination of employment of Laura Shawver, Ph.D., the Chief Executive Officer of Silverback, effective as of September 2, 2022 (the

"Transition Date"), to extend our cash runway and to allow Dr. Shawver to pursue other employment opportunities. Dr. Shawver has entered into a consulting agreement with Silverback effective as of the Transition Date pursuant to which she has agreed to provide, on an as-needed basis not to exceed 20 hours per week unless mutually agreed, transition services and to advise, consult and support Silverback's management team in connection with the closing of the Merger, winddown activities related thereto, the sale of Silverback's legacy assets and other services from the Transition Date until the earlier of (a) the Closing and (b) December 31, 2022. As consideration for her consulting services, Dr. Shawver will be paid an hourly rate of $300 and all outstanding equity awards held by Dr. Shawver as of the Transition Date will continue to vest and will remain exercisable during the consulting period. Dr. Shawver will also continue to serve as a member of the Silverback Board and is expected to serve on the combined company's board of directors following the Closing.

Effective as of the Transition Date, Jeffrey Pepe, Ph.D., J.D., has been appointed to serve as the Interim Chief Executive Officer, General Counsel and Corporate Secretary of Silverback.

ARS Pharmaceuticals, Inc.
11682 El Camino Real, Suite 120
San Diego, CA 92130
(858) 771-9307

ARS Pharma is a biopharmaceutical company focused on the development of a novel, potentially first-in-class product candidate, *neffy*® (previously referred to as ARS-1) for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail®, which allows *neffy* to provide injection-like absorption of epinephrine at a low dose, in a small, easy-to-carry, easy-to-use, rapidly administered and reliable nasal spray. Type I severe allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine injection, the only U.S. Food and Drug Administration ("FDA")-approved medication for these reactions. While epinephrine injection devices have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. Delay in treatment can allow the allergic reaction to progress in severity leading to symptoms that seriously impact patient quality of life, to potential need for emergency services and/or hospitalizations, and to life-threatening symptoms or events.

There are approximately 25 to 40 million people in the United States who experience Type I severe allergic reactions. Of this group, approximately 16 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only 3.3 million currently have an active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector. Even if patients or caregivers carry an autoinjector, more than half either delay or do not administer the device when needed in an emergency.

ARS Pharma believes *neffy's* "no needle, no injection" delivery that eliminates needle-related apprehension and injury concerns, with its small pocket size, ease of use, and high reliability would, if approved, increase prescriptions for epinephrine and make it more likely for patients and caregivers to administer epinephrine sooner, achieve more rapid symptom relief and prevent the allergic reaction from progressing to a level of severity that could lead to hospitalization or even death. Data from ARS Pharma's studies of *neffy* in more than 500 subjects demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products.

ARS Pharma submitted a New Drug Application ("NDA") to the FDA in the third quarter of 2022 and if the NDA is approved, ARS Pharma believes *neffy* will be the first "no needle, no injection" marketed epinephrine product for the emergency treatment of Type I allergic reactions. However, the timing for regulatory approvals is outside ARS Pharma's control, may be delayed and is uncertain.

The Merger (see page 110)

On July 21, 2022, Silverback, Merger Sub, and ARS Pharma entered into the Merger Agreement, pursuant to which Merger Sub will merge with and into ARS Pharma, with ARS Pharma surviving as a wholly owned subsidiary of Silverback. Silverback Common Stock will be issued to the stockholders of ARS Pharma at the Effective Time and Silverback will assume each ARS Pharma option and warrant which will become options and warrants to purchase Silverback Common Stock at the Effective Time. In connection with the Closing, Silverback will change its name to "ARS Pharmaceuticals, Inc.," and ARS Pharma is expected to change its name to "ARS Subsidiary, Inc." References to the combined company in this proxy statement are references to Silverback and its consolidated subsidiaries following the Merger and references to the surviving company are to ARS Pharma following the Merger.

Silverback and ARS Pharma expect the Merger to be consummated during the fourth quarter of 2022, subject to satisfaction or waiver of certain conditions to the Closing, including, among other things, approval by Silverback's stockholders of the Merger Proposal.

Immediately following the consummation of the Merger, the equity holders of ARS Pharma (including the holders of any outstanding and unexercised options to purchase ARS Pharma Common Stock and the holders of any outstanding and unexercised warrants to purchase ARS Pharma Common Stock) immediately prior to the Merger and after giving effect to the Preferred Stock Conversion are expected to hold approximately 63% of the shares of Silverback Common Stock outstanding immediately following the Merger and the equity holders of Silverback immediately prior to the Merger are expected to hold approximately 37% of the Silverback Common Stock outstanding immediately following the Merger, in each case, on a fully diluted basis using the treasury stock method and assuming Silverback Net Cash at Closing is $240 million. If Silverback Net Cash at Closing is less than $240 million, the pre-Merger equity holders of Silverback are expected to hold between 34% and 36% of the outstanding shares of Silverback Common Stock, and if Silverback Net Cash at Closing is more than $240 million, the pre-Merger equity holders of Silverback are expected to hold between 37% and 38% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method. The Net Cash Condition requires that Silverback Net Cash must be no less than $210 million nor greater than $255 million; provided that Silverback may declare a dividend to its stockholders for any amount of Silverback Net Cash that exceeds $255 million or ARS Pharma may waive such condition. For a more complete description of the Merger and the potential adjustments in the Exchange Ratio, please see the section titled "*The Merger Agreement—Merger Consideration and Exchange Ratio*."

Reasons for the Merger (see page 120)

The Silverback Board considered various reasons for the Merger, as described later in this proxy statement under the section titled "*The Merger—Silverback Reasons for the Merger*."

Opinion of Silverback's Financial Advisor (see page 124)

Silverback retained SVB Securities LLC ("SVB Securities") as its financial advisor in connection with the Merger and the other Contemplated Transactions. On July 20, 2022, SVB Securities rendered

to the Silverback Board its oral opinion, which was subsequently confirmed by delivery of a written opinion dated July 20, 2022, that, as of such date and based upon and subject to the various assumptions made, and the qualifications and limitations upon the review undertaken by SVB Securities in preparing its opinion, the Exchange Ratio proposed to be paid by Silverback pursuant to the Merger Agreement was fair, from a financial point of view, to Silverback.

The full text of the written opinion of SVB Securities, dated July 20, 2022, which describes the assumptions made and the qualifications and limitations upon the review undertaken by SVB Securities in preparing its opinion, is attached as Annex B to this proxy statement and is incorporated herein by reference. **SVB Securities' financial advisory services and opinion were provided for the information and assistance of the Silverback Board (in their capacity as directors and not in any other capacity) in connection with and for purposes of the Silverback Board's consideration of the Merger and the opinion of SVB Securities addressed only the fairness, from a financial point of view, as of the date thereof, to Silverback of the Exchange Ratio proposed to be paid by Silverback pursuant to the terms of the Merger Agreement. The opinion of SVB Securities did not address any other term or aspect of the Merger Agreement or the Merger and does not constitute a recommendation to any stockholder of Silverback as to whether or how such holder should vote with respect to the merger or otherwise act with respect to the Merger or any other matter.**

The full text of the written opinion of SVB Securities should be read carefully in its entirety for a description of the assumptions made and limitations upon the review undertaken by SVB Securities in preparing its opinion.

Overview of the Merger Agreement and Agreements Related to the Merger Agreement

Merger Consideration and Exchange Ratio (see page 141)

Pursuant to the Merger Agreement, at the Effective Time, each share of ARS Pharma Capital Stock outstanding immediately prior to the Effective Time and after giving effect to the Preferred Stock Conversion (excluding shares held as treasury stock by ARS Pharma or held or owned by Silverback, Merger Sub or any subsidiary of Silverback or ARS Pharma and excluding dissenting shares) will be automatically converted solely into the right to receive a number of shares of Silverback Common Stock equal to the Exchange Ratio.

No fractional shares of Silverback Common Stock will be issued in connection with the Merger, and no certificates or scrip for any such fractional shares will be issued. Any fractional shares of Silverback Common Stock that a holder of ARS Pharma Capital Stock would otherwise be entitled to receive will be aggregated with all fractional shares of Silverback Common Stock issuable to such holder and any remaining fractional shares will be rounded up to the nearest whole share.

The Exchange Ratio formula is derived based upon an ARS Pharma fixed valuation of $435 million and a Silverback equity value of $255 million and is subject to certain adjustments, including based upon Silverback Net Cash at Closing. The calculation of Silverback Net Cash at Closing includes, among other things, a credit for cash proceeds Silverback receives from the sale of its pre-clinical assets prior to or substantially concurrently with the Closing and a reduction for certain liabilities, including certain short and long term liabilities accrued at Closing, including severance and change in control payments, D&O insurance premium and unpaid transaction expenses. The Net Cash Condition requires that Silverback Net Cash be no less than $210 million nor greater than $255 million; provided that Silverback may declare a dividend to its stockholders for any amount of Silverback Net Cash that exceeds $255 million or ARS Pharma may waive such condition.

Immediately following the Merger, assuming Silverback Net Cash at Closing is $240 million, the pre-Merger equity holders of ARS Pharma are expected to hold approximately 63% of the outstanding shares of Silverback Common Stock and the pre-Merger equity holders of Silverback are expected to hold approximately 37% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method. As currently anticipated, the Exchange Ratio is expected to be approximately 1.2441. If Silverback Net Cash at Closing is less than $240 million, the pre-Merger equity holders of Silverback are expected to hold between 34% and 36% of the outstanding shares of Silverback Common Stock, and if Silverback Net Cash at Closing is more than $240 million, the pre-Merger equity holders of Silverback are expected to hold between 37% and 38% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method.

For a more complete description of the Merger, the potential adjustments in the Exchange Ratio and the calculation of Silverback Net Cash, please see the section titled "*The Merger Agreement —Merger Consideration and Exchange Ratio*."

Treatment of ARS Pharma Stock Options

Under the terms of the Merger Agreement, each option to purchase shares of ARS Pharma Common Stock that is outstanding and unexercised immediately prior to the Effective Time, whether or not vested, will be converted into an option to purchase shares of Silverback Common Stock. Silverback will assume ARS Pharma's 2018 Equity Incentive Plan (the "ARS 2018 Plan"), and all rights with respect to each outstanding option to purchase ARS Pharma Common Stock in accordance with its terms and the terms of the stock option agreement by which such option is evidenced.

Accordingly, from and after the Effective Time: (i) each outstanding ARS Pharma stock option assumed by Silverback may be exercised solely for shares of Silverback Common Stock; (ii) the number of shares of Silverback Common Stock subject to each outstanding ARS Pharma stock option assumed by Silverback will be determined by multiplying (A) the number of shares of ARS Pharma Common Stock that were subject to such ARS Pharma stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Silverback Common Stock; (iii) the per share exercise price for the Silverback Common Stock issuable upon exercise of each ARS Pharma stock option assumed by Silverback will be determined by dividing (A) the per share exercise price of Silverback Common Stock subject to such ARS Pharma stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any ARS Pharma stock option assumed by Silverback will continue in full force and effect and the term, exercisability, vesting schedule, accelerated vesting provisions, and any other provisions of such ARS Pharma stock option will otherwise remain unchanged; provided, however, that the Silverback Board or a committee thereof will succeed to the authority and responsibility of the board of directors of ARS Pharma (the "ARS Pharma Board") or any committee thereof with respect to each ARS Pharma stock option assumed by Silverback.

Treatment of ARS Pharma Warrants

Under the terms of the Merger Agreement, each warrant to purchase shares of ARS Pharma Common Stock that is outstanding and unexercised immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion), will be converted into and become a warrant to purchase shares of Silverback Common Stock and Silverback will assume each ARS Pharma warrant in accordance with its terms.

Accordingly, from and after the Effective Time: (i) each outstanding ARS Pharma warrant assumed by Silverback may be exercised solely for shares of Silverback Common Stock; (ii) the number of shares of Silverback Common Stock subject to each outstanding ARS Pharma warrant assumed by Silverback will be determined by multiplying (A) the number of shares of ARS Pharma Common Stock that were subject to such ARS Pharma warrant, as in effect immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion), by (B) the Exchange Ratio, and rounding the resulting number up to the nearest whole number of shares of Silverback Common Stock; (iii) the per share exercise price for the Silverback Common Stock issuable upon exercise of each ARS Pharma warrant assumed by Silverback will be determined by dividing (A) the per share exercise price of Silverback Common Stock subject to such ARS Pharma warrant as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any ARS Pharma warrant assumed by Silverback will continue in full force and effect and the term and other provisions of such ARS Pharma warrant will otherwise remain unchanged.

Treatment of Silverback Stock Options and Restricted Stock Units

All outstanding and unexercised options to purchase shares of Silverback Common Stock and all outstanding and unvested restricted stock units will remain outstanding to the extent they are not forfeited or, for restricted stock units, accelerated (and settled) in connection with the Merger. As of June 30, 2022, there were outstanding options to purchase up to an aggregate of 8,649,255 shares of Silverback Common Stock and unvested restricted stock units covering 745,675 shares of Silverback Common Stock. As of June 30, 2022, Silverback's executive officers and directors, including any director or executive officer who served in such capacity since the beginning of the last fiscal year, collectively owned outstanding options to purchase an aggregate of 4,692,413 shares of Silverback Common Stock and unvested restricted stock units covering 266,614 shares of Silverback Common Stock.

Conditions to the Completion of the Merger (see page 145)

The obligations to consummate the Merger and the other Contemplated Transactions are subject to the satisfaction or waiver, on or prior to the Effective Time, of the conditions set forth in the section entitled "*The Merger Agreement—Conditions to the Completion of the Merger*" below.

Non-Solicitation (see page 152)

Both Silverback and ARS Pharma are prohibited by the terms of the Merger Agreement, other than, in the case of Silverback, with respect to any Asset Disposition, from (i) soliciting, initiating or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any Acquisition Proposal (as defined below) or Acquisition Inquiry (as defined below) or taking any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnishing any non-public information regarding such party to any person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engaging in discussions or negotiations with any person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approving, endorsing or recommending any Acquisition Proposal; (v) executing or entering into any letter of intent or any contract contemplating or otherwise relating to any Acquisition Transaction (as defined below) (other than, in the case of Silverback, a confidentiality agreement permitted as described below); or (vi) publicly proposing to do any of the foregoing.

Subject to certain restrictions and prior to obtaining the approval of the Merger Proposal by the Required Silverback Stockholder Vote (as defined below), Silverback may furnish non-public

information regarding Silverback to, and enter into discussions or negotiations with, any person in response to an unsolicited *bona fide* Acquisition Proposal by such person, which the Silverback Board determines in good faith, after consultation with its outside financial advisors and outside legal counsel, constitutes, or could be reasonably likely to result in, a Superior Offer (as defined below) (and is not withdrawn) if: (A) neither Silverback nor any of its representatives have breached the non-solicitation restrictions in the Merger Agreement in any material respect, (B) the Silverback Board concludes in good faith, based on the advice of outside legal counsel, that the failure to take such action could be reasonably likely to be inconsistent with the fiduciary duties of the Silverback Board under applicable law; (C) Silverback receives from such person an executed confidentiality agreement containing provisions, in the aggregate, at least as favorable to it as those contained in the confidentiality agreement entered into between Silverback and ARS Pharma in connection with the Merger; and (D) substantially contemporaneously with furnishing any such nonpublic information to such person, Silverback furnishes such nonpublic information to the ARS Pharma (to the extent such information has not been previously furnished to ARS Pharma).

For a more complete description of the non-solicitation provisions, please see the section titled "*The Merger Agreement—Non-Solicitation*."

Termination and Termination Fees (see page 160)

The Merger Agreement contains certain customary termination rights, including the right of either Silverback or ARS Pharma to terminate the Merger Agreement if Silverback's stockholders fail to adopt and approve the Merger Proposal, the right of ARS Pharma to terminate the Merger Agreement if the Silverback Board changes or withdraws its recommendation in favor of the Merger Proposal or publicly approves or enters into an agreement relating to an Acquisition Proposal and the right of Silverback to terminate the Merger Agreement to enter into an agreement relating to a Superior Offer.

Upon termination of the Merger Agreement by ARS Pharma or Silverback in certain circumstances, a termination fee of $6 million may be payable by ARS Pharma to Silverback or by Silverback to ARS Pharma. Additionally, in the event of a termination under certain circumstances by Silverback to enter into an agreement relating to a Superior Offer, a termination fee of $10 million may be payable by Silverback to ARS Pharma. Silverback has also agreed to reimburse ARS Pharma for up to $1.5 million in expenses if the Merger Agreement is terminated by either Silverback or ARS Pharma due to the failure to obtain the approval of the Merger Proposal from Silverback's stockholders.

For a more complete description of the termination provisions and termination fees, please see the section titled "*The Merger Agreement—Termination and Termination Fees.*"

Support Agreements (see page 165)

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of Silverback entered into support agreements (the "Silverback Support Agreements") in favor of ARS Pharma relating to the Merger representing approximately 31% of Silverback's outstanding shares of Silverback Common Stock as of immediately prior to the date of the Merger Agreement. The Silverback Support Agreements provide, among other things, that such officers, directors and stockholders will vote all of their shares of Silverback Common Stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the Merger Proposal, and the other Contemplated Transactions, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any acquisition proposal involving a third party.

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of ARS Pharma entered into support agreements (the "ARS Pharma Support Agreements") in favor of Silverback relating to the Merger representing approximately 83% of the outstanding shares of ARS Pharma Capital Stock immediately prior to the date of the Merger Agreement. The ARS Pharma Support Agreements provide, among other things, that such executive officers, directors and stockholders vote all of their shares of ARS Pharma Capital Stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the ARS Pharma Stockholder Matters, and the other Contemplated Transactions, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any acquisition proposal involving a third party.

Lock-Up Agreements (see page 165)

Concurrently with the execution of the Merger Agreement, (i) certain executive officers, directors and stockholders of ARS Pharma representing approximately 84% of the outstanding shares of ARS Pharma Capital Stock immediately prior to the date of the Merger Agreement and (ii) certain stockholders of Silverback and each executive officer and director of Silverback expected to continue as an executive officer or director of the combined company representing approximately 31% of Silverback's outstanding shares of Silverback Common Stock as of immediately prior to the date of the Merger Agreement, entered into lock-up agreements (the "Lock-Up Agreements"), pursuant to which such executive officers, directors and stockholders accepted certain restrictions on transfers of the shares of Silverback Common Stock held by such executive officer, director or stockholder for the 180 day period following the Effective Time.

Appraisal Rights and Dissenters' Rights (see page 140)

Under the Delaware General Corporation Law ("DGCL"), Silverback stockholders are not entitled to appraisal rights in connection with the Merger.

ARS Pharma stockholders are entitled to statutory appraisal rights in connection with the Merger under Section 262 of the DGCL and under Chapter 13 of the California Corporations Code. One of the conditions to Silverback's obligation to consummate the Merger is that no stockholders of ARS Pharma have exercised statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of California Corporations Code with respect to their shares of ARS Pharma Capital Stock.

As of the date of the Merger Agreement, ARS Pharma stockholders representing approximately 83% of the outstanding shares of ARS Capital Stock immediately prior to the date of the Merger Agreement waived any statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of California Corporations Code with respect to their shares of ARS Pharma Capital Stock.

Management Following the Merger (see page 233)

Immediately following the Merger, the executive management team of the combined company is expected to be comprised of the following individuals with such additional officers as may be added by ARS Pharma or the combined company:

Name	Position with the Combined Company	Current Position
Richard Lowenthal, M.S., MSEL	President and Chief Executive Officer	President and Chief Executive Officer of ARS Pharma
Kathleen Scott	Chief Financial Officer	Chief Financial Officer of ARS Pharma

Sarina Tanimoto, M.D., M.B.A.	Chief Medical Officer	Chief Medical Officer of ARS Pharma
Eric Karas	Chief Commercial Officer	Chief Commercial Officer of ARS Pharma
Justin Chakma	Chief Business Officer	Chief Business Officer of ARS Pharma

Directors of the Combined Company Following the Merger

At the Effective Time, the combined company is expected to initially have an eleven member board of directors, comprised of (a) Richard Lowenthal, M.S., MSEL, Pratik Shah, Ph.D., Peter Kolchinsky, Ph.D., Rajeev Dadoo, Ph.D., Brenton L. Saunders, Phillip Schneider, Michael Kelly and Jonathan Leff, each as an ARS Pharma designee, and (b) Laura Shawver, Ph.D., Peter A. Thompson, M.D. and Saqib Islam, J.D., each as a Silverback designee, until their respective successors are duly elected or appointed and qualified or their earlier death, resignation or removal.

The aforementioned board of directors will have an audit committee, a compensation committee and a nominating and corporate governance committee, in accordance with the Nasdaq rules. All of Silverback's current directors, other than Dr. Shawver, Dr. Thompson and Mr. Islam, are expected to resign from their positions as directors of Silverback, effective as of the Effective Time.

For more information about the executive officers and directors of the combined company following the Merger, please see the section titled "*Management Following the Merger*."

Interests of the Silverback Directors and Executive Officers in the Merger (see page 133)

In considering the recommendation of the Silverback Board with respect to the issuance of Silverback Common Stock pursuant to the Merger Agreement and the other matters to be acted upon by Silverback's stockholders at the Silverback virtual special meeting, Silverback's stockholders should be aware that certain members of the Silverback Board and executive officers of Silverback have interests in the Merger that may be different from, or in addition to, interests they have as Silverback's stockholders.

As of June 30, 2022, Silverback's directors and executive officers (including affiliates) beneficially owned, in the aggregate approximately 30% of the outstanding shares of Silverback Common Stock.

The compensation arrangements with Silverback's officers and directors are discussed in greater detail in the section titled "*The Merger—Interests of the Silverback Directors and Executive Officers in the Merger*." Additionally, as described elsewhere in this proxy statement, including in the section captioned "*Management Following the Merger*," Dr. Shawver, Dr. Thompson and Mr. Islam are expected to remain directors of the combined company.

Certain executive officers and directors of Silverback and ARS Pharma and certain of their respective affiliates have entered into the Silverback Support Agreements and the ARS Support Agreements, pursuant to which such directors, officers and certain of their affiliates, respectively, have agreed, solely in their capacity as stockholders of Silverback and ARS Pharma, respectively, to vote all of their shares of Silverback Common Stock or ARS Pharma Capital Stock, as applicable, in favor of, among other things, the adoption or approval, respectively, of the Merger Agreement and the Contemplated Transactions. The Silverback Support Agreements and ARS Support Agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger—Support Agreements*."

Material U.S. Federal Income Tax Consequences of the Merger (see page 137)

Silverback and ARS Pharma intend the Merger to qualify as a reorganization within the meaning of Section 368(a) of the Code, as described in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*." If the Merger qualifies as a reorganization within the meaning of Section 368(a) of the Code, ARS Pharma stockholders will not recognize gain or loss for U.S. federal income tax purposes on the receipt of shares of Silverback Common Stock issued in connection with the Merger.

Regulatory Approvals Required for the Merger

In the United States, Silverback must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with the issuance of shares of Silverback Common Stock to ARS Pharma's stockholders in connection with the Merger and the other Contemplated Transactions and the filing of this proxy statement with the SEC. Silverback does not intend to seek any regulatory approval from antitrust authorities to consummate the Merger and the other transactions and actions contemplated by the Merger Agreement, other than under the HSR Act, as described below.

Under the Merger Agreement, Silverback and ARS Pharma have agreed to use reasonable best efforts to obtain all regulatory approvals required to consummate the Merger and the other transactions contemplated by the Merger Agreement, including filing notifications required pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act") and the expiration or termination of the applicable waiting period thereunder.

On August 4, 2022, Silverback and ARS Pharma made the necessary filings required to be made under the HSR Act. The applicable waiting period under the HSR Act expired on September 6, 2022.

For more information, please see the section titled "*The Merger—Regulatory Approvals Required for the Merger.*"

Risk Factors (see page 25)

- Failure to complete the Merger may result in Silverback and ARS Pharma paying a termination fee to the other party and could harm the price of Silverback Common Stock and future business and operations of each company.
- Silverback may not be able to divest its legacy programs within the timeframe under the Merger Agreement, on favorable terms or at all, which may result in the value of such assets not being included in the calculation of the Exchange Ratio.
- If the conditions to the closing of the Merger are not met, the Merger may not occur.
- The Merger may be completed even though certain events occur prior to the Closing that materially and adversely affect Silverback and/or ARS Pharma.
- Some executive officers and directors of Silverback have interests in the Merger that are different from the stockholders of Silverback and that may influence them to support or approve the Merger without regard to the interests of the stockholders of Silverback.
- The market price of Silverback Common Stock following the Merger may decline as a result of the Merger.

- Silverback and ARS Pharma securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in the respective companies.
- During the pendency of the Merger Agreement, Silverback and ARS Pharma may not be able to enter into alternative acquisition transactions with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.
- Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.
- Because the lack of a public market for the ARS Pharma Capital Stock makes it difficult to evaluate the fairness of the Merger, the stockholders of ARS Pharma may receive consideration in the Merger that is less than the fair market value of the ARS Pharma Capital Stock and/or Silverback may pay more than the fair market value of the ARS Pharma Capital Stock.
- Silverback and ARS Pharma may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of Silverback and ARS Pharma management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.
- ARS Pharma is a clinical-stage biopharmaceutical company and has incurred significant losses since its inception. ARS Pharma anticipates that it will continue to incur significant losses for the foreseeable future.
- ARS Pharma has a limited operating history and only one current product candidate, *neffy*, which is in the clinical stage of development and has no commercial sales, which may make it difficult to evaluate the prospects for ARS Pharma's future viability.
- ARS Pharma has never generated revenue from product sales and may never be profitable.
- ARS Pharma may need additional funding, and if it is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development activities or commercialization efforts.
- ARS Pharma currently depends on the success of *neffy*, which is its only current product candidate. If ARS Pharma is unable to obtain regulatory approval for, and successfully commercialize, *neffy*, or experiences significant delays in doing so, its business will be materially harmed.
- The regulatory approval processes of the FDA, the EMA and other comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if ARS Pharma is ultimately unable to obtain regulatory approval for *neffy* or any future product candidates, its business will be substantially harmed.
- Competitive products may reduce or eliminate the commercial opportunity for *neffy* for its current or future indications. If ARS Pharma's competitors develop technologies or product candidates more rapidly than ARS Pharma, or their technologies or product candidates are more effective or safer than ARS Pharma's, its ability to develop and successfully commercialize *neffy* may be adversely affected.
- ARS Pharma intends to rely completely on third parties to manufacture and distribute ARS Pharma's supply of *neffy* and intends to rely on third parties to manufacture and distribute any future product candidates.

- ARS Pharma is dependent on international third-party licensees and assignees for the development and commercialization of *neffy* in several countries outside the United States. The failure of these third parties to meet their contractual, regulatory or other obligations could adversely affect ARS Pharma's business.
- ARS Pharma may seek to enter into additional collaborations, licenses and other similar arrangements for *neffy* or any future product candidate and may not be successful in doing so, and even if it is, it may relinquish valuable rights and may not realize the benefits of such relationships.
- The market for *neffy* and any future product candidates ARS Pharma may develop may be smaller than it expects.
- ARS Pharma's commercial success depends on its ability to obtain and maintain sufficient intellectual property protection for its product candidates and other proprietary technologies.
- A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect ARS Pharma's business, including its nonclinical studies, clinical trials, third parties on whom ARS Pharma relies, ARS Pharma's supply chain, its ability to raise capital, its ability to conduct regular business and its financial results.
- ARS Pharma's success is highly dependent on its ability to attract and retain highly skilled executive officers and employees.
- If any of the events described under the sections titled "*Risk Factors—Risks Related to the Merger*" and "*Risk Factors—Risks Related to ARS Pharma*" occur, those events could cause the potential benefits of the Merger not to be realized.

These risks and other risks are discussed in greater detail under the section titled "*Risk Factors*". Silverback encourages you to read and consider all of these risks carefully.

Nasdaq Market Listing (see page 139)

Shares of Silverback Common Stock are currently listed on The Nasdaq Global Market under the symbol "SBTX." Silverback has filed an initial listing application with Nasdaq pursuant to Nasdaq's "reverse merger" rules for the purposes of listing the shares of Silverback Common Stock issuable pursuant to the Merger. Substantially concurrent with the completion of the Merger, Silverback will be renamed "ARS Pharmaceuticals, Inc." and expects to trade on The Nasdaq Global Market under the symbol "SPRY."

Anticipated Accounting Treatment (see page 140)

The Merger will be accounted for as a reverse recapitalization under U.S. generally accepted accounting principles ("GAAP"). For accounting purposes, ARS Pharma is considered to be acquiring Silverback in this transaction. This determination was primarily based on the expectations that, immediately following the Merger: (i) ARS Pharma stockholders will own a substantial majority of the voting rights; (ii) ARS Pharma will designate a majority (eight of eleven) of the initial members of the board of directors of the combined company; and (iii) ARS Pharma's executive management team will become the management of the combined company. Accordingly, for accounting purposes, the Merger will be treated as the equivalent of ARS Pharma issuing stock to acquire the net assets of Silverback. Apart from cash and cash equivalents and other highly liquid assets, the other assets and liabilities being acquired are expected to be nominal. At the close of the Merger, the net assets of Silverback will be recorded at their acquisition-date fair value in the financial statements of ARS Pharma and the reported operating results prior to the Merger will be those of ARS Pharma.

Silverback Virtual Special Meeting (see page 104)

The Silverback virtual special meeting will be held exclusively online via audio-only webcast on November 4, 2022 at 10:00 a.m. Pacific Time, unless postponed or adjourned to a later date. The Silverback virtual special meeting can be accessed by visiting www.proxydocs.com/SBTX, where you will be able to vote your shares and submit questions during the Silverback virtual special meeting webcast by logging in to the website listed above using the control number included in your proxy card. Online check-in will begin at 10:00 a.m. Pacific Time, and we encourage you to allow ample time for the online check-in procedures. Please note that you will not be able to attend the Silverback virtual special meeting in person. For more information on the Silverback virtual special meeting, see the section titled "*The Virtual Special Meeting of Silverback's Stockholders*."

MARKET PRICE AND DIVIDEND INFORMATION

Silverback Common Stock is currently listed on The Nasdaq Global Market under the symbol "SBTX." ARS Pharma is a private company and the shares of ARS Pharma Capital Stock are not publicly traded.

Silverback Common Stock

The closing price of Silverback Common Stock on July 20, 2022, the trading day immediately prior to the public announcement of the Merger on July 21, 2022, as reported on The Nasdaq Global Market, was $4.44 per share. The closing price of Silverback Common Stock on October 5, 2022, as reported on The Nasdaq Global Market, was $5.10 per share.

Because the market price of Silverback Common Stock is subject to fluctuation, the market value of the shares of Silverback Common Stock that ARS Pharma stockholders will be entitled to receive in the Merger may increase or decrease.

Assuming successful application for initial listing with Nasdaq, following the consummation of the Merger, Silverback anticipates that the Silverback Common Stock will trade under Silverback's new name "ARS Pharmaceuticals, Inc." and the new trading symbol "SPRY" on The Nasdaq Global Market.

As of September 19, 2022, the record date for the Silverback virtual special meeting, there were 8 holders of record of the Silverback Common Stock.

Dividends

Silverback has never declared or paid any cash dividends on the Silverback Common Stock and does not anticipate paying cash dividends on the Silverback Common Stock for the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends subsequent to the Merger will be at the discretion of the combined company's then-current board of directors and will depend upon a number of factors, including the combined company's results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the then-current board of directors deems relevant.

ARS Pharma has never declared or paid any cash dividends on shares of the ARS Pharma Capital Stock. ARS Pharma anticipates that the combined company will retain all of its future earnings to advance the development and potential commercialization of *neffy*, and does not anticipate paying any cash dividends on shares of its common stock in the foreseeable future. Any future determination to declare cash dividends on shares of the combined company's common stock will be made at the discretion of its board of directors, subject to applicable law and contractual restrictions and will depend on its financial condition, results of operations, capital requirements, general business conditions and other factors that its board of directors may deem relevant.

RISK FACTORS

The combined company will be faced with a market environment that cannot be predicted and that involves significant risks, many of which will be beyond its control. In addition to the other information contained in this proxy statement, you should carefully consider the material risks described below before deciding how to vote your shares of Silverback Common Stock. You should also read and consider the other information in this proxy statement. Please see the section titled "Where You Can Find More Information."

Risks Related to the Merger

Failure to complete the Merger may result in Silverback and ARS Pharma paying a termination fee to the other party and could harm the price of Silverback Common Stock and future business and operations of each company.

If the Merger is not completed, each of Silverback and ARS Pharma is subject to the following risks:

- upon termination of the Merger Agreement, ARS Pharma may be required to pay Silverback a termination fee of $6 million, under certain circumstances, or Silverback may be required to pay ARS Pharma a termination fee of $6 million or $10 million, under certain circumstances, and may be required to reimburse ARS Pharma for up to $1.5 million in expenses under certain circumstances;
- the parties will have incurred significant expenses related to the Merger, such as legal and accounting fees, which must be paid even if the Merger is not completed; and
- Silverback may be forced to cease its operations, dissolve and liquidate its assets.

In addition, if the Merger Agreement is terminated and the board of directors of Silverback or ARS Pharma determines to seek another business combination, there can be no assurance that either Silverback or ARS Pharma will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger or any partner at all.

Silverback may not be able to divest its legacy programs within the timeframe under the Merger Agreement, on favorable terms or at all, which may result in the value of such assets not being included in the calculation of the Exchange Ratio

Silverback is currently exploring opportunities to divest its legacy programs and other preclinical assets but there can be no assurance that Silverback will be able to divest such assets of favorable terms or at all. Under the terms of the Merger Agreement, cash proceeds that Silverback receives from Asset Dispositions prior to or substantially concurrently with the Closing will be included in the calculation of Silverback Net Cash at Closing, which may decrease the expected Exchange Ratio and increase the expected ownership percentage of pre-Merger Silverback equity holders in the combined company following the Merger. In addition, Silverback will be required to seek ARS Pharma's consent to enter into any Asset Dispositions that would create any material post-disposition liabilities for the combined company following the Closing, to the extent consistent with applicable laws, and there is no guarantee Silverback will obtain ARS Pharma's consent in such case. If the Asset Dispositions are not completed prior to, concurrently with, or immediately following the Closing, such assets will be retained by the combined company and the value of such assets will have no impact on the calculation of the Exchange Ratio. In addition, if any Asset Disposition arrangement includes milestone or other deferred or contingent compensation, such compensation will have no impact on the Exchange Ratio. If Silverback is unable to divest its assets within the required timeframe under the Merger Agreement, on favorable terms or at all, Silverback's stockholders may lose the benefit of the value of such assets that would otherwise be included in the calculation of the Exchange Ratio.

If the conditions to the closing of the Merger are not met, the Merger may not occur.

Even if the Merger Proposal is approved by the stockholders of Silverback, specified conditions must be satisfied or waived to complete the Merger. These conditions are set forth in the Merger Agreement and described in the section titled "*The Merger Agreement—Conditions to the Completion of the Merger.*" Silverback and ARS Pharma cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or will be delayed, and Silverback and ARS Pharma each may lose some or all the intended benefits of the Merger.

The Merger may be completed even though certain events occur prior to the Closing that materially and adversely affect Silverback and/or ARS Pharma.

In general, either party can refuse to complete the Merger if there is a material adverse change affecting the other party between July 21, 2022, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could have a material adverse effect on Silverback and/or ARS Pharma, including:

- general business or economic conditions generally affecting the industry in which Silverback and ARS Pharma operate;
- acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions;
- changes in financial, banking or securities markets;
- any change in the stock price or trading volume of Silverback Common Stock;
- the failure of Silverback to meet internal or analysts' expectations or projections or the results of operations of Silverback;
- any change in, or any compliance with or action taken for the purpose of complying with, any law or GAAP (or interpretations of any law or GAAP);
- any change resulting from the announcement of the Merger Agreement or the pendency of the Contemplated Transactions; or
- any change resulting from the taking of any action required to be taken by the Merger Agreement.

If one or more material adverse changes occur and Silverback and ARS Pharma still complete the Merger, the stock price of the combined company following the closing of the Merger may suffer. This in turn may reduce the value of the Merger to the stockholders of Silverback, ARS Pharma or both.

Some executive officers and directors of Silverback have interests in the Merger that are different from the stockholders of Silverback and that may influence them to support or approve the Merger without regard to the interests of the stockholders of Silverback.

Some officers and directors of Silverback are parties to arrangements that provide them with interests in the Merger that are different from the stockholders of Silverback, including, among others, service as a director of the combined company following the closing of the Merger, severance and retention benefits, the acceleration of equity award vesting, and continued indemnification. For more

information regarding the interests of Silverback's executive officers and directors in the Merger, see the sections titled "*The Merger—Interests of the Silverback Directors and Executive Officers in the Merger*."

The market price of Silverback Common Stock following the Merger may decline as a result of the Merger.

The market price of Silverback Common Stock may decline as a result of the Merger for a number of reasons, including if:

- investors react negatively to the prospects of the combined company's business and prospects following the closing of the Merger;
- the effect of the Merger on the combined company's business and prospects following the closing of the Merger is not consistent with the expectations of financial or industry analysts; or
- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by stockholders or financial or industry analysts.

Silverback and ARS Pharma securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the closing of the Merger as compared to their current ownership and voting interest in the respective companies.

After the completion of the Merger, the current securityholders of Silverback and ARS Pharma will own a smaller percentage of the combined company than their ownership in their respective companies prior to the Merger. Immediately following the Merger, assuming Silverback Net Cash at Closing is $240 million, the pre-Merger equity holders of ARS Pharma are expected to hold approximately 63% of the outstanding shares of Silverback Common Stock and the pre-Merger equity holders of Silverback are expected to hold approximately 37% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method. These estimates are based on the anticipated Exchange Ratio of approximately 1.2441 and are subject to adjustment as provided in the Merger Agreement. For a more complete description of the Merger and the potential adjustments in the Exchange Ratio, please see the section titled "*The Merger Agreement—Merger Consideration and Exchange Ratio*."

In addition, the eleven member board of directors of the combined company will initially consist of eight individuals with prior affiliations with ARS Pharma and three individuals with prior affiliation with Silverback. Consequently, securityholders of ARS Pharma and Silverback will be able to exercise less influence over the management and policies of the combined company following the closing of the Merger than they currently exercise over the management and policies of their respective companies.

During the pendency of the Merger Agreement, Silverback and ARS Pharma may not be able to enter into alternative acquisition transactions with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede the ability of Silverback or ARS Pharma to enter into alternative acquisition transactions, subject to specified exceptions for Silverback relating to fiduciary duties of the Silverback Board, or enter into acquisition transactions or sales or other divestitures of assets, excluding, in the case of Silverback, any Asset Dispositions. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of Silverback and ARS Pharma from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except, in the case of Silverback, in limited circumstances when the Silverback Board determines in good faith, after consultation with its independent financial advisor, if any, and outside counsel, that an unsolicited competing proposal constitutes, or would reasonably be expected to result in, a Superior Offer and that failure to take action could be reasonably likely to be inconsistent with the fiduciary duties of the Silverback Board under applicable law. In addition, if Silverback or ARS Pharma terminate the Merger Agreement under specified circumstances, including terminating because of a decision to recommend an Acquisition Proposal, ARS Pharma may be required to pay Silverback a termination fee of $6 million or Silverback may be required to pay ARS Pharma a termination fee of $6 million or $10 million, as described under "*The Merger Agreement—Termination and Termination Fees.*" This termination fee may discourage third parties from submitting competing proposals to Silverback or ARS Pharma or their stockholders and may cause the ARS Pharma Board or Silverback Board, as applicable, to be less inclined to recommend a competing proposal.

Because the lack of a public market for the ARS Pharma Capital Stock makes it difficult to evaluate the fairness of the Merger, the stockholders of ARS Pharma may receive consideration in the Merger that is less than the fair market value of the ARS Pharma Capital Stock and/or Silverback may pay more than the fair market value of the ARS Pharma Capital Stock.

The outstanding shares of ARS Pharma Capital Stock are privately held and are not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of the ARS Pharma Capital Stock. Because the percentage of Silverback equity to be issued to ARS Pharma stockholders was determined based on negotiations between the parties, it is possible that the value of the Silverback Common Stock to be received by ARS Pharma stockholders will be less than the fair market value of the ARS Pharma Capital Stock, or Silverback may pay more than the aggregate fair market value for the ARS Pharma Capital Stock.

The fairness opinion delivered by SVB Securities to the Silverback Board prior to the entry into the Merger Agreement does not reflect changes in circumstances that may have occurred since the date of the Opinion.

The Silverback Board has not obtained an updated fairness opinion either as of the date of this proxy statement or as of any other date subsequent to the date of the Opinion from SVB Securities, Silverback's financial advisor. Changes in circumstances, including in the operations and prospects of Silverback or ARS Pharma, stock prices, general market and economic conditions and other factors, some or all of which may be beyond the control of Silverback and ARS Pharma are not reflected in such Opinion. The Opinion does not speak as of any date other than the date of the Opinion.

Because the Merger will result in an ownership change under Section 382 of the Code for Silverback, Silverback's pre-Merger net operating loss ("NOL") carryforwards and certain other tax attributes will be subject to limitations. The NOL carryforwards and other tax attributes of ARS Pharma and of the combined company may also be subject to limitations as a result of ownership changes.

As of December 31, 2021, Silverback had U.S. federal NOL carryforwards of $160.3 million, and ARS Pharma had U.S. federal NOL carryforwards and state NOL carryforwards of approximately $25.6 million and $6.9 million, respectively. If a corporation undergoes an "ownership change" within

the meaning of Section 382 of the Code ("Section 382"), the corporation's NOL carryforwards and certain other tax attributes arising before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The Merger will result in an ownership change for Silverback and, accordingly, Silverback's NOL carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after the Merger. ARS Pharma's NOL carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on Silverback's, ARS Pharma's and the combined company's NOL carryforwards. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of Silverback's, ARS Pharma's or the combined company's NOL carryforwards and other tax attributes, which could have an adverse effect on cash flow and results of operations. For more information on limitations on NOL carryforwards and certain other tax attributes, see *"Risk Factors—Risks related to the Combined Company—The combined company's ability to use its NOL carryforwards and certain other tax attributes may be limited."*

Silverback and ARS Pharma may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of Silverback and ARS Pharma management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. Silverback and ARS Pharma may become involved in this type of litigation in connection with the Merger, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect the business of Silverback, ARS Pharma, and the combined company.

If the Merger does not qualify as a "reorganization" for U.S. federal income tax purposes, U.S. holders of ARS Pharma Capital Stock will be required to recognize gain or loss for U.S. federal income tax purposes upon the exchange of ARS Pharma Capital Stock for Silverback Common Stock in the Merger.

The U.S. federal income tax consequences of the Merger to U.S. Holders (as defined in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*") will depend on whether the Merger qualifies as a "reorganization" for U.S. federal income tax purposes. If the Merger fails to qualify as a reorganization within the meaning of Section 368(a) of the Code, a U.S. Holder would recognize gain or loss for U.S. federal income tax purposes upon the exchange of ARS Pharma Capital Stock for Silverback Common Stock in the Merger. For a more complete discussion of the material U.S. federal income tax consequences of the Merger, please review the information set forth in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*" in this proxy statement.

Risks Related to Silverback

For risks related to the business of Silverback, please refer to the section entitled "Item 1A. Risk Factors" set forth in Silverback's Form 10-K for the year ended December 31, 2021, filed with the SEC on March 31, 2022, and Silverback's Form 10-Q for the quarterly period ended on June 30, 2022, filed with the SEC on August 11, 2022, which reports are incorporated by reference herein.

Risks Related to ARS Pharma

Risks Related to ARS Pharma's Financial Position and Need for Capital

ARS Pharma is a clinical-stage biopharmaceutical company and has incurred significant losses since its inception. ARS Pharma anticipates that it will continue to incur significant losses for the foreseeable future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. ARS Pharma's only product candidate, *neffy*, is in the clinical stage of development. ARS Pharma has no products approved for commercial sale and has not generated any revenue from product sales to date, and ARS Pharma will continue to incur significant research and development and other expenses related to ARS Pharma's clinical development and ongoing operations. As a result, ARS Pharma is not profitable and has incurred losses in each period since its inception. Since its inception, ARS Pharma has devoted substantially all of its efforts and financial resources to organizing and staffing ARS Pharma, business planning, raising capital, performing research and development activities, and providing general and administrative support for these operations. ARS Pharma's financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on ARS Pharma's stockholders' equity and working capital. ARS Pharma's net losses were approximately $1.1 million and $20.2 million for the years ended December 31, 2020 and 2021, respectively. As of June 30, 2022, ARS Pharma had an accumulated deficit of $55.9 million. ARS Pharma expects to continue to incur significant losses for the foreseeable future, and ARS Pharma expects these losses to increase as ARS Pharma continues its research and development of, seeks regulatory approvals and prepares for commercialization for its product candidate, *neffy*, an investigational, new formulation of epinephrine, for the emergency treatment of Type I allergic reactions and potential additional indications.

ARS Pharma anticipates that its expenses will increase substantially if and as it:

- continues to develop and conduct nonclinical studies and clinical trials for *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications;
- seeks regulatory approvals in the United States, the European Union ("EU") and other geographic regions for *neffy* for the emergency treatment of Type I allergic reactions and other indications that successfully complete clinical development;
- seeks to identify additional product candidates;
- initiates and continues research, preclinical and clinical development efforts for any future product candidates;
- experiences any delays or encounters any issues with any of the above, including but not limited to failed studies, negative or mixed clinical trial results, safety issues or other regulatory challenges, the risk of which in each case may be exacerbated by the ongoing COVID-19 pandemic;
- adds clinical, scientific, operational, financial and management information systems and personnel, including personnel to support its product candidate development and potential future commercialization efforts and help it comply with its obligations as a public company;
- maintains, expands and protects its intellectual property portfolio;

- establishes or expands its sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize any products for which it may obtain regulatory approval; and
- acquires or in-licenses other product candidates and technologies.

ARS Pharma's expenses could increase beyond its expectations if ARS Pharma is required by the FDA, the European Medicines Agency ("EMA") or other regulatory authorities to perform clinical trials or conduct nonclinical studies in addition to those that ARS Pharma currently expects, or if there are any delays in completing its clinical trials or the development of *neffy*, or if ARS Pharma chooses to develop any future product candidates.

ARS Pharma has never generated revenue from product sales and may never be profitable.

ARS Pharma's ability to become and remain profitable depends on its ability to generate significant revenue from product sales. ARS Pharma does not expect to generate significant revenue, if any, unless and until ARS Pharma, either alone or with a collaborator, is able to obtain regulatory approval for, and successfully commercialize, *neffy* for its initial indication and potential additional indications. Successful commercialization of *neffy* will require achievement of many key milestones, which vary by jurisdiction and may include demonstrating safety and efficacy in clinical trials, and obtaining regulatory approval for *neffy*. If *neffy* is approved, ARS Pharma, or any of its current or future licensing and collaboration partners must also comply with post-approval requirements, such as those relating to marketing and manufacturing. Finally, obtaining adequate coverage and reimbursement for *neffy* from private or government payors will be crucial to *neffy's* commercial success. Because of the uncertainties and risks associated with these activities, ARS Pharma is unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when ARS Pharma might achieve profitability. ARS Pharma and any current and future licensing and collaboration partners may never succeed in these activities and, even if ARS Pharma does, or any current or future licensing and collaboration partners do, ARS Pharma may never generate revenues that are large enough for it to achieve profitability. Even if ARS Pharma does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis.

ARS Pharma's failure to become and remain profitable may depress the market price of the combined company's common stock and could impair its ability to raise capital, expand its business or continue its operations.

ARS Pharma has a limited operating history and only one current product candidate, neffy, which is in the clinical stage of development and has no commercial sales, which may make it difficult to evaluate the prospects for ARS Pharma's future viability.

ARS Pharma is a biopharmaceutical company founded in 2015, and its operations to date have been limited to organizing, staffing and financing the company, raising capital, and conducting research and development activities, including preclinical and nonclinical studies and clinical trials, for its only product candidate, *neffy*. ARS Pharma has not yet demonstrated an ability to generate product revenues, obtain regulatory approvals, manufacture a commercial product, or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider ARS Pharma's prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ARS Pharma. Any predictions you make about ARS Pharma's future success or viability may not be as accurate as they could be if ARS Pharma had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

ARS Pharma may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving ARS Pharma's business objectives. ARS Pharma is preparing

to transition from a company with a development focus to a company capable of supporting commercial activities. ARS Pharma may not be successful in such a transition.

ARS Pharma may need additional funding, and if it is unable to raise capital when needed, it could be forced to delay, reduce or eliminate its product development activities or commercialization efforts.

ARS Pharma's operations have consumed significant amounts of cash since inception. Based upon ARS Pharma's current operating plan, ARS Pharma believes that its cash and cash equivalents, along with the Silverback Net Cash following the Merger, will fund the combined company's operating and capital expenses for at least three years from Closing. ARS Pharma expects ARS Pharma's spending levels to increase in connection with seeking regulatory approval and preparing for commercialization of *neffy* for the emergency treatment of Type I allergic reactions. In addition, if ARS Pharma obtains regulatory approval for the marketing of *neffy*, ARS Pharma expects to incur significant expenses related to commercial launch, product sales, medical affairs, marketing, manufacturing and distribution. Further, ARS Pharma expects to incur additional costs associated with operating as a public company following the Closing. Even if its nonclinical and clinical development of *neffy* is successful and ARS Pharma is able to gain marketing approval for *neffy* for the emergency treatment of Type I allergic reactions in the timeframe it anticipates, ARS Pharma may require significant additional amounts of cash in order to launch and commercialize *neffy* for this indication in the United States or for any additional indications for which *neffy* receives regulatory approval. In addition, other unanticipated costs may arise in the course of ARS Pharma's development efforts. Because the outcome of ARS Pharma's ongoing and anticipated clinical trials and timeframe for regulatory approvals for *neffy* is highly uncertain, it cannot reasonably estimate the actual amounts of cash necessary to successfully complete the development and commercialization of *neffy* for any indication it is pursuing.

ARS Pharma's future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications, as well as any future product candidates ARS Pharma may develop;
- the timing of, and the costs involved in, obtaining regulatory approval for the marketing of *neffy* for the emergency treatment of Type I allergic reactions and potential additional indications, and any future product candidates ARS Pharma may develop and pursue;
- the number of future product candidates that ARS Pharma may pursue and their development requirements, if any;
- if approved, the costs of commercialization activities for *neffy* for any approved indications, or the similar cost of any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any current or future licensing and collaboration partners, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue received from commercial sales of *neffy* for any approved indications or from future product candidates, if any;
- the amount and timing of potential royalty and milestone payments to ARS Pharma's current or future licensing and collaboration partners;
- the receipt of licensing fees, royalties and potential milestone payments under ARS Pharma's current or future out-licensing arrangements;
- the extent to which ARS Pharma in-licenses or acquires rights to other products, product candidates or technologies;

- ARS Pharma's headcount growth and associated costs as ARS Pharma expands its personnel, including personnel to support its product candidate development and potential future commercialization efforts and help it comply with its obligations as a public company following the Merger;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting ARS Pharma's intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company following the Merger.

ARS Pharma cannot be certain that additional funding will be available on acceptable terms, or at all. As a result of the ongoing COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive. In addition, the Loan and Security Agreement (the "ARS Loan and Security Agreement"), dated September 30, 2019, as amended, between ARS Pharma and Silicon Valley Bank contains restrictive covenants that prevents ARS Pharma from, among other things, incurring additional indebtedness without Silicon Valley Bank's consent.

Following the Merger, ARS Pharma believes that the combined company's existing cash and cash equivalents will be sufficient to fund its planned operations for at least three years following the Closing. This estimate may prove to be wrong, and ARS Pharma could use its available capital resources sooner than it currently expects. Further, changing circumstances, some of which may be beyond ARS Pharma's control, could cause it to consume capital significantly faster than it currently anticipates, and ARS Pharma may need to seek additional funds sooner than planned.

The combined company will have no committed source of additional capital other than potential milestone payments and royalties under its collaboration and licensing agreements. If ARS Pharma is unable to raise additional capital in sufficient amounts or on terms acceptable to it, ARS Pharma may have to significantly delay, scale back or discontinue the development or potential commercialization of *neffy* for additional indications. ARS Pharma may need to seek licensing and collaboration partners for *neffy* for commercialization in additional indications on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms its rights to *neffy* in markets where ARS Pharma otherwise would seek to pursue development or commercialization itself. Any of the above events could significantly harm ARS Pharma's business, prospects, financial condition, and results of operations.

Raising additional capital may cause dilution to the combined company's stockholders, restrict it operations or require it to relinquish rights to its technologies or product candidate.

ARS Pharma expects its expenses to increase in connection with its planned operations. Based upon ARS Pharma's current operating plan, ARS Pharma believes that its cash and cash equivalents along with the Silverback Net Cash following the Closing will fund its operating and capital expenses for at least three years following the Closing. However, unless and until ARS Pharma can generate a substantial amount of revenue from *neffy*, ARS Pharma may seek to finance its future cash needs through public or private equity offerings, royalty-based or debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, ARS Pharma may seek additional capital due to favorable market conditions or strategic considerations, even if ARS Pharma believes that it has sufficient funds for its current or future operating plans.

To the extent that ARS Pharma raises additional capital through the sale of common stock, convertible securities or other equity securities, stockholders' interests may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect its stockholders' rights. In addition, new debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that further limit ARS Pharma's ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact its ability to conduct its business. In addition, securing financing could require a substantial amount of time and attention from ARS Pharma's management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect management's ability to oversee the development and potential future commercialization of *neffy.*

If ARS Pharma raises additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, ARS Pharma may have to relinquish valuable rights to its technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to ARS Pharma.

ARS Pharma's existing indebtedness may limit its flexibility in financing and operating its business and adversely affect its business, financial condition and results of operations.

As of June 30, 2022, there was $6.7 million of principal owed under the ARS Loan and Security Agreement. The ARS Loan and Security Agreement contains customary conditions to borrowing, events of default and affirmative and negative covenants, including covenants that restrict ARS Pharma's ability (and the ability of certain of its subsidiaries) to incur additional indebtedness, grant liens, dispose of assets, enter into certain licensing and collaboration agreements, change its business, pay dividends or make other distributions to holders of its stock, engage in mergers and acquisitions, permit or suffer any change in control, make investments or engage in transactions with its affiliates. Such restrictions could limit ARS Pharma's ability to take certain actions or reduce its flexibility to run and manage its business which could have an adverse effect on its results of operations. The obligations under the ARS Loan and Security Agreement are also secured by liens on substantially all of ARS Pharma's assets, excluding its intellectual property on which there is a negative pledge, subject to customary exceptions. If ARS Pharma were unable to repay amounts due under the ARS Loan and Security Agreement, Silicon Valley Bank could proceed against such assets. Any declaration by Silicon Valley Bank of an event of default could significantly harm ARS Pharma's business and prospects and could cause the price of the combined company's common stock to decline.

Changes in tax law could adversely affect ARS Pharma's business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect ARS Pharma or holders of the combined company's common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on ARS Pharma's business, cash flow, financial condition or results of operations.

Risks Related to the Development of *neffy* or Any Future Product Candidates

ARS Pharma currently depends on the success of neffy, which is its only current product candidate. If ARS Pharma is unable to obtain regulatory approval for, and successfully commercialize, neffy, or experiences significant delays in doing so, its business will be materially harmed.

ARS Pharma currently only has one product candidate, *neffy*, and its business and future success depends entirely on its ability to develop, obtain regulatory approval for, and then successfully commercialize, *neffy*, which is currently in clinical development for the emergency treatment of Type I allergic reactions in adults and children age 4 to 18 years. This may make an investment in the combined company riskier than similar companies that have multiple product candidates in active development that may be able to better sustain failure of a lead product candidate.

ARS Pharma currently has no products approved for marketing and is investing the majority of its efforts and financial resources in the development of its sole product candidate, *neffy,* for the emergency treatment of Type I allergic reactions and potential other indications. Successful continued development and ultimate regulatory approval of *neffy* for ARS Pharma's initial indication and potential additional indications is critical to the future success of its business. ARS Pharma will need to successfully complete its clinical development of *neffy* for the emergency treatment of Type I allergic reactions and other indications. The future regulatory and commercial success of *neffy* and any future product candidates is subject to a number of risks, including the following:

- successful completion of nonclinical studies and clinical trials;
- successful patient enrollment in clinical trials;
- successful data from ARS Pharma's nonclinical studies and clinical trials that support an acceptable risk-benefit profile of *neffy* or any future product candidates in the intended populations and indications;
- satisfaction of applicable regulatory requirements, including to satisfy applicable rules governing combination products;
- potential unforeseen safety issues or adverse side effects;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- remaining in compliance with post-marketing regulatory requirements;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for *neffy* or any future product candidates;
- making arrangements or maintaining existing arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of *neffy* or any future product candidates;
- entry into collaborations to further the development of *neffy* or any future product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of any approved products, whether alone or in collaboration with others;
- successfully launching commercial sales of *neffy* or any future product candidates, if and when approved;
- acceptance of *neffy* or any future product candidates, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- products, following approval, maintaining a continued acceptable safety profile;

- effectively competing with other therapies;
- ensuring that ARS Pharma promotes and distributes ARS Pharma's products consistent with all applicable healthcare laws; and
- enforcing and defending intellectual property rights and claims.

Many of these risks are beyond ARS Pharma's control, including the risks related to clinical development, the regulatory submission and review process, potential threats to ARS Pharma's intellectual property rights and the manufacturing, marketing and sales efforts of any current or future collaboration partner. If ARS Pharma is unable to develop, receive regulatory approval for, or successfully commercialize *neffy* for the indications ARS Pharma is developing it for, or if ARS Pharma experience delays as a result of any of these risks or otherwise, its business will be materially harmed.

In addition, of the large number of products in development in the pharmaceutical industry, only a small percentage result in the submission of an NDA to the FDA or a Market Authorization Application ("MAA") to the EMA, and even fewer are approved for marketing and commercialization. Furthermore, even if ARS Pharma does receive regulatory approval to market *neffy* for any indication, any such approval may be subject to limitations on the indications or uses or the patient populations for which ARS Pharma may market the product. Accordingly, even if ARS Pharma is able to obtain the requisite financing to continue to fund ARS Pharma's development activities, ARS Pharma cannot assure you that ARS Pharma will successfully develop or commercialize *neffy* for any indication. If ARS Pharma or any of its current or future licensing and collaboration partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize *neffy* for ARS Pharma's initial indication or potential additional indications, ARS Pharma may not be able to generate sufficient revenue to continue its business. In addition, ARS Pharma's failure to satisfy other regulatory requirements could adversely affect its development efforts for *neffy* in other indications.

The denial of regulatory approval for neffy could mean that ARS Pharma needs to delay or even cease operations, and a delay in obtaining such approval would delay commercialization of neffy and adversely impact ARS Pharma's ability to generate revenue, ARS Pharma's business and ARS Pharma's results of operations.

If ARS Pharma is not successful in commercializing *neffy*, or is significantly delayed in doing so, its business will be materially harmed, and ARS Pharma may need to curtail or cease operations. ARS Pharma currently has no pharmaceutical products approved for marketing, and ARS Pharma may never obtain regulatory approval to market and commercialize *neffy* for any indication. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pharmaceutical products are subject to extensive regulation by the FDA, the EMA, and other regulatory agencies in the United States, EU and other countries, and such regulations differ from country to country. ARS Pharma is not permitted to market *neffy* until ARS Pharma receives approval or marketing authorization from the relevant regulatory authority. The FDA, the EMA or any other foreign regulatory agency can delay, limit or deny approval to market *neffy* for many reasons, including:

- ARS Pharma's inability to demonstrate to the satisfaction of the FDA, the EMA or any other applicable foreign regulatory agency that *neffy* is safe and effective for the requested indication;
- ARS Pharma's inability to gain agreement from applicable foreign regulatory authorities that *neffy* is appropriate for approval under applicable regulatory pathways;
- the FDA's, the EMA's or any other applicable foreign regulatory agency's disagreement with the interpretation of data from nonclinical and clinical studies and trials;
- ARS Pharma's inability to demonstrate that the clinical and other benefits of *neffy* outweigh any safety or other perceived risks;

- ARS Pharma's ability to enroll an adequate number of patients in and successfully complete ARS Pharma's ongoing and any future clinical trials, including ARS Pharma's pediatric clinical study EPI-10;
- the FDA's, the EMA's or any other applicable foreign regulatory agency's requirement for additional nonclinical or clinical studies or trials, including studies to satisfy applicable rules governing combination products;
- the FDA's, the EMA's or any other applicable foreign regulatory agency's having differing requirements for the trial protocols used in ARS Pharma's clinical trials;
- the FDA's, the EMA's or any other applicable foreign regulatory agency's non-approval of the formulation, labeling and/or the specifications of *neffy*;
- the FDA's, the EMA's or any other applicable foreign regulatory agency's failure to accept the manufacturing processes or third-party manufacturers with which ARS Pharma contracts; or
- the potential for approval policies or regulations of the FDA, the EMA or any other applicable foreign regulatory agencies to significantly change in a manner rendering ARS Pharma's clinical data insufficient for approval.

Of the large number of pharmaceutical products in development, only a small percentage successfully complete the FDA, the EMA or other regulatory approval processes and are commercialized.

Even if ARS Pharma eventually completes clinical testing and receives approval of an NDA, MAA or other foreign marketing authorization for *neffy*, the FDA, the EMA or other applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, which may be required after approval. The FDA, the EMA or other applicable foreign regulatory agency may also approve *neffy* for a more limited indication and/or a narrower patient population than ARS Pharma originally requests, and the FDA, the EMA or any other applicable foreign regulatory agency may not approve the labeling that ARS Pharma believes is necessary or desirable for the successful commercialization of *neffy*. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would delay or prevent commercialization of *neffy* and would materially adversely impact ARS Pharma's business and prospects.

ARS Pharma has never commercialized a product and may experience delays or unexpected costs or difficulties in obtaining regulatory approval for neffy for its initial indication or potential additional indications.

ARS Pharma has never obtained regulatory approval for, or commercialized, a pharmaceutical product. It is possible that the FDA and the EMA may refuse to accept any or all of ARS Pharma's submitted or planned NDAs and MAAs for substantive review or may conclude after review of ARS Pharma's data that an application is insufficient to obtain regulatory approval for *neffy* or any future product candidates. For example, the EMA is requiring that ARS Pharma submit its preclinical dog anaphylaxis study results prior to issuing an approval decision for its marketing applications for *neffy.* If the FDA and the EMA do not initially approve any of ARS Pharma's submitted or planned NDAs or MAAs, such regulatory authorities may require that ARS Pharma conduct additional costly clinical, nonclinical or manufacturing validation studies before they will reconsider ARS Pharma's future applications. Depending on the extent of these or any other required studies, approval of any NDA, MAA or other application that ARS Pharma submit may be significantly delayed, possibly for several years, or may require ARS Pharma to expend more resources than ARS Pharma has available. Any failure or delay in obtaining regulatory approvals would prevent ARS Pharma from commercializing *neffy* for any indication or any other product candidate, generating revenues and achieving and

sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or EMA to approve any NDA, MAA or other application that ARS Pharma submits. For example, the FDA has indicated that ARS Pharma's ongoing pediatric clinical trial, EPI-10, would be sufficient to support a submission of ARS Pharma's NDA for pediatric approval of a 2.0 mg dose of *neffy* for children weighing more than 30 kg, and to support a separate submission for pediatric approval of a 1mg dose of *neffy* for children weighing between 15 and 30 kg; however, the FDA has not reviewed ARS Pharma's complete clinical data, to date, and therefore there is no guarantee that the FDA will determine that the NDA currently under review by the FDA for approval of a 2.0 mg dose of *neffy* for children weighing more than 30 kg or any future NDA ARS Pharma submits is sufficient for issuing a marketing approval of *neffy* for the emergency treatment of Type I allergic reactions in children. If any of these outcomes occur, ARS Pharma may be forced to abandon the development of *neffy* or any future product candidates, which would materially adversely affect ARS Pharma's business and could potentially cause ARS Pharma to cease operations. ARS Pharma faces similar risks for its applications in other foreign jurisdictions. In addition, difficulties in obtaining approval of *neffy* for the emergency treatment of Type I allergic reactions, could adversely affect ARS Pharma's efforts to seek approval from regulatory authorities for *neffy* for use in other potential indications.

The regulatory approval processes of the FDA, the EMA and other comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if ARS Pharma is ultimately unable to obtain regulatory approval for neffy or any future product candidates, its business will be substantially harmed.

ARS Pharma, and any current and future licensing and collaboration partners, are not permitted to commercialize, market, promote or sell any product candidate in the United States or the EU without obtaining regulatory approval from the FDA or the EMA, respectively. Regulatory authorities in other jurisdictions may have similar requirements. The time required to obtain approval by the FDA, the EMA and other comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of such regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, other than the NDA for *neffy* that ARS Pharma submitted to the FDA in the third quarter of 2022, ARS Pharma has not submitted any product approval submissions for *neffy* or any other product candidate to the FDA, EMA or other comparable foreign regulatory authorities for *neffy* and there can be no assurance that ARS Pharma will receive such approval from such regulatory authorities after submitting any product approval application.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. ARS Pharma cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of *neffy* or any future product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate safety or efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA, the EMA or any other comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. Additionally, ARS Pharma's expenses could increase if it is required by the FDA, the EMA or any other comparable foreign regulatory authority to perform clinical trials or studies in addition to those currently expected, or if there are any delays in completing ARS Pharma's clinical trials or the development of *neffy* for additional indications. It is possible that even if *neffy* or any future product candidate has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of ARS Pharma's clinical trials. Conversely, as a result of the same

factors, ARS Pharma's clinical trials may indicate an apparent positive effect of *neffy* or any future product candidate that is greater than the actual positive effect, if any. Similarly, in its clinical trials ARS Pharma may fail to detect toxicity of or intolerability caused by *neffy* or any future product candidate, or mistakenly believe that *neffy* or any future product candidates are toxic or not well-tolerated when that is not in fact the case.

neffy and any future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or other comparable foreign regulatory authorities may disagree as to the design or implementation of ARS Pharma's clinical trials;
- ARS Pharma may be unable to demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication and, if necessary, that a product candidate and any active components thereof are safe and effective for the proposed indication;
- the FDA, the EMA or other comparable foreign regulatory authorities may find deficiencies with regards to the formulation components or specifications of *neffy,* including, without limitation, with respect to appearance, identity, impurities, or particle size;
- the results of clinical trials may not meet the level of evidence or criteria required by the FDA, the EMA or other comparable foreign regulatory authorities for approval;
- ARS Pharma may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA and comparable authorities in other countries may disagree with ARS Pharma's interpretation of data from clinical trials or nonclinical studies and may require additional trials or studies to support marketing approval;
- the data collected from clinical trials of *neffy* or any future product candidates may not be sufficient to support the submission of an NDA or other submission to the FDA or to obtain regulatory approval in the United States, the EU or elsewhere;
- the FDA, the EMA or other comparable foreign regulatory authorities may find deficiencies with clinical trial sites or fail to approve the manufacturing processes or facilities of third-party manufacturers with which ARS Pharma contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering ARS Pharma's clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in ARS Pharma's failing to obtain regulatory approval to market *neffy* or any future product candidate ARS Pharma develops, which would significantly harm its business, results of operations and prospects. Although ARS Pharma has successfully completed a pre-NDA meeting with the FDA, there is no assurance that the endpoints and trial designs used for the approval of a new formulation of epinephrine for the emergency treatment of Type I allergic reactions will be acceptable for *neffy*. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that ARS Pharma develops. Even if ARS Pharma believes the data collected from current or future clinical trials of *neffy* or any future product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

There can be no assurance that the FDA and other regulatory agencies, including the EMA, will not require additional clinical trials or studies to support an application for the marketing of *neffy* in the

emergency treatment of Type I allergic reactions or any other indication. This may be the case particularly as these regulatory authorities may consult with one another or as ARS Pharma may be required to apprise the respective agencies of studies ARS Pharma is conducting of *neffy* in conjunction with ARS Pharma's requests for marketing approval or in response to requests and updates from the respective agency.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that ARS Pharma encounters difficulties or delays in initiating, screening, enrolling, conducting, or completing its ongoing and planned nonclinical studies and clinical trials. Clinical site initiation and patient screening and enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Investigators and patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services or ARS Pharma's ability to conduct clinical trial site monitoring. Similarly, ARS Pharma's ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be limited, which in turn could adversely impact ARS Pharma's clinical trial operations. Additionally, ARS Pharma may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic. Completion of clinical sample bioanalysis or study reports by third-party contract research organizations could be adversely impacted due to labor shortages or staff turnover due to the ongoing COVID-19 pandemic. As a result of the COVID-19 pandemic, ARS Pharma may face delays in meeting its anticipated timelines for its ongoing and planned clinical trials.

Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period.

Since March 2020, when foreign and domestic inspections were largely placed on hold due to the COVID-19 pandemic, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and has employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. For example, with respect to new sites or facilities in the European Economic Area ("EEA"), which have never had a current Good Manufacturing Practices ("cGMP") inspection or authorization, the EMA has stated that a distant assessment may be

conducted in order to evaluate if the site could be authorized without an on-site pre-approval inspection. If an approval is granted, it should be indicated that the certificate has been granted on the basis of a distant assessment and an on-site inspection should be conducted when circumstances permit. If a cGMP certificate cannot be granted as a result of the distant assessment, a clock-stop in the regulatory approval process will be imposed until an on-site inspection is possible. In addition, even if ARS Pharma were to obtain approval, regulatory authorities may approve *neffy* or any future product candidates for fewer or more limited indications than ARS request, may not approve the price ARS Pharma intends to charge for its products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for *neffy* or any future product candidates.

If the FDA does not conclude that neffy or any future product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as ARS Pharma expects, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

While ARS Pharma believes that ARS Pharma will have the necessary supporting data to submit a marketing application under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("Section 505(b)(2)") regulatory pathway to the FDA for *neffy* for the emergency treatment of Type I allergic reactions for adults and children greater than 30 kg in weight, and upon completion of ARS Pharma's ongoing pediatric study, EPI-10, for children between 15 and 30 kg in weight, there can be no assurance that the FDA will agree that the Section 505(b)(2) pathway is appropriate or will approve any such application or any future application for additional indication or future product candidates.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act ("FDCA"). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to ARS Pharma under the FDCA, would allow an NDA ARS Pharma submits to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for ARS Pharma's future product candidates by potentially decreasing the amount of nonclinical and/or clinical data that ARS Pharma would need to generate in order to obtain FDA approval. This pathway does not, however, expedite the FDA review process timelines.

If the FDA does not allow ARS Pharma to pursue the Section 505(b)(2) regulatory pathway as anticipated, ARS Pharma may need to conduct additional nonclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for *neffy* or any future product candidate, and complications and risks associated with such product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than any product candidates ARS Pharma develops, which could adversely impact ARS Pharma's competitive position and prospects. Even if ARS Pharma is allowed to pursue the Section 505(b)(2) regulatory pathway, ARS Pharma cannot assure you that *neffy* or any future product candidates ARS Pharma develops will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's

interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that ARS Pharma submits under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of ARS Pharma's NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if ARS Pharma is able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval. Finally, a competitor might receive FDA approval before *neffy* and obtain non-patent market exclusivity, which could delay approval of *neffy*.

neffy contains a sprayer component that if not considered as packaging by the FDA is subject to additional regulatory requirements that may further delay or prevent marketing approval of neffy and substantially harm ARS Pharma's business.

neffy is a drug product that also contains a sprayer component that ARS Pharma believes is considered packaging by the FDA, which may require coordination within the FDA and comparable regulatory agencies for review of their drug and such components. Although the FDA and comparable foreign agencies have systems in place for the review and approval of products such as *neffy*, ARS Pharma may experience additional delays in the development and commercialization of *neffy* or any future product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although ARS Pharma anticipates based on historical precedents of other nasal spray products that the sprayer component of *neffy* and any future product candidates ARS Pharma develops will be packaging, reviewed in connection with the evaluation of the underlying drug marketing application, and that no separate marketing application for the sprayer components of such product candidates will be required, the FDA or comparable regulatory authorities may disagree and require that ARS Pharma obtain a separate clearance or approval of the sprayer component as a medical device, which could further delay or prevent marketing approval of such product candidates. Any such delay or inability to obtain marketing approval of *neffy* or any future product candidate could substantially harm ARS Pharma's business.

ARS Pharma may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of neffy or any future product candidates.

To obtain the requisite regulatory approvals to market and commercialize *neffy* and any future product candidates, ARS Pharma must demonstrate through extensive nonclinical studies and clinical trials that such product candidates are safe and effective for their intended use in humans. Nonclinical and clinical testing are expensive and can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and ARS Pharma's future clinical trial results may not be successful.

ARS Pharma may experience delays in completing its clinical trials or nonclinical studies and initiating or completing additional studies or clinical trials. ARS Pharma may also experience numerous

unforeseen events during its clinical trials that could delay or prevent its ability to receive marketing approval or commercialize *neffy* or any future product candidates ARS Pharma develops, including:

- regulators, or institutional review boards ("IRBs") or other reviewing bodies may not authorize ARS Pharma or its investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- ARS Pharma may not reach an agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- a delay in receiving study or clinical trial material from outside the United States;
- the number of subjects or patients required for clinical trials of *neffy* in an indication or any future product candidate may be larger than ARS Pharma anticipates, enrollment in these clinical trials may be insufficient or slower than ARS Pharma anticipates, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than ARS Pharma anticipates;
- ARS Pharma's third-party contractors, including those manufacturing *neffy* or any future product candidates or conducting clinical trials on its behalf, may fail to comply with regulatory requirements or meet their contractual obligations to ARS Pharma in a timely manner, or at all;
- ARS Pharma may have to amend clinical trial protocol(s) submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which ARS Pharma may be required to resubmit to an IRB and regulatory authorities for re-examination;
- unforeseen safety events may occur during the course of a clinical trial and these events may result in the temporary suspension or termination of a clinical trial, or require urgent safety measures or restrictions to protect human subjects during the conduct of a clinical trial;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which ARS Pharma has entered and may enter into agreement for clinical and commercial supplies, or the supply or quality of *neffy* or any future product candidate or other materials necessary to conduct clinical trials of *neffy* or any future product candidates may be insufficient, inadequate or not available at an acceptable cost, or ARS Pharma may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA, the EMA or any other applicable foreign regulatory agencies to significantly change in a manner rendering ARS Pharma's clinical data insufficient for approval.

Regulators, IRBs of the institutions in which clinical trials are being conducted, or data monitoring committees may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or ARS Pharma's clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to appear to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Negative or inconclusive impressions of the results from ARS Pharma's earlier clinical trials of *neffy* for the emergency treatment of Type I allergic reactions or any other clinical trial or nonclinical studies in animals that ARS Pharma has conducted, could mandate repeated or additional nonclinical studies or clinical trials and could delay marketing approvals or result in changes to or delays in

nonclinical studies or clinical trials of *neffy* for other indications. While data from ARS Pharma's studies of *neffy* demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products, ARS Pharma does not know whether any future clinical trials or studies that ARS Pharma may conduct will demonstrate adequate efficacy and safety necessary to result in obtaining regulatory approval to market *neffy* for its initial indication or potential additional indications, or any future product candidate. If later stage clinical trials, including ARS Pharma's ongoing pediatric clinical study, EPI-10, do not produce favorable results that meet regulatory authority criteria, ARS Pharma's ability to obtain regulatory approval for *neffy* for the emergency treatment of Type I allergic reactions or potential additional indications, or any future product candidate, may be adversely impacted.

ARS Pharma's failure to successfully initiate and complete clinical trials of *neffy* for the emergency treatment of Type I allergic reactions or potential additional indications and to demonstrate the efficacy and safety of *neffy*, necessary to obtain regulatory approval to market *neffy* would significantly harm ARS Pharma's business. ARS Pharma's product candidate development costs will also increase if ARS Pharma experiences delays in testing or regulatory approvals and ARS Pharma may be required to obtain additional funds to complete clinical trials. ARS Pharma cannot assure you that its clinical trials will begin as planned or be completed on schedule, if at all, or that ARS Pharma will not need to restructure its trials after they have begun. Significant clinical trial delays also could shorten any periods during which ARS Pharma may have the exclusive right to commercialize *neffy* or any future product candidates or allow its competitors to bring products to market before ARS Pharma does and impair ARS Pharma's ability to successfully commercialize such product candidates, which may harm its business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of *neffy* or any future product candidate.

Even if ARS Pharma completes the necessary nonclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent ARS Pharma or any future licensing and collaboration partners from obtaining approvals for the commercialization of neffy or maintaining any conditional authorization for ARS Pharma's initial indication or potential additional indications as well as for any future product candidate ARS Pharma develops.

Any product candidate ARS Pharma may develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA, the EMA and other regulatory authorities in the United States and in other countries. Failure to obtain marketing approval for a product candidate will prevent ARS Pharma from commercializing that product candidate in a given jurisdiction. ARS Pharma has not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates ARS Pharma may seek to develop in the future will ever obtain regulatory approval. ARS Pharma has no experience in filing and supporting the applications necessary to gain marketing approvals and expects to rely on third-party CROs or regulatory consultants to assist ARS Pharma in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the product's manufacturing process, and usually requires a pre-approval inspection of manufacturing facilities by the relevant regulatory authority. Any product candidates ARS Pharma develops may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that outweigh any benefits of the product candidate and may preclude ARS Pharma from obtaining marketing approval or otherwise prevent or limit commercial use.

The process of obtaining marketing approvals, in the United States, EU and other foreign jurisdictions, is expensive, may take many years if additional preclinical or clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA, the EMA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide during the review process that ARS Pharma's data are insufficient for approval and require additional nonclinical, clinical or other studies. For example, the EMA requested additional support for ARS Pharma's clinical data regarding the similarities in the pharmacokinetic and pharmacodynamic profiles of intra-muscular epinephrine injectable products to 1.0 mg of *neffy*. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. As such, ARS Pharma may be unable to obtain the marketing approvals ARS Pharma pursues and any marketing approvals ARS Pharma ultimately obtains, including any conditional approvals, may be limited or subject to restrictions or post-approval commitments that could render the approved product not commercially viable.

Moreover, principal investigators for ARS Pharma's clinical trials may serve as scientific advisors or consultants to ARS Pharma from time to time and receive compensation in connection with such services. Under certain circumstances, ARS Pharma may be required to report some of these relationships to the FDA, the EMA or comparable foreign regulatory authorities. The FDA, the EMA or comparable foreign regulatory authorities may conclude that a financial relationship between ARS Pharma and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA, the EMA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of ARS Pharma's marketing applications by the FDA, the EMA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of *neffy* or any future product candidate.

If ARS Pharma experiences delays in obtaining approval or if ARS Pharma fails to obtain approval of any product candidates ARS Pharma may develop, the commercial prospects for those product candidates, including for *neffy* for other indications, may be harmed, and ARS Pharma's ability to generate revenues will be materially impaired.

The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial data in ARS Pharma's clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials ARS Pharma commences may not be predictive of the results of the later-stage clinical trials. In addition, initial data in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of ARS Pharma's ongoing, planned or future clinical trials will ultimately be successful or support further clinical development or regulatory approval of *neffy* or any future product candidates. There is a high failure rate for drugs and biologics candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in ARS Pharma's clinical development could have a material adverse effect on its business and operating results.

Interim topline and preliminary data from ARS Pharma's clinical trials that ARS Pharma announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, ARS Pharma may publish interim topline or preliminary data from ARS Pharma's clinical trials. Interim data from clinical trials that ARS Pharma may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data ARS Pharma previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm ARS Pharma's reputation and business prospects.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside ARS Pharma's control.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of ARS Pharma's clinical trials depends, in part, on the speed at which ARS Pharma can recruit patients to participate in its trials, as well as completion of required follow-up periods. ARS Pharma may not be able to initiate or continue clinical trials for *neffy* or any future product candidates if it is unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, the EMA or other comparable foreign regulatory authorities. Additionally, certain clinical trials for *neffy* and any future product candidates may be focused on specific patient populations, particularly pediatric populations, that may be difficult to enroll due to apprehension by patients or caregivers, or on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than ARS Pharma anticipates. The eligibility criteria of ARS Pharma's clinical trials, once established, may further limit the pool of available trial participants. For example, ARS Pharma estimates that are only three million people in the United States who have experienced severe Type I allergic reactions and are at risk of anaphylaxis currently have a filled prescription for an epinephrine intra-muscular injectable device. As a result, ARS Pharma may encounter difficulties in enrolling patients in ARS Pharma's clinical trials, thereby delaying or preventing development and approval of *neffy* for potential additional indications or any future product candidates. Even once enrolled, ARS Pharma may be unable to retain a sufficient number of patients to complete any of ARS Pharma's trials, which could result in discontinuations and delays of its clinical trials and impact the integrity of data from its clinical trials.

Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the severity of the disease under investigation, the nature of the trial protocol, the existing body of safety and efficacy data for the product candidate, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial, the ability to adequately monitor patients during a trial, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied and the risk that patients will drop out of a trial before completing all site visits. Furthermore, ARS Pharma's efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in its clinical trials.

Any negative results ARS Pharma may report in clinical trials of *neffy* or any future product candidate may also make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on ARS Pharma's ability to

develop *neffy* for the emergency treatment of Type I allergic reactions and additional indications and any future product candidates, or could render further development impossible. For example, the impact of public health epidemics, such as the ongoing COVID-19 pandemic, may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay ARS Pharma's clinical trials, or prevent ARS Pharma or its partners from completing ARS Pharma's clinical trials at all, and harm ARS Pharma's ability to obtain approval for such product candidate. Further, if patients drop out of ARS Pharma's clinical trials, miss follow-up visits or otherwise fail to follow clinical trial protocols, whether as a result of the COVID-19 pandemic and related illness or actions taken to slow the spread of COVID-19 or otherwise, the integrity of data from ARS Pharma's clinical trials may be compromised or not accepted by the FDA, the EMA or other regulatory authorities, which would represent a significant setback for the applicable program. In addition, ARS Pharma may rely on CROs and clinical trial sites to ensure proper and timely conduct of ARS Pharma's future clinical trials and, while ARS Pharma intends to enter into agreements governing their services, ARS Pharma will be limited in its ability to compel their actual performance.

neffy or any future product candidate may cause undesirable side effects, adverse events, or have other properties that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects or adverse events caused by *neffy*, or any future product candidate, could cause ARS Pharma or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or comparable foreign regulatory authorities. Although ARS Pharma's clinical studies to date have demonstrated that *neffy* is well-tolerated by patients with no serious treatment-related adverse events, and reported adverse events generally no more severe than grade 1 and comparable with injection products, and with no meaningful pain or irritation based on formal scoring, results of ARS Pharma's ongoing or future clinical trials for *neffy* or any future product candidate could reveal a high and unacceptable severity and prevalence of side effects, adverse events, or unexpected characteristics. Many compounds that initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects or adverse events that prevented further development of the compound.

If unacceptable side effects or adverse events arise in the development of *neffy* or any future product candidates, ARS Pharma, the FDA, the EMA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which ARS Pharma's trials are conducted, or the independent safety monitoring committee could suspend or terminate ARS Pharma's clinical trials or regulatory authorities could order ARS Pharma to cease clinical trials or deny approval of *neffy* or any future product candidates for any or all targeted indications. Treatment-emergent side effects and adverse events that are deemed to be drug-related could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Undesirable side effects or adverse events in one of ARS Pharma's clinical trials for *neffy* in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of *neffy* in other indications. Additionally, there may be negative findings regarding components of *neffy* or future product candidates by other parties. Any negative findings by third parties may impact the future approvability or labeling of *neffy* or other product candidates ARS Pharma may develop. In addition, all side effects and adverse events may not be appropriately recognized or managed by the treating medical staff. Inadequate training in recognizing or managing the potential side effects and adverse events of *neffy* or any future product candidates could result in patient injury or death. Any of these occurrences may harm ARS Pharma's business, financial condition and prospects significantly.

In addition, clinical trials of *neffy* are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that ARS Pharma's clinical trials, or

those of any future collaborator, may indicate an apparent positive effect of *neffy* or a future product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

Finally, *neffy* is comprised of epinephrine and Intravail® that is delivered via an intranasal device that is considered packaging. Intra-muscular injection of epinephrine has been approved by the FDA and other regulatory authorities for the emergency treatment of Type I allergic reactions. In addition, Intravail® has previously been included in the formulations of FDA approved products such as VALTOCO® and TOSYMRA® nasal sprays. The intranasal apparatus ARS Pharma uses to deliver *neffy* has been used to deliver several drugs approved by the FDA and other regulatory authorities, including VALTOCO®, TOSYMRA® and NARCAN®. Even if *neffy* were to receive marketing approval or be commercialized, ARS Pharma would continue to be subject to the risks that the FDA, EMA or similar regulatory authorities could revoke approval of intra-muscular epinephrine injection products, other drug formulations containing Intravail® or utilizing the same intranasal apparatus, or that efficacy, manufacturing or supply issues could arise with epinephrine API, Intravail® or ARS Pharma's intranasal apparatus. This could result in ARS Pharma's own products being removed from the market or being less commercially successful.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about ARS Pharma's clinical development activities and the indications *neffy* is being developed to treat, and ARS Pharma intends to utilize appropriate social media in connection with ARS Pharma's commercialization efforts following regulatory approval of *neffy*, if any. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to ARS Pharma's business, resulting in potential regulatory actions against ARS Pharma, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the Federal Trade Commission ("FTC"), the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged side effect or adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that ARS Pharma may fail to monitor and comply with applicable adverse event reporting obligations or that ARS Pharma may not be able to defend ARS Pharma's business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what ARS Pharma may say about ARS Pharma's product candidates. There is also a risk of inappropriate disclosure of sensitive or confidential information or negative or inaccurate posts or comments about ARS Pharma on any social networking website. In addition, ARS Pharma may encounter attacks on social media regarding ARS Pharma, its management, *neffy* or future product candidates. If any of these events were to occur or ARS Pharma otherwise fail to comply with applicable regulations, ARS Pharma could incur liability, face regulatory actions or incur other harm to its business.

If ARS Pharma fails to develop and commercialize neffy for additional indications or fails to discover, develop and commercialize other product candidates, ARS Pharma may be unable to grow its business and its ability to achieve its strategic objectives would be impaired.

Although the development and commercialization of *neffy* for the emergency treatment of Type I allergic reactions is ARS Pharma's current primary focus, as part of ARS Pharma's longer-term growth strategy, ARS Pharma plans to evaluate *neffy* for use in other indications and may develop other product candidates. ARS Pharma intends to evaluate internal opportunities from *neffy* and may do so for other potential product candidates or choose to in-license or acquire other product candidates as well as commercial products to treat other indications like Type I allergic reactions. These other

potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA, the EMA and/or other applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, ARS Pharma cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Research activities to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. ARS Pharma's research activities may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render ARS Pharma's potential product candidates obsolete;
- product candidates that ARS Pharma develops may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If ARS Pharma is unsuccessful in identifying and developing *neffy* for additional indications or other product candidates, its potential for growth and achieving its strategic objectives may be impaired.

Even if neffy is approved for the emergency treatment of Type I allergic reactions, there remains significant uncertainty as to whether neffy will be successfully developed and ultimately approved for any other indication ARS Pharma is exploring or pursuing.

As part of ARS Pharma's longer-term growth strategy, ARS Pharma plans to evaluate and potentially develop *neffy* for other indications. ARS Pharma's programs for such other indications are at a very early stage and there remains significant uncertainty as to whether *neffy* will be successfully developed and ultimately approved for any other indication ARS Pharma is exploring or pursuing. Even if *neffy* is approved for the emergency treatment of Type I allergic reactions, there will remain significant uncertainty regarding whether *neffy* will be successfully developed or approved for any other indication. If ARS Pharma is unable to successfully develop, or if regulatory authorities do not approve, *neffy* for any other indication, ARS Pharma's potential for growth and achieving ARS Pharma's strategic objectives may be impaired.

ARS Pharma may not be successful in its efforts to expand its pipeline by identifying additional indications for which to investigate neffy in the future. ARS Pharma may expend its limited resources to pursue a particular indication or formulation for neffy and fail to capitalize on product candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.

Because ARS Pharma has limited financial and managerial resources, ARS Pharma is focused on specific indications for *neffy*. As a result, ARS Pharma may fail to generate additional clinical development opportunities for *neffy* for a number of reasons, including, that *neffy* may in certain indications, on further study, be shown to have harmful side effects, limited to no efficacy or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. In addition, ARS Pharma may forgo or delay pursuit of opportunities with other indications that could have had greater commercial potential or likelihood of success. Furthermore, research activities to identify additional indications for *neffy* require substantial technical, financial and human resources. ARS Pharma may not be able to develop *neffy* for any additional indications based on resource allocation decisions and other reasons. ARS Pharma's resource allocation decisions may cause ARS Pharma to fail to capitalize on viable commercial products or profitable market opportunities. ARS Pharma's spending on current and future research and development activities for specific indications may not yield any commercially viable products.

Additionally, ARS Pharma may pursue in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to ARS Pharma. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of ARS Pharma's management's time and the expenditure of ARS Pharma's resources with no resulting benefit.

For example, if ARS Pharma is unable to identify programs that ultimately result in approved products, ARS Pharma may spend material amounts of its capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on its investment.

Competitive products may reduce or eliminate the commercial opportunity for neffy for its current or future indications. If ARS Pharma's competitors develop technologies or product candidates more rapidly than ARS Pharma, or their technologies or product candidates are more effective or safer than ARS Pharma's, its ability to develop and successfully commercialize neffy may be adversely affected.

The clinical and commercial landscape for the emergency treatment of Type I allergic reactions is highly competitive and subject to significant technological change. ARS Pharma faces competition with respect to ARS Pharma's current indications for *neffy* and will face competition with respect to any future indications of *neffy* or other product candidates that ARS Pharma may seek to develop or commercialize in the future from large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. If approved, ARS Pharma anticipates that *neffy* will compete primarily against epinephrine intra-muscular injectable products, for the emergency treatment of Type I allergic reactions including EpiPen® and its generics, which is marketed by Viatris, Inc. and Teva Pharmaceuticals, Inc.; Adrenaclick®, which is marketed by Amneal Pharmaceuticals, Inc.; Auvi-Q®, which is marketed by Kaleo, Inc.; and Symjepi®, which is marketed by Sandoz, Inc., a Novartis division. Several other companies are also clinically developing larger dose intranasal epinephrine product candidates that may compete with *neffy*, including Bryn Pharma, Nasus Pharma and Hikma Pharmaceuticals, Inc. (previously INSYS Therapeutics, Inc.), Amphastar Pharmaceuticals is developing an intranasal candidate with an undisclosed dose, and Aquestive Therapeutics is developing a sublingual candidate

based on a prodrug of epinephrine. If *neffy* is approved for other indications, it would also compete with a range of other therapeutic treatments that are well established or in development.

Many of ARS Pharma's potential competitors have substantially greater financial, technical, commercial and human resources than ARS Pharma does and significantly more experience in the discovery, development and regulatory approval of product candidates and the commercialization of those products. Accordingly, ARS Pharma's competitors may be more successful than ARS Pharma may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. ARS Pharma's competitors' products may be more effective, or more effectively marketed and sold, than any product candidate ARS Pharma may commercialize and may render *neffy* or any future product candidates obsolete or non-competitive before ARS Pharma can recover development and commercialization expenses. In addition, ARS Pharma's competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than *neffy* or any future product candidates that ARS Pharma may develop, which could render such product candidates obsolete and noncompetitive.

If ARS Pharma obtains approval for *neffy* or any other future product candidate, ARS Pharma may face competition based on many different factors, including the efficacy, safety and tolerability of ARS Pharma's products, the ease with which ARS Pharma's products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products ARS Pharma may develop. Competitive products may make any products ARS Pharma develop obsolete or noncompetitive before ARS Pharma recovers the expense of developing and commercializing its product candidates. Such competitors could also recruit ARS Pharma's employees, which could negatively impact ARS Pharma's level of expertise and its ability to execute its business plan.

In addition, ARS Pharma's competitors may obtain patent protection, regulatory exclusivities or regulatory approval and commercialize products more rapidly than it does, which may impact future approvals or sales of any of ARS Pharma's product candidates that receive regulatory approval. If the FDA or the EMA approves the marketing and commercial sale of *neffy* or any future product candidate, ARS Pharma will also be competing with respect to marketing capabilities and manufacturing efficiency. ARS Pharma expects competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. ARS Pharma's profitability and financial position will suffer if ARS Pharma's product candidates receive regulatory approval but cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of ARS Pharma's competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with ARS Pharma in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, ARS Pharma's activities.

If the FDA, the EMA or other comparable foreign regulatory authorities approve generic versions of neffy or any future product candidate of ours that receives regulatory approval, or such authorities do not grant ARS Pharma's products appropriate periods of non-patent exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.

In the United States, once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications ("ANDAs") in the United States. In support of an ANDA, a generic manufacturer generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, and adequate labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning, in part, that it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Moreover, third-party insurers require, and many states allow or require, substitution of therapeutically equivalent generic drugs at the pharmacy level even if the branded drug is prescribed. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be lost to the generic product.

The FDA may not finally approve an ANDA for a generic product or a Section 505(b)(2) NDA of a competitor until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the listed drug is invalid, unenforceable or will not be infringed by the generic product. In that case, the applicant may submit its application four years following approval of the listed drug and seek to launch its generic product even if ARS Pharma still has patent protection for ARS Pharma's product unless an infringement suit is timely filed by the NDA or patent holder in which case the FDA cannot approve the ANDA or a Section 505(b)(2) NDA for 30 months unless a court decision in favor of the generic manufacturer is issued earlier.

Competition that neffy or any future products, if approved, may face from competitor versions of such products could negatively impact ARS Pharma's future revenue, profitability and cash flows and substantially limit ARS Pharma's ability to obtain a return on ARS Pharma's investments in those product candidates. Obtaining and maintaining regulatory approval of neffy or any future product candidates in one jurisdiction does not mean that ARS Pharma will be successful in obtaining regulatory approval of those product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of *neffy* and any future product candidates in one jurisdiction does not guarantee that ARS Pharma will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if a regulatory authority, such as the EMA, grants marketing approval of *neffy*, comparable regulatory authorities in the United States and other foreign jurisdictions must also approve the manufacturing, marketing and promotion of *neffy* in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United

States or the EU including additional nonclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States including certain jurisdictions in the EU, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that ARS Pharma intends to charge for ARS Pharma's products is also subject to approval.

ARS Pharma plans to submit marketing applications in the United States and in the EU. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which ARS Pharma must comply prior to marketing in those jurisdictions and such regulatory requirements can vary widely from country to country. Obtaining other regulatory approvals and compliance with other regulatory requirements could result in significant delays, difficulties and costs for ARS Pharma and could require additional nonclinical studies or clinical trials, which could be costly and time-consuming and could delay or prevent the introduction of ARS Pharma's products in certain countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. ARS Pharma does not have any product candidates approved for sale in any jurisdiction, including international markets, and ARS Pharma does not have experience in obtaining regulatory approval in either domestic or international markets. If ARS Pharma fails to comply with the regulatory requirements in international markets and/or obtain and maintain applicable marketing approvals, ARS Pharma's target market will be reduced and ARS Pharma's ability to realize the full market potential of *neffy* or any future product candidates will be harmed.

ARS Pharma received Fast Track designation for neffy in the United States and may in the future pursue Fast Track designation for other product candidates that ARS Pharma may develop, but ARS Pharma might not receive such future designations, and Fast Track designations may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the FDA may grant a product candidate Fast Track designation. Fast Track designation is intended to expedite or facilitate the process for reviewing new drug products meeting the specified criteria and gives the sponsor of a Fast Track product opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. ARS Pharma was granted Fast Track designation for *neffy* for the treatment of Type I allergic reactions and may in the future request Fast Track designation for additional indications for *neffy* or for any future product candidates, however, ARS Pharma cannot assume that any such applications will meet the criteria for that designation. The FDA has broad discretion whether or not to grant this designation, so even if ARS Pharma believes a particular product candidate is eligible for this designation, ARS Pharma cannot assure you that the FDA would decide to grant it. Even if ARS Pharma does receive Fast Track Designation, ARS Pharma may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from ARS Pharma's clinical development activities.

ARS Pharma may seek priority review by the FDA for neffy or a future product candidate, and ARS Pharma may be unsuccessful. If ARS Pharma is successful, the designation may not actually lead to a faster development or regulatory review or approval process.

A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. ARS Pharma may in the future request priority review designation for *neffy* and any future product candidates, however, ARS Pharma cannot

assume that any application for priority review will meet the criteria for that designation. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if ARS Pharma believes a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to standard FDA review and approval. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Product liability lawsuits against ARS Pharma or any of its current and future licensing and collaboration partners could divert ARS Pharma's resources and attention, cause its to incur substantial liabilities and limit commercialization of neffy or any future product candidates.

ARS Pharma is exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, ARS Pharma has no products that have been approved for commercial sale; however, the use of *neffy* by ARS Pharma and any current and future licensing and collaboration partners in clinical trials, and the sale of *neffy*, if approved, in the future, may expose ARS Pharma to liability claims. Product liability claims may be brought against ARS Pharma or ARS Pharma's partners by participants enrolled in ARS Pharma's clinical trials, patients, health care providers, pharmaceutical companies, ARS Pharma's current and future licensing and collaboration partners or others using, administering or selling any of ARS Pharma's future approved products. If ARS Pharma cannot successfully defend itself against any such claims, ARS Pharma may incur substantial liabilities or be required to limit commercialization of *neffy* or any future product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of ARS Pharma's future approved products;
- injury to ARS Pharma's reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs, including with respect to potential class action lawsuits;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from ARS Pharma's business operations; and
- the inability to commercialize *neffy* or any future product candidates.

Although the clinical trial process is designed to identify and assess potential side effects and adverse events, clinical development does not always fully characterize the safety and efficacy profile of a new drug, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If *neffy* was to cause adverse events or side effects during clinical trials or after approval, ARS Pharma may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects, side effects, and patients who should not use *neffy* or any of ARS Pharma's future product candidates. If any of ARS Pharma's current or future product candidates, including *neffy*, are approved for marketing and commercial sale,

ARS Pharma will be highly dependent upon consumer perceptions of ARS Pharma and the safety and quality of ARS Pharma's products. ARS Pharma could be adversely affected if it is subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of its products or any similar products distributed by other companies.

Although ARS Pharma maintains product liability insurance coverage in the amount of up to $5.0 million in the aggregate, including clinical trial liability, this insurance may not fully cover potential liabilities that ARS Pharma may incur. In addition, if a judgment is entered against ARS Pharma and its product liability insurance coverage does not provide adequate coverage, ARS Pharma may suffer an event of default under the terms of the ARS Loan and Security Agreement. The cost of any product liability litigation or other proceeding, even if resolved in ARS Pharma's favor, could be substantial. ARS Pharma will need to increase its insurance coverage if ARS Pharma commercializes *neffy* or any future product candidate that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If ARS Pharma is unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of *neffy* or any future product candidates, which could harm ARS Pharma's business, financial condition, results of operations and prospects.

If ARS Pharma fails to comply with environmental, health and safety laws and regulations, ARS Pharma could become subject to fines or penalties or incur costs that could harm ARS Pharma's business.

ARS Pharma is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, ARS Pharma's operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if ARS Pharma contracts with third parties for the disposal of these materials and waste products, ARS Pharma cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of ARS Pharma's hazardous materials, ARS Pharma could be held liable for any resulting damages, and any liability could exceed ARS Pharma's resources. ARS Pharma also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

ARS Pharma maintains workers' compensation insurance to cover ARS Pharma for costs and expenses ARS Pharma may incur due to injuries to ARS Pharma's employees, but this insurance may not provide adequate coverage against potential liabilities. However, ARS Pharma does not maintain insurance for environmental liability or toxic tort claims that may be asserted against ARS Pharma.

In addition, ARS Pharma may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Environmental laws and regulations may impair ARS Pharma's research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

ARS Pharma's business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which ARS may operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit ARS Pharma's ability to compete in foreign markets and subject ARS Pharma to liability if it violates them.

If ARS Pharma further expand ARS Pharma's operations outside of the United States, ARS Pharma must dedicate additional resources to comply with numerous laws and regulations in each

jurisdiction in which ARS Pharma plans to operate. ARS Pharma's business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which ARS Pharma operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. ARS Pharma's business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of ARS Pharma's employees, agents or contractors, or those of ARS Pharma's affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against ARS Pharma, its officers or employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of ARS Pharma's business. Any such violations could include prohibitions on ARS Pharma's ability to offer *neffy* or any future product candidates in one or more countries and could materially damage its reputation, brand, international activities, ability to attract and retain employees, and business, prospects, operating results and financial condition.

In addition, *neffy* and any of ARS Pharma's future product candidates and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of *neffy* or any future product candidates, or ARS Pharma's failure to obtain any required import or export authorization for *neffy* or any future product candidates, when applicable, could harm ARS Pharma's international sales and adversely affect ARS Pharma's revenue. Compliance with applicable regulatory requirements regarding the export of *neffy* or any future product candidates may create delays in the introduction of ARS Pharma's product candidates in international markets or, in some cases, prevent the export of ARS Pharma's product candidates to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If ARS Pharma fails to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of *neffy* or any future product candidates by, or in ARS Pharma's decreased ability to export *neffy* or any future product candidates to existing or potential customers with international operations. Any decreased use of *neffy* or any future product candidates or limitation on ARS Pharma's ability to export or sell access to *neffy* or any future product candidates would likely adversely affect ARS Pharma's business.

Cyber-attacks or other failures in ARS Pharma's telecommunications or information technology systems, or those of ARS Pharma's licensing and collaboration partners, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of ARS Pharma's business operations.

ARS Pharma, its licensing and collaboration partners, its CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology ("IT") systems and networks to process, transmit and store electronic information in connection with ARS's business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining

access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. These threats pose a risk to the security of ARS Pharma's, its licensing and collaboration partners', its CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of ARS Pharma's data. There can be no assurance that ARS Pharma will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that ARS Pharma's licensing and collaboration partners, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting ARS Pharma's clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws, and subject ARS Pharma to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, ARS Pharma's general liability insurance and corporate risk program may not cover all potential claims to which ARS Pharma is exposed and may not be adequate to indemnify ARS Pharma for all liability that maybe imposed; and could have a material adverse effect on ARS Pharma's business and prospects. For example, the loss of clinical trial data from completed, ongoing or future clinical trials for *neffy* or any of ARS Pharma's future product candidates could result in delays in ARS Pharma's development and regulatory approval efforts and significantly increase ARS Pharma's costs to recover or reproduce the data. In addition, ARS Pharma may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Risks Related to ARS Pharma's Dependence on Third Parties

ARS Pharma intends to rely completely on third parties to manufacture and distribute ARS Pharma's supply of neffy and intends to rely on third parties to manufacture and distribute any future product candidates.

ARS Pharma does not currently have, nor does ARS Pharma plan to acquire, the infrastructure or capability to manufacture or distribute commercial quantities of *neffy*. ARS Pharma's ability to commercially supply *neffy*, if approved, depends, in part, on the ability of third-party manufacturers to supply and manufacture *neffy*, the raw materials, API and other important components related to the manufacture of *neffy*, including Intravail® and ARS Pharma's nasal sprayer apparatus. ARS Pharma also intends to rely on third parties to label and package the finished product. These third-party manufacturers may have limited experience manufacturing *neffy*, the raw materials and API for *neffy* to be supplied to patients in the United States. While ARS Pharma will work with ARS Pharma's third-party suppliers and manufacturers to optimize the manufacturing process for *neffy* and any future product candidates, if approved, ARS cannot guarantee that such efforts will be successful. If ARS Pharma fails to develop and maintain supply relationships with these third parties, ARS Pharma may be unable to successfully commercialize *neffy* or any future product candidate, if approved.

ARS Pharma has entered into a commercial supply agreement with Renaissance Lakewood LLC ("Renaissance"), which has been actively involved in supporting the manufacture of *neffy* in ARS Pharma's clinical development, and ARS Pharma intends to rely on Renaissance as the primary source for drug product manufacturing and final packaging. Unless and until ARS Pharma can secure an alternative source for drug product manufacturing and final packaging, ARS Pharma's dependence on Renaissance will subject ARS Pharma to the possible risks of shortages, interruptions and price fluctuations if *neffy* is approved for commercialization.

ARS Pharma may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if ARS Pharma is able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture *neffy* or any future product candidates according to ARS Pharma's schedule, or at all, including if ARS Pharma's third-party contractors give greater priority to the supply of other products over ARS Pharma's products or product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between ARS Pharma and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by ARS Pharma's third-party contractors at a time that is costly or inconvenient for ARS Pharma;
- the breach by the third-party contractors of ARS Pharma's agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, whether related to *neffy* or another product;
- the failure of the third party to manufacture ARS Pharma's product candidates according to ARS Pharma's specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of ARS Pharma's proprietary information, including ARS Pharma's trade secrets and know-how.

ARS Pharma does not have complete control over all aspects of the manufacturing process of, and are dependent on, ARS Pharma's contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If ARS Pharma's contract manufacturers cannot successfully manufacture material that conforms to ARS Pharma's specifications and the strict regulatory requirements of the FDA and other foreign regulatory authorities, this could affect the review of the NDA submitted for *neffy* or post-approval sales. In addition, other than to conduct audits, ARS Pharma does not have control over the ability of ARS Pharma's contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of *neffy* or any future product candidates or if it withdraws any such approval in the future, ARS Pharma may need to find alternative manufacturing facilities, which would significantly impact ARS Pharma's ability to develop, obtain marketing approvals for or commercialize *neffy* or any future product candidate. ARS Pharma's failure, or the failure of ARS Pharma's third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on ARS Pharma, including fines, injunctions, civil penalties, application review delays, suspension or withdrawal of approvals, license revocation, import alerts, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of ARS Pharma's *neffy* or any future product candidates or drugs and harm ARS Pharma's business and results of operations. ARS Pharma's current and anticipated future dependence upon others for the manufacture of *neffy* or any future product candidates or drugs may adversely affect ARS Pharma's future profit margins and ARS Pharma's ability to commercialize *neffy* or any future product candidate that receives marketing approval on a timely and competitive basis.

ARS Pharma relies on third parties to conduct its nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, ARS Pharma's development programs and its ability to seek or obtain regulatory approval for or commercialize neffy or any future product candidates may be delayed.

ARS Pharma is dependent on third parties to conduct ARS Pharma's nonclinical studies and any clinical trials. Specifically, ARS Pharma has used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct its nonclinical studies and past clinical trials in accordance with its clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these studies and trials. While ARS Pharma has and will have agreements governing the activities of ARS Pharma's third-party contractors, ARS Pharma has limited influence over their actual performance. Nevertheless, ARS Pharma is responsible for ensuring that each of ARS Pharma's clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and ARS Pharma's reliance on its CROs and other third parties does not relieve it of its regulatory responsibilities. ARS Pharma and its CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of ARS Pharma's product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If ARS Pharma or any of its CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in ARS Pharma's clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require ARS Pharma to perform additional clinical trials before approving ARS Pharma's marketing applications. In addition, ARS Pharma's clinical trials must be conducted with products produced under cGMP regulations. ARS Pharma's failure to comply with these regulations may require ARS Pharma to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of ARS Pharma's CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to ARS Pharma's clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, ARS Pharma's clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom ARS Pharma contract may also have relationships with other commercial entities, including ARS Pharma's competitors, for whom they may also be conducting clinical trials or other development activities that could harm ARS Pharma's competitive position. In addition, principal investigators for ARS Pharma's clinical trials are expected to serve as scientific advisors or consultants to ARS Pharma from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA ARS Pharma submits. Any such delay or rejection could prevent ARS Pharma from commercializing *neffy* or any future product candidates.

ARS Pharma's CROs have the right to terminate their agreements with ARS Pharma in the event of an uncured material breach. In addition, some of ARS Pharma's CROs have an ability to terminate their respective agreements with ARS Pharma if it can be reasonably demonstrated that the safety of the subjects participating in ARS Pharma's clinical trials warrants such termination, if ARS Pharma make a general assignment for the benefit of its creditors or if ARS Pharma is liquidated. If any of ARS Pharma's relationships with these third parties terminate, ARS Pharma may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires ARS

Pharma's management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact ARS Pharma's ability to meet ARS Pharma's desired clinical development timelines. Though ARS Pharma carefully manage its relationships with its CROs, investigators and other third parties, there can be no assurance that ARS Pharma will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on ARS Pharma's business, financial condition and prospects.

ARS Pharma is dependent on international third-party licensees and assignees for the development and commercialization of neffy in several countries outside the United States. The failure of these third parties to meet their contractual, regulatory or other obligations could adversely affect ARS Pharma's business.

ARS Pharma has entered into exclusive licensing and collaboration agreements for the development and commercialization of *neffy* with Recordati in the EU, United Kingdom, and certain countries in the Middle East, Africa and Eurasia, including Russia and the Commonwealth of Independent States (the "CIS"), with Alfresa Pharma in Japan and Pediatrix Therapeutics in China, Macau, Hong Kong and Taiwan. As a result, ARS Pharma is dependent on these parties to achieve regulatory approval of *neffy* for marketing in these countries and for the commercialization of *neffy*, if approved. The timing and amount of any milestone and royalty payments ARS Pharma may receive under these agreements, as well as the commercial success of *neffy* in those regions outside of the United States, will depend on, among other things, the efforts, allocation of resources and successful commercialization of *neffy* by Recordati, Alfresa Pharma and Pediatrix Therapeutics. ARS Pharma also depends on such licensing and collaboration partners to comply with all applicable laws relative to the development and commercialization of *neffy* in those countries. They may take actions or fail to take actions that result in safety issues with *neffy* in their licensed territory, and such safety issues could negatively impact *neffy* in countries outside of the licensed territory. ARS Pharma does not control the individual efforts of its licensing and collaboration partners and have limited ability to terminate these agreements or have assigned assets returned to ARS Pharma if such licensing and collaboration partners do not perform as anticipated.

In addition, Russia is one of the territories covered by ARS Pharma's licensing and collaboration agreement with Recordati. On February 24, 2022, Russia launched an invasion of Ukraine which has resulted in increased volatility in various financial markets and across various sectors. The U.S. and other countries, along with certain international organizations, have imposed economic sanctions on Russia and certain Russian individuals, banking entities and corporations as a response to the invasion. The extent and duration of the military action, resulting sanctions and future market disruptions in the region are impossible to predict. Although Russia is not expected to be a material territory for *neffy*, if approved, the commercialization opportunities for *neffy* in Russia could be adversely affected by the ongoing military action and resulting sanctions and future market disruptions. Moreover, the ongoing effects of the hostilities and sanctions may not be limited to Russia and Russian companies and may spill over to and negatively impact other regional and global economic markets of the world, including Europe and the U.S. The ongoing military action along with the potential for a wider conflict could further increase financial market volatility and cause negative effects on regional and global economic markets, industries, and companies, which could in turn adversely impact the ability of ARS Pharma's licensing and collaboration partners to develop and commercialize *neffy* in their licensed territories. It is not currently possible to determine the severity of any potential adverse impact of this event on ARS Pharma's financial condition, or more broadly, upon the global economy.

The failure of ARS Pharma's licensing and collaboration partners to devote sufficient time and effort to the development and commercialization of *neffy*; to meet their obligations to ARS Pharma, including for future royalty and milestone payments; to adequately deploy business continuity plans in the event of a crisis; to adequately respond to the adverse impact of military action, sanctions and

market disruptions, including those caused by Russia's invasion of Ukraine; and/or to satisfactorily resolve significant disagreements with ARS Pharma or address other factors could have an adverse impact on its financial results and operations. In addition, if these third parties violate, or are alleged to have violated, any laws or regulations during the performance of their obligations for ARS Pharma, including with respect to safety, patient and data privacy, antitrust, and bribery and corruption, it is possible that ARS Pharma could suffer financial and reputational harm or other negative outcomes, including possible legal consequences and liabilities. ARS Pharma may not be successful in enforcing the terms and conditions of its licensing and collaboration agreements in court or via agreed upon dispute resolution mechanisms, and even if ARS Pharma were to prevail in any such dispute, the remedies may not be adequate to compensate ARS Pharma for the losses. Any termination, breach or expiration of any of these licensing or collaboration agreements could have a material adverse effect on ARS Pharma's financial position by reducing or eliminating the potential for ARS Pharma to receive license fees, milestones and royalties. In such an event, ARS Pharma may be required to devote additional efforts and to incur additional costs associated with pursuing regulatory approval and commercialization of *neffy*. Alternatively, ARS Pharma may attempt to identify and transact with a new assignee or licensee, but there can be no assurance that it would be able to identify a suitable partner or transact on terms that are favorable to ARS Pharma.

ARS Pharma may seek to enter into additional collaborations, licenses and other similar arrangements for neffy or any future product candidate and may not be successful in doing so, and even if it is, it may relinquish valuable rights and may not realize the benefits of such relationships.

ARS Pharma may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of *neffy* in other geographic regions or of any future product candidates, due to capital costs required to develop or commercialize *neffy* or any future product candidate or manufacturing constraints. Such collaborative efforts may not be profitable. ARS Pharma may not be successful in its efforts to establish or maintain such collaborations for *neffy* or any future product candidates because its research and development pipeline may be insufficient, its product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view its product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, ARS Pharma faces significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. ARS Pharma may have to relinquish valuable rights to its future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to ARS Pharma, as part of any such arrangement, and such arrangements may restrict ARS Pharma from entering into additional agreements with other potential licensing and collaboration partners. ARS Pharma cannot be certain that, following a collaboration, license or strategic transaction, ARS Pharma will achieve an economic benefit that justifies such transaction. In addition, the terms of the ARS Loan and Security Agreement prohibit ARS Pharma from entering into certain licensing and collaboration agreements without Silicon Valley Bank's consent, including any licensing that grant exclusive rights as to territories except as to discreet geographical areas outside of the United States.

Even if ARS Pharma is successful in its efforts to establish such collaborations, the terms that ARS Pharma agree upon may not be favorable to ARS Pharma, and it may not be able to maintain such collaborations if, for example, the development or approval of *neffy* or any future product candidate is delayed, the safety of *neffy* or any future product candidate is questioned or the sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by ARS Pharma's strategic partners, and ARS Pharma may not be able to adequately protect ARS Pharma's rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions

regarding the development and commercialization of *neffy* or any future product candidate, if approved, and may not conduct those activities in the same manner as ARS Pharma does. Any termination of collaborations ARS Pharma enters into in the future, or any delay in entering into collaborations related to *neffy* or any future product candidate, could delay the development and commercialization of *neffy* or any future product candidate and reduce their competitiveness if they reach the market, which could have a material adverse effect on ARS Pharma's business, financial condition and results of operations.

ARS Pharma's reliance on third parties requires it to share its trade secrets, know-how and other proprietary information, which increases the possibility that a competitor will discover them or that ARS Pharma's trade secrets will be misappropriated or disclosed.

Because ARS Pharma currently relies on third parties to manufacture *neffy* and to perform quality testing, ARS Pharma must, at times, share its proprietary information, including trade secrets and know-how, with them. ARS Pharma seeks to protect its proprietary information, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its current and future licensing and collaboration partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose ARS Pharma's proprietary information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets, know-how and other proprietary information increases the risk that such proprietary information become known by ARS Pharma's competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. ARS Pharma relies, in part, on trade secrets, know-how and other proprietary information to develop and maintain its competitive position and a competitor's discovery of its proprietary information or other unauthorized use or disclosure would impair its competitive position and may have a material adverse effect on its business, financial condition, results of operations and prospects.

Risks Related to Commercialization of *neffy* or Any Future Product Candidates

ARS Pharma currently has limited marketing, sales or distribution infrastructure. If ARS Pharma is unable to fully develop its sales, marketing and distribution capability on its own or through collaborations with marketing partners, it may not be successful in commercializing its product candidates.

ARS Pharma is currently building its marketing, sales or distribution capabilities. As a company ARS Pharma has not commercialized or marketed any products to date. If *neffy* is approved for the emergency treatment of Type I allergic reactions or other future indications or any future product candidate is approved, ARS Pharma will need to expand ARS Pharma's sales and marketing organization, on ARS Pharma's own and in collaboration with third parties, and add further technical expertise and supporting distribution capabilities to commercialize the approved product in key territories, which will require substantial additional resources. Some or all of these costs may be incurred in advance of any approval of *neffy* or any future product candidate. There are risks involved with both establishing ARS Pharma's own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a commercial organization is expensive and time consuming and could delay any product launch. If the commercial launch of *neffy* or any future product candidate for which ARS Pharma recruits a sales force and establish marketing capabilities is delayed or does not occur for any reason, ARS Pharma would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and ARS Pharma's investment would be lost if ARS Pharma cannot retain or reposition its sales and marketing personnel. Any failure or delay in the development of ARS Pharma's or third parties'

internal sales, marketing and distribution capabilities would adversely impact the commercialization of *neffy* and any future product candidates.

Factors that may inhibit ARS Pharma's efforts to commercialize *neffy* or any future product candidate on its own include:

- ARS Pharma's inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of allergists, pediatricians and other physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put ARS Pharma at a competitive disadvantage relative to companies with more extensive product lines;
- the availability of adequate coverage by and reimbursement from third-party payors; and
- unforeseen costs and expenses associated with building out an independent sales and marketing organization.

ARS Pharma has entered into exclusive licensing and collaboration agreements for the development and commercialization of *neffy* with Recordati in the EU, United Kingdom, and certain countries in the Middle East, Africa and Eurasia, including Russia and CIS, with Alfresa Pharma in Japan and Pediatrix Therapeutics in China, Macau, Hong Kong and Taiwan. These licensing and collaboration partners have direct sales forces and established distribution systems to serve as an alternative to ARS Pharma's own sales force and distribution systems. ARS Pharma may enter into additional licensing and collaboration agreements in other territories for the commercialization of *neffy* or any future product candidates, however, ARS Pharma may be unable to enter into such agreements on favorable terms, if at all. ARS Pharma's product revenue may be lower than if ARS Pharma directly marketed or sold ARS Pharma's products, if approved. In addition, any revenue ARS Pharma receives will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within ARS Pharma's control.

ARS Pharma also competes with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. ARS Pharma also faces competition in its search for third parties to assist ARS Pharma with the sales and marketing efforts of *neffy* and any future product candidates, if approved. Without an internal team or the support of a third-party to perform marketing and sales functions, ARS Pharma may be unable to compete successfully against these more established companies.

If ARS Pharma does not expand its sales and marketing capabilities successfully, on its own and in collaboration with third parties, ARS Pharma will not be successful in commercializing *neffy* or any future product candidates. If ARS Pharma is not successful in commercializing any approved products, its future product revenue will suffer and ARS Pharma may incur significant additional losses.

Furthermore, ARS Pharma's efforts to educate patients, caregivers, allergists, pediatricians and other physicians, and payors on the benefits of *neffy* or any future product candidates may require more resources than ARS Pharma anticipates and may never be successful. Even if *neffy* or any future product candidates are approved, if ARS Pharma is unable to successfully market ARS Pharma's products successfully, ARS Pharma will not be able to generate significant revenues from such products, if approved.

The market for neffy and any future product candidates ARS Pharma may develop may be smaller than it expects.

ARS Pharma has focused its development of *neffy* for the emergency treatment of Type I allergic reactions. ARS Pharma bases its market opportunity estimates on a variety of factors, including its estimates of the number of people who have experienced severe Type I allergic reactions and are at risk of anaphylaxis, the continued growth rate of ARS Pharma's patient population, the number of those in its patient population who ARS Pharma expects will fill a prescription for *neffy*, including those that currently do not fill prescriptions for epinephrine intra-muscular injectable devices or whose prescriptions have lapsed, the estimated increase in per patient device acquisition of *neffy* as compared to epinephrine intra-muscular injectable devices and the net sales of epinephrine intra-muscular injectable devices. These estimates are based on many assumptions and may prove incorrect, and new studies or market research may reduce ARS Pharma's estimated patient population and potential device sales. If ARS Pharma is unable to advance *neffy* or any future product candidates with attractive market opportunities or if ARS Pharma's market opportunities are smaller than ARS Pharma expected, ARS Pharma's future product revenues may be smaller than anticipated, which would adversely affect its business, financial condition, results of operations and prospects.

Any of ARS Pharma's current and future product candidates for which ARS Pharma, or any current or future licensing and collaboration partners, obtain regulatory approval in the future will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, neffy and any future product candidates could be subject to post-marketing restrictions or withdrawal from the market and ARS Pharma, or any current or future licensing and collaboration partners, may be subject to substantial penalties if ARS Pharma, or they, fail to comply with regulatory requirements or if ARS Pharma, or they, experience unanticipated problems with ARS Pharma's products following approval.

neffy or any future product candidates for which ARS Pharma, or any current or future licensing and collaboration partners, obtain regulatory approval, as well as the manufacturing processes, post-approval studies, labeling, post-approval pharmacovigilance monitoring, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA, the EMA and other applicable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. ARS Pharma and ARS Pharma's contract manufacturers will also be subject to user fees and periodic inspection by regulatory authorities to monitor compliance with these requirements and the terms of any product approval ARS Pharma may obtain. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indications or uses for which the product may be marketed or to the conditions of approval, including the requirement in the United States to implement a Risk Evaluation and Mitigation Strategy or the inclusion of a Boxed Warning, which highlights a specific life-threatening safety risk.

The FDA, the EMA and other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. For example, the FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured,

marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use. However, companies generally may share truthful and not misleading information that is otherwise consistent with a product's approved labeling. If ARS Pharma, or any current or future licensing and collaboration partners, do not market *neffy* or any of ARS Pharma's future product candidates for which ARS Pharma, or they, receive regulatory approval for only their approved indications, ARS Pharma, or they, may be subject to warnings or enforcement action for off-label marketing if it is alleged that ARS Pharma is doing so. Violation of laws and regulations relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, including the False Claims Act and any comparable foreign laws. In the EU, the direct-to-consumer advertising of prescription-only medicinal products is prohibited. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of ARS Pharma's products to the general public, and may also impose limitations on ARS Pharma's promotional activities with health care professionals.

In addition, later discovery of previously unknown side effects, adverse events or other problems with ARS Pharma's products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the manufacturing of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that ARS Pharma submits;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- exclusion from federal health care programs such as Medicare and Medicaid;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Even if ARS Pharma, or any current or future licensing and collaboration partners, obtains regulatory approvals for neffy or any future product candidate, the terms of approvals and ongoing regulation of ARS Pharma's products may limit how ARS Pharma manufactures and markets its products, which could impair its ability to generate revenue.

Once regulatory approval has been granted, an approved product and its manufacturer and distributor are subject to ongoing review and extensive regulation. ARS Pharma, and any current and

future licensing and collaboration partners, must therefore comply with requirements concerning advertising and promotion for *neffy* or any future product candidate for which ARS Pharma or they obtain regulatory approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, ARS Pharma and any current and future licensing and collaboration partners will not be able to promote any products ARS Pharma develops for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA, EMA and other foreign regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. ARS Pharma, its contract manufacturers, any current and future licensing and collaboration partners and their contract manufacturers would be subject to periodic unannounced inspections by the FDA, the EMA and other foreign regulators to monitor and ensure compliance with cGMPs. Despite ARS Pharma's efforts to inspect and verify regulatory compliance, one or more of ARS Pharma's third-party manufacturing vendors may be found on regulatory inspection by the FDA, the EMA or other foreign regulators to be not in compliance with cGMP regulations, which may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect ARS Pharma's ability to supply and market its drug products.

Accordingly, assuming ARS Pharma, or any current or future licensing and collaboration partners, receive regulatory approval for *neffy* or one or more future product candidates, ARS, and any current and future licensing and collaboration partners, and ARS Pharma's and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If ARS Pharma, and any current and future licensing and collaboration partners, are not able to comply with post-approval regulatory requirements, ARS, and any current and future licensing and collaboration partners, could have the regulatory approvals for *neffy* or any future products withdrawn by regulatory authorities and ARS Pharma's, or any current or future licensing and collaboration partners', ability to market any future products could be limited, which could adversely affect ARS Pharma's ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on ARS's operating results and financial condition.

Even if neffy or any future product candidate of ours receives regulatory approval, it may fail to achieve the degree of market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community necessary for commercial success, in which case ARS Pharma may not generate significant revenues or become profitable.

ARS Pharma has never commercialized a product, and even if *neffy* for the treatment of any indication, or any future product candidate of ours, is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community. Physicians may be reluctant to prescribe *neffy* in place of well-established epinephrine intra-muscular injectable devices. Further, patients and caregivers may be reluctant to switch unless their physicians recommend switching products or are required to switch due to lack of coverage and adequate reimbursement. In addition, even if ARS Pharma is able to demonstrate *neffy's* or any future product candidate's safety and efficacy to the FDA, the EMA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate patients, caregivers, the medical community and third-party payors on the benefits of *neffy* and any future product candidates may require more resources that ARS Pharma anticipates, including management time and financial resources, and may not be successful. If *neffy* or any future product candidate is approved but does not achieve an adequate level of market acceptance, ARS Pharma may not generate significant revenues and ARS Pharma may not become profitable. The degree of market acceptance of *neffy* and any future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies and ARS Pharma's ability to successfully publicize these advantages or highlight them in any marketing materials;
- the prevalence and severity of any side effects;
- ARS Pharma's ability, or the ability of any current or future licensing or collaboration partners, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by *neffy* or any future product candidate of ours that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect ARS Pharma's business prospects.

Recently enacted and future legislation may increase the difficulty and cost for ARS Pharma to obtain marketing approval of and commercialize neffy or any future product candidates and affect the prices ARS Pharma may obtain.

In the United States and some foreign jurisdictions, there have been, and ARS Pharma expects there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system, including cost-containment measures, that could reduce or limit coverage and reimbursement for newly approved drugs, prevent or delay marketing approval of *neffy* or any future product candidates, restrict or regulate post-approval activities and affect ARS Pharma's ability to profitably sell *neffy* or any future product candidates for which ARS Pharma obtains marketing approval.

For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), was signed into law. The ACA was intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA and subsequent regulations increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs and revised the definition of "average manufacturer price" for reporting purposes,

which could further increase the amount of Medicaid drug rebates to states. However, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. Further, the ACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products, increased the number of entities eligible for discounts under the 340B program and included a discount on brand name drugs for Medicare Part D beneficiaries in the coverage gap, or "donut hole." Substantial provisions affecting compliance have also been enacted, which may require ARS Pharma to modify its business practices with healthcare practitioners.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and ARS Pharma's business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year pursuant to the Budget Control Act of 2011, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In addition, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. However, several lawsuits have been brought against Health and Human Services ("HHS") challenging various aspects of the rules implemented during the Trump administration. As a result, the Biden administration and HHS have delayed the implementation or published rules rescinding some of these Trump-era policies. Additionally, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that

outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future.

At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

These laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on ARS Pharma's industry generally and on its ability to successfully develop and commercialize *neffy* or any future product candidates.

Governments outside the United States may impose strict price controls, which may adversely affect ARS Pharma's revenues, if any.

In some countries, including certain Member States of the EU, the pricing of prescription drugs is, in part, subject to governmental control. Additional countries may adopt similar approaches to the pricing of prescription drugs. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. The EU provides options for the EU Member States to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, ARS Pharma may be required to conduct a clinical study or other studies that compare the cost-effectiveness of *neffy* or any future product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval, which is time-consuming and costly. ARS cannot be sure that such prices and reimbursement will be acceptable to ARS Pharma. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of ARS Pharma's products is unavailable or limited in scope or amount, ARS Pharma's revenues from sales by ARS Pharma or its strategic partners and the potential profitability of *neffy* or any future product candidates in those countries would be negatively affected.

The successful commercialization of neffy or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for ARS Pharma's products could limit its ability to market those products and decrease its ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are

essential for most patients to be able to afford prescription medications such as *neffy* or any future product candidates, if approved. ARS Pharma's ability to achieve coverage and acceptable levels of reimbursement for its products by third-party payors will have an effect on its ability to successfully commercialize those products. Accordingly, ARS Pharma will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if ARS Pharma obtains coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. ARS Pharma cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for *neffy* or any future product candidate that ARS Pharma may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider *neffy* or any future product candidate as substitutable and only offer to reimburse patients for the less expensive product. Even if ARS Pharma is successful in demonstrating improved efficacy or improved convenience of administration with *neffy* or any future product candidates, pricing of existing drugs may limit the amount ARS Pharma will be able to charge for *neffy* or any future product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable ARS Pharma to realize an appropriate return on its investment in product development. If reimbursement is not available or is available only at limited levels, ARS may not be able to successfully commercialize or obtain a satisfactory financial return on *neffy* or any future product candidates that ARS Pharma may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for *neffy* or any future product candidates.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require ARS Pharma to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and ARS Pharma believes that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and ARS Pharma believes the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of *neffy* or any future product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could

restrict the amount that ARS Pharma is able to charge for *neffy* or any future product candidates. Accordingly, in markets outside the United States, the reimbursement for *neffy* or any future product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for *neffy* or any future product candidates. ARS Pharma expects to experience pricing pressures in connection with the sale of *neffy* or any future product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on ARS Pharma's business and results of operations.

ARS Pharma's relationships with customers, health care professionals and third-party payors may be subject to applicable healthcare laws, which could expose ARS Pharma to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of ARS's operations and diminished future profits and earnings.

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of *neffy* or any future product candidates for which ARS Pharma obtains marketing approval. ARS Pharma's current and future arrangements with customers, healthcare professionals and third-party payors may expose ARS Pharma to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which ARS Pharma conducts research, market, sell and distribute *neffy* or any future product candidates for which ARS Pharma obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, among others:

- the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Further a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including the False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, including: allegedly providing free items and services, sham consulting fees and grants and

other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to government healthcare programs for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Drug Rebate Program to reduce liability for Medicaid rebates. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, of any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless or the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal price reporting laws require manufactures to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal and state consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws that require biotechnology companies to comply with the industry's voluntary

compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration or pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of ARS Pharma's business activities, particularly any sales and marketing activities after *neffy* or any future product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If ARS Pharma's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non-compliance, imprisonment, and the curtailment or restructuring of ARS Pharma's operations, any of which could adversely affect its ability to operate its business and its financial results. In addition, the incurrence of certain penalties, fines or other liabilities could result in an event of default under the terms of the ARS Loan and Security Agreement, which could significantly harm ARS Pharma's business and prospects.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to ARS Pharma or inhibit its ability to collect and process data globally, and the failure to comply with such requirements could subject ARS to significant fines and penalties, which may have a material adverse effect on its business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other information processing worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which ARS Pharma operates has established its own data security and privacy frameworks with which ARS Pharma must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation (the "GDPR") which took effect across all member states of the EEA in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining the consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases ARS Pharma's obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require the destruction of improperly gathered or used personal information and or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or underway in the United States. There are a broad variety of data protection laws that are applicable to ARS Pharma's activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General are all aggressive in reviewing consumers' privacy and data security protections. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act—which went into effect on January 1, 2020—is creating similar risks and obligations as those created by GDPR, though the California Consumer Privacy Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects. Many other states are considering similar legislation. A broad range of legislative measures also has been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding the privacy and security of personal information could expose ARS Pharma to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if ARS Pharma is not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm its reputation and its business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time-intensive and requires significant resources and a review of ARS Pharma's technologies, systems and practices, as well as those of any third-party licensing and collaboration partners, service providers, contractors or consultants that process or transfer personal data collected in the EU. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from ARS Pharma's clinical trials, could require it to change its business practices and put in place additional compliance mechanisms, may interrupt or delay its development, regulatory and commercialization activities and increase its cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against it and could have a material adverse effect on its business, financial condition or results of operations.

Risks Related to ARS Pharma's Intellectual Property

ARS Pharma's commercial success depends on its ability to obtain and maintain sufficient intellectual property protection for its product candidates and other proprietary technologies.

ARS Pharma's commercial success will depend, in part, on its ability to obtain and maintain patent protection in the United States and other countries with respect to its product candidates. If ARS Pharma is unable to obtain or maintain patent protection with respect to its product candidates, and their uses, its business, financial condition, results of operations and prospects could be materially harmed.

ARS Pharma generally seeks to protect its proprietary position by filing or in-licensing patent applications in the United States and abroad related to its product candidates that are important to its business, as appropriate. ARS Pharma's pending and future patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that ARS Pharma's patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for ARS Pharma's proprietary rights is uncertain. Only limited protection may be

available and may not adequately protect ARS Pharma's rights or permit ARS Pharma to gain or keep any competitive advantage. This failure to obtain the intellectual property rights relating to ARS Pharma's product candidates could have a material adverse effect on ARS Pharma's financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that ARS Pharma or any of its potential future collaborators will be successful in protecting ARS Pharma's product candidates by obtaining and defending patents. Obtaining and enforcing patents is expensive and time-consuming, and ARS Pharma may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on ARS Pharma's patent applications, at a reasonable cost or in a timely manner. It is also possible that ARS Pharma will fail to identify patentable aspects of its research and development results before it is too late to obtain patent protection.

Although ARS Pharma enters into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of ARS Pharma's research and development output, such as ARS Pharma's employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, independent contractors, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing ARS Pharma's ability to seek adequate patent protection.

If the scope of any patent protection ARS Pharma obtains is not sufficiently broad, or if ARS Pharma loses any of its patent protection, its ability to prevent its competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including United States Supreme Court decisions, that have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect ARS Pharma's rights to the same extent as the laws of the United States, or vice versa.

Further, ARS Pharma may not be aware of all third-party intellectual property rights potentially relating to ARS Pharma's research programs and product candidates, or their intended uses, and as a result the potential impact of such third-party intellectual property rights upon the patentability of ARS Pharma's own patents and patent applications, as well as the potential impact of such third-party intellectual property upon ARS Pharma's freedom to operate, is highly uncertain. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, ARS Pharma may be unaware of third-party patents that may be infringed by commercialization of any of its product candidates, and ARS Pharma cannot be certain that ARS Pharma was the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that ARS Pharma's product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to ARS Pharma's technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which ARS Pharma is aware, but which ARS Pharma does not believe is relevant to its business, which may, nonetheless, ultimately be found to limit its ability to make, use, sell, offer for sale or import its products that may be approved in the future, or impair its competitive position. In addition, third parties may obtain patents in the future and claim that use of ARS Pharma's technologies infringes upon these patents. As a result, the issuance, scope, validity, enforceability, and commercial value of ARS Pharma's patent rights are highly uncertain.

ARS Pharma's patents or pending patent applications, or the patents or pending patent applications that ARS Pharma licenses, may be challenged in the courts or patent offices in the United States and other foreign jurisdictions. For example, ARS Pharma may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (the "USPTO") or become involved in post-grant review procedures, derivations, reexaminations, or inter parties review proceedings, in the United States or oppositions or similar proceedings in foreign jurisdictions, challenging ARS Pharma's patent rights. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit ARS Pharma's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of ARS Pharma's technology and products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, ARS Pharma's intellectual property may not provide ARS Pharma with sufficient rights to exclude others from commercializing products similar or identical to ours.

ARS Pharma may not be able to protect its intellectual property rights throughout the world, which could negatively impact its business.

Although ARS Pharma co-owns or exclusively license four issued United States patents, one granted Australia patent, one granted Japanese patent, one granted South Korea patent, and two granted United Kingdom patents for ARS Pharma's *neffy* product candidate and pending patent applications in the United States, Europe, Japan, Australia, South Korea, United Kingdom and other foreign jurisdictions for ARS Pharma's *neffy* product candidate, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and ARS's intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, ARS Pharma may not be able to prevent third parties from practicing ARS Pharma's inventions in all countries outside the United States or from selling or importing products made using ARS Pharma's inventions in and into the United States or other jurisdictions. Competitors may use ARS Pharma's technologies in jurisdictions where ARS Pharma has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where ARS has patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with ARS's product candidates, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for ARS Pharma to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce ARS Pharma's patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert its efforts and attention from other aspects of its business, could put its patents at risk of being invalidated or interpreted narrowly and its patent applications at risk of not issuing, and could provoke third parties to assert claims against ARS Pharma. ARS Pharma may not prevail in any lawsuits that ARS Pharma initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, ARS Pharma's efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that ARS

Pharma develops or licenses. Furthermore, while ARS Pharma intends to protect its intellectual property rights in its expected significant markets, ARS Pharma cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which it may wish to market its product candidates. Accordingly, ARS Pharma's efforts to protect its intellectual property rights in such countries may be inadequate, which may have an adverse effect on ARS Pharma's ability to successfully commercialize its product candidates in all of its expected significant foreign markets.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If ARS Pharma is forced to grant a license to third parties with respect to any patents relevant to its business, its competitive position may be impaired, and its business, financial condition, results of operations and prospects may be adversely affected. Accordingly, ARS Pharma's efforts to protect or enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that ARS Pharma develops or licenses. Furthermore, while ARS Pharma intends to protect its intellectual property rights in its expected significant markets, ARS Pharma cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which ARS Pharma may wish to market its product candidates. Accordingly, ARS Pharma's efforts to protect its intellectual property rights in such countries may be inadequate, which may have an adverse effect on ARS Pharma's ability to successfully commercialize its product candidates in all of its expected significant foreign markets.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, ARS Pharma does not know the degree of future protection that it will have on its technologies, products and product candidates. While ARS Pharma will endeavor to try to protect its technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of ARS Pharma's patent applications and the enforcement or defense of its issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law in the United States. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before ARS Pharma could therefore be awarded a patent covering any of its inventions even if ARS Pharma had made the invention before it was made by such third party. This will require ARS Pharma to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, ARS Pharma's ability to obtain and maintain valid and enforceable patents depends on whether the differences between its technology, or the technologies ARS Pharma licenses for its product candidates, and the prior art allow the technology ARS Pharma uses for its product candidates to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, ARS Pharma cannot be certain that it was the first to either file any patent application related to its product candidates or invent any of the inventions claimed in its patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including Post Grant Review, Inter Partes Review, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, ARS Pharma's patent rights, which could adversely affect ARS Pharma's competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate ARS Pharma's patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of ARS Pharma's patent applications and the enforcement or defense of its issued patents, all of which could have a material adverse effect on its business, financial condition, results of operations and prospects.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing ARS Pharma's ability to protect its product candidates.

As is the case with other pharmaceutical companies, ARS Pharma's success is heavily dependent on intellectual property, particularly patents relating to its product candidates. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws, rules and regulations in the United States and other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. ARS Pharma cannot predict the breadth of claims that may be allowed or enforced in the patents ARS Pharma owns, co-owns or licenses from third-parties. In addition, U.S. Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to ARS Pharma.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken ARS Pharma's ability to obtain new patents or to enforce the existing patents ARS Pharma owns, co-owns or licenses and patents ARS Pharma or its licensors might obtain in the future. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to ARS Pharma's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken ARS Pharma's ability to obtain new patents or to enforce the existing patents ARS Pharma owns, co-owns or licenses and patents that ARS Pharma or its licensors might obtain in the future.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and ARS Pharma's patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the USPTO and various foreign patent agencies at various stages over the lifetime of ARS Pharma's patents and/or patent applications. ARS Pharma has systems in place to remind ARS Pharma to pay these fees, and ARS Pharma relies on its outside patent annuity service to pay these fees when due. In addition, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. ARS Pharma employs reputable law firms and other professionals to help it comply with these provisions. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on ARS Pharma's business. If ARS Pharma or its licensors fail to maintain the patents and patent applications covering ARS Pharma's product candidates, ARS Pharma's competitors might be able to enter the market, which would have a material adverse effect on its business, financial conditions, results of operations and growth prospects.

Patent terms may be inadequate to protect ARS Pharma's competitive position on its product candidates for an adequate amount of time and may adversely affect its anticipated future revenues and operating earnings.

ARS Pharma relies on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of ARS Pharma's product candidates. In particular, patent protection is important in the development and eventual commercialization of ARS Pharma's product candidates. Patents covering ARS Pharma's product candidates normally provide market exclusivity, which is important in order for its product candidates to become profitable.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering ARS Pharma's product candidates are obtained, once the patent life has expired for a product, ARS Pharma may be open to competition from generic products. As a result, ARS Pharma's patent portfolio may not provide ARS Pharma with sufficient rights to exclude others from commercializing products similar or identical to ours.

The patents ARS Pharma currently co-owns or exclusively licenses for *neffy* are expected to expire as early as 2038, absent any patent term adjustments. The API in *neffy* is epinephrine, a generic API that is used in FDA-approved intra-muscular injectables. If *neffy* is approved by the FDA under the 505(b)(2) regulatory pathway, ARS Pharma's U.S. patents for *neffy* will not be eligible for patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984. While ARS Pharma is planning to seek additional patent coverage for *neffy*, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if ARS Pharma is successful in obtaining a patent, patents have a limited lifespan. Without patent protection, ARS Pharma may be open to competition from generic versions of *neffy*.

ARS Pharma cannot ensure that patent rights relating to inventions described and claimed in its pending patent applications will issue or that patents based on its patent applications will not be challenged and rendered invalid and/or unenforceable.

ARS Pharma co-owns or exclusively licenses patent applications in ARS Pharma's portfolio relating to its product candidates that are pending at the patent offices in the United States, Europe, Japan, and other foreign jurisdictions, however, ARS Pharma cannot predict:

- if and when patents may issue based on the patent applications ARS Pharma owns, co-owns or exclusively licenses;
- the scope of protection of any patent issuing based on the patent applications ARS Pharma owns, co-owns or exclusively licenses;
- whether the claims of any patent issuing based on the patent applications ARS Pharma owns, co-owns or exclusively licenses will provide protection against competitors,
- whether or not third parties will find ways to invalidate or circumvent ARS Pharma's patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by the patent applications ARS Pharma owns, co-owns or exclusively licenses;
- whether ARS Pharma will need to initiate litigation or administrative proceedings to enforce and/or defend ARS Pharma's patent rights which will be costly whether ARS Pharma wins or loses;
- whether the patent applications that ARS Pharma owns, co-owns or exclusively licenses will result in issued patents with claims that cover ARS Pharma's product candidates or uses thereof; and/or
- whether, as the COVID-19 pandemic continues to spread around the globe, ARS Pharma may experience patent office interruption or delays to ARS Pharma's ability to timely secure patent coverage to ARS Pharma's product candidates.

ARS Pharma cannot be certain that the claims in ARS Pharma's pending patent applications directed to ARS Pharma's product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of ARS Pharma's inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which ARS Pharma is not aware that may affect the patentability of ARS Pharma's patent claims or, if issued, affect the validity or enforceability of a patent claim relevant to ARS Pharma's business. There is no assurance that there is not prior art of which ARS Pharma is aware, but which ARS Pharma does not believe is relevant to ARS Pharma's business, which may, nonetheless, ultimately be found to limit ARS Pharma's ability to make, use, sell, offer for sale or import ARS Pharma's products that may be approved in the future, or impair its competitive position. Even if the patents do issue based on the patent applications ARS Pharma owns, co-owns or exclusively licenses, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in ARS Pharma's portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around ARS Pharma's claims. If the breadth or strength of ARS Pharma's intellectual property position with respect to ARS Pharma's product candidates is threatened, it could dissuade companies from collaborating with ARS Pharma to develop, and threaten ARS Pharma's ability to commercialize, its product candidates. In the event of litigation or administrative proceedings, ARS Pharma cannot be certain that the claims in any of its issued patents will be considered valid by courts in the United States or foreign countries.

ARS Pharma may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect its ability to develop and market its products.

As the pharmaceutical industry expands and more patents are issued, the risk increases that ARS Pharma's product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that ARS's operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to ARS Pharma's operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. ARS Pharma cannot guarantee that any of ARS Pharma's patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can ARS Pharma be certain that it has identified each and every third-party patent and pending application in the United States and abroad that is relevant to ARS's operations or necessary for the commercialization of its product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in ARS Pharma's market that are owned by third parties. ARS Pharma's competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with ARS Pharma's ability to make, use and sell its products. ARS Pharma does not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover ARS Pharma's technologies, its products or the use of its products. As such, there may be applications of others now pending or recently revived patents of which ARS Pharma is unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with ARS Pharma's ability to make, use or sell its product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. ARS Pharma's interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact its ability to market its products. ARS Pharma may incorrectly determine that its products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. ARS Pharma's determination of the expiration date of any patent in the United States or abroad that ARS Pharma considers relevant may be incorrect, which may negatively impact ARS Pharma's ability to develop and market its product candidates. ARS's failure to identify and correctly interpret relevant patents may negatively impact its ability to develop and market its products.

ARS Pharma cannot provide any assurances that third-party patents do not exist which might be enforced against its current technology, including its research programs, product candidates, their respective methods of use, and manufacture thereof, and could result in either an injunction prohibiting ARS Pharma's manufacture or future sales, or, with respect to its future sales, an obligation on ARS Pharma's part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If ARS Pharma is sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay ARS Pharma from developing or commercializing its product candidates.

ARS Pharma's commercial success depends, in part, on its ability to develop, manufacture, market and sell its product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that ARS Pharma has infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in ARS Pharma's favor, is likely to divert significant resources from its core business, including distracting its technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase ARS Pharma's operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. ARS may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of ARS Pharma's competitors may be able to sustain the costs of such litigation or proceedings more effectively than ARS Pharma can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on ARS Pharma's ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the pharmaceutical industry, and ARS Pharma may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to its products candidates. Third parties may assert infringement claims against ARS Pharma based on existing or future intellectual property rights. The pharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including ARS Pharma, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If ARS Pharma were sued for patent infringement, ARS Pharma would need to demonstrate that ARS Pharma's product candidates, or of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and ARS Pharma may not be able to do this. Proving invalidity of third-party patents may be difficult and uncertain. Even if ARS Pharma is successful in these proceedings, ARS Pharma may incur substantial costs and the time and attention of its management and scientific personnel could be diverted in defending its rights in these proceedings, which could have a material adverse effect on its business and operations. In addition, ARS Pharma may not have sufficient resources to bring these actions to a successful conclusion.

If ARS Pharma is found to infringe a third party's intellectual property rights, ARS Pharma could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, ARS Pharma may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, ARS Pharma may not be able to obtain any required license on commercially reasonable terms or at all. Even if ARS Pharma were able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to ARS. In addition, ARS Pharma could be found liable for monetary damages, including treble damages and attorneys' fees if ARS Pharma is found to have willfully infringed a patent. A finding of infringement could prevent ARS Pharma from commercializing its product candidates or force ARS Pharma to cease some of its business operations, which could materially harm its business. Claims that ARS Pharma has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

ARS Pharma may become involved in lawsuits to protect or enforce its patents or other intellectual property, which could be expensive, time consuming and unsuccessful and could result in a court or administrative body finding its patents to be invalid or unenforceable.

Even if the patent applications ARS Pharma owns, co-owns or licenses are issued, third parties may challenge or infringe upon ARS Pharma's patents. To counter infringement, ARS Pharma may be required to file infringement claims, which can be expensive and time-consuming. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness (or inventive step), written description or enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution.

Third parties may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation or cancellation of or amendment to ARS Pharma's patents in such a way that they no longer cover its current or future products or provide any competitive advantage. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, ARS Pharma could lose part or all of the patent protection on one or more of its current or future products, which could result in its competitors and other third parties using its technology to compete with it. Such a loss of patent protection could have a material adverse impact on ARS Pharma's business, financial condition, results of operations, cash flows and prospects.

ARS Pharma is currently a party to an *inter partes* review of U.S. Patent No. 10,682,414 B2 that was instituted on February 14, 2022, and may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with ARS Pharma's ability to sell and market its products. Some of ARS Pharma's competitors may be able to sustain the costs of complex patent litigation more effectively than ARS can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on ARS Pharma's ability to raise the funds necessary to continue its operations. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target ARS Pharma, especially as ARS Pharma gains greater visibility and market exposure as a public company following the Merger.

In an infringement proceeding, even one initiated by ARS Pharma, there is a risk that a court will decide that ARS Pharma's patents are not valid and that ARS Pharma does not have the right to stop the other party from using the inventions they describe. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe ARS Pharma's rights to these patents.

An adverse outcome in a litigation or proceeding involving ARS Pharma's patents could limit ARS Pharma's ability to assert its patents against competitors, affect its ability to receive royalties or other licensing consideration from its licensees, and may curtail or preclude its ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could have a

material adverse effect on its business, financial condition, results of operations, cash flows and prospects.

Competitors may infringe ARS Pharma's patents, trademarks, copyrights or other intellectual property that relate to its research programs and product candidates, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, ARS Pharma may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of ARS Pharma's management and scientific personnel. Any claims ARS Pharma asserts against perceived infringers could provoke these parties to assert counterclaims against ARS Pharma alleging that ARS Pharma infringes their patents, in addition to counterclaims asserting that ARS Pharma's patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent that ARS owns or has licensed is invalid or unenforceable, in whole or in part, and that ARS Pharma does not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of ARS Pharma's patents is upheld, the court will construe the claims of its patents narrowly or decide that ARS Pharma does not have the right to stop the other party from using the invention at issue on the grounds that ARS Pharma's patent claims do not cover the invention at issue. An adverse outcome in a litigation or proceeding involving ARS Pharma's patents could limit its ability to assert its patents against those parties or other competitors, and may curtail or preclude its ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect ARS Pharma's competitive business position, business prospects and financial condition. Similarly, if ARS Pharma asserts trademark infringement claims, a court may determine that the marks ARS Pharma has asserted are invalid or unenforceable, or that the party against whom ARS Pharma has asserted trademark infringement has superior rights to the marks in question. In this case, ARS Pharma could ultimately be forced to cease use of such trademarks.

Even if ARS Pharma established infringement by competitors, a court may decide not to grant an injunction against further infringing activity by competitors and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of ARS Pharma's confidential information could be compromised by disclosure during litigation. Moreover, ARS Pharma cannot assure you that ARS Pharma will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if ARS Pharma ultimately prevails in such infringement claims, the monetary cost of such litigation and the diversion of the attention of its management and scientific personnel could outweigh any benefit ARS Pharma receive as a result of the proceedings.

ARS Pharma's product candidates may face competition sooner than expected, and its patents may be challenged.

ARS Pharma's success will depend in part on its ability to obtain and maintain patent protection for its product candidates and technologies and to prevent third parties from infringing upon its proprietary rights. ARS Pharma must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. However, the patent applications ARS Pharma has filed or may file in the future may never yield patents that protect its inventions and intellectual property assets. Failure to obtain patents that sufficiently cover ARS Pharma's formulations and technologies would limit its protection against generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy its products, produce substantially similar products or use technologies substantially similar to those ARS Pharma owns, co-owns, or exclusively licenses.

ARS Pharma does not expect to receive non-patent regulatory exclusivity for *neffy* if approved by the FDA under the 505(b)(2) regulatory pathway. Without non-patent marketing exclusivity for *neffy*,

ARS Pharma may face competition by third parties seeking to market generic versions of *neffy* as early as ARS Pharma's approval by the FDA. In seeking approval for a drug product under the 505(b)(2) regulatory pathway, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug product listed in the Orange Book or an NDA submitted under the 505(b)(2) regulatory pathway referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. Although ARS Pharma expects that its patents will be vigorously defended from infringement by third parties, there can be no assurances that ARS Pharma will be successful with respect to such defense or any other legal proceedings which may arise in the ordinary course of its business. Such a failure may have a material impact on ARS Pharma's business, results of operations and financial condition in the future.

Because of the expense and uncertainty of litigation, ARS Pharma may not be in a position to enforce its intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, ARS Pharma may conclude that even if a third party is infringing any one of its issued patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such an infringement claim or action may be too high or not in the best interest of its company or its stockholders. In such cases, ARS Pharma may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Intellectual property litigation may lead to unfavorable publicity that harms ARS Pharma's reputation.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. Such announcements could harm ARS Pharma's reputation, the perceived value of ARS Pharma's intellectual property or the market for its existing or future products, which could have a material adverse effect on its business.

ARS Pharma may become subject to claims challenging the inventorship or ownership of its patents and other intellectual property.

ARS Pharma may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in its patents or other intellectual property as an owner, co-owner, inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing ARS Pharma's product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, ARS Pharma may enter into agreements to clarify the scope of

ARS Pharma's rights in such intellectual property. If ARS Pharma fails in defending any such claims, in addition to paying monetary damages, ARS Pharma may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on ARS Pharma's business. Even if ARS Pharma is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If ARS Pharma's trademarks and trade names are not adequately protected, then ARS Pharma may not be able to build name recognition in its markets of interest and its business may be adversely affected.

ARS Pharma has registered trademarks with the appropriate agencies in the United States, as well as in foreign jurisdictions, including the International Bureau (WIPO), United Kingdom, European Union, and Japan. ARS Pharma's future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. ARS Pharma may not be able to protect its rights to these trademarks and trade names or may be forced to stop using these names, which ARS Pharma needs for name recognition by potential partners or customers in ARS Pharma's markets of interest. During trademark registration proceedings, ARS Pharma may receive rejections. Although ARS Pharma would be given an opportunity to respond to those rejections, ARS Pharma may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against ARS Pharma's trademarks, and its trademarks may not survive such proceedings. If ARS Pharma is unable to establish name recognition based on its trademarks and trade names, ARS Pharma may not be able to compete effectively and its business may be adversely affected. ARS Pharma may license its trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how ARS Pharma's trademarks and trade names may be used, a breach of these agreements or misuse of its trademarks and tradenames by its licensees may jeopardize ARS Pharma's rights in or diminish the goodwill associated with its trademarks and trade names.

Intellectual property rights do not necessarily address all potential threats to ARS Pharma's competitive advantage.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by ARS Pharma's intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect ARS Pharma's business. The following examples are illustrative:

- others may be able to make formulations that are similar to *neffy* or any of ARS Pharma's future product candidates but that are not covered by the claims of ARS Pharma's patent rights;
- the patents of third parties may have an adverse effect on ARS Pharma's business;
- ARS Pharma or its licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that ARS Pharma owns, co-owns or exclusively licensed;

- ARS Pharma or its licensors or any future strategic partners might not have been the first to file patent applications covering certain of ARS Pharma's inventions;
- others may independently develop similar or alternative technologies or duplicate any of ARS Pharma's technologies without infringing ARS Pharma's intellectual property rights;
- it is possible that ARS Pharma's pending patent applications will not lead to issued patents;
- issued patents that ARS Pharma may own or co-own or that ARS Pharma exclusively licenses in the future may not provide ARS Pharma with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by ARS Pharma's competitors;
- ARS Pharma's competitors might conduct research and development activities in countries where ARS Pharma does not have patent rights and then use the information learned from such activities to develop competitive products for sale in ARS Pharma's major commercial markets;
- third parties performing manufacturing or testing for ARS Pharma using ARS Pharma's product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- ARS Pharma may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on ARS Pharma's business.

Should any of these events occur, they could have a material adverse effect on ARS Pharma's business, financial condition, results of operations and prospects.

If ARS Pharma is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.

In addition to seeking patent protection for some of ARS Pharma's technology and product candidates, ARS Pharma also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain ARS Pharma's competitive position. Elements of ARS Pharma's product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects ARS Pharma may consider trade secrets and know-how to be ARS Pharma's primary intellectual property. Any disclosure, either intentional or unintentional, by ARS Pharma's employees, the employees of third parties with whom ARS Pharma shares its facilities or third-party consultants and vendors that ARS Pharma engages to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of ARS Pharma's trade secrets or proprietary information could enable competitors to duplicate or surpass ARS Pharma's technological achievements, thus eroding its competitive position in its market.

Trade secrets and unpatented know-how can be difficult to protect. ARS Pharma requires its employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to ARS any inventions generated in the course of their employment. ARS Pharma and any third parties with whom ARS Pharma shares facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how and information. ARS Pharma further seeks to protect its potential trade secrets, proprietary know-how and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as ARS Pharma's corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With ARS Pharma's consultants, contractors and outside scientific collaborators, these agreements typically include invention

assignment obligations. Although ARS has taken steps to protect ARS Pharma's trade secrets and unpatented know-how, ARS Pharma cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose ARS Pharma's proprietary information, including ARS Pharma's trade secrets, and ARS Pharma may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and ARS does not know whether the steps ARS Pharma has taken to protect ARS Pharma's proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of ARS Pharma's products that ARS Pharma considers proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secrets may be independently developed by others in a manner that could prevent legal recourse by ARS Pharma. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of skilled personnel from company to company or academic to industry scientific positions. Though ARS Pharma's agreements with third parties typically restrict the ability of ARS Pharma's advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to ARS Pharma's trade secrets, ARS Pharma's agreements may contain certain limited publication rights. Because from time-to-time ARS Pharma expects to rely on third parties in the development, manufacture and distribution of ARS Pharma's products and provision of ARS Pharma's services, ARS Pharma must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by ARS Pharma's competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of ARS Pharma's trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, ARS Pharma would have no right to prevent them from using that technology or information to compete with ARS Pharma. If any of ARS Pharma's trade secrets were to be disclosed to or independently developed by a competitor or other third party, ARS Pharma's competitive position would be harmed.

ARS Pharma may be subject to claims that its employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

ARS Pharma employs individuals who previously worked with other companies, including its competitors or potential competitors. ARS Pharma could in the future be subject to claims that ARS Pharma or its employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors. Although ARS Pharma tries to ensure that its employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for ARS Pharma, ARS Pharma may become subject to claims that ARS Pharma caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that ARS Pharma or these individuals have, inadvertently or otherwise, used or disclosed the alleged intellectual property, proprietary information, know-how or trade secrets of a current or former employer or competitor.

While ARS Pharma may litigate to defend against these claims, even if ARS Pharma is successful, litigation could result in substantial costs and could be a distraction to management and other employees. If ARS Pharma's defenses to these claims fail, in addition to requiring ARS Pharma to pay monetary damages, a court could prohibit ARS Pharma from using technologies that are essential to ARS Pharma's product candidates, if such technologies are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers.

Moreover, any such litigation or the threat thereof may adversely affect its reputation, its ability to form strategic alliances or sublicense its rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on its business, results of operations and financial condition.

In the future, ARS Pharma may need to obtain additional licenses of third-party technology that may not be available to ARS Pharma or are available only on commercially unreasonable terms, and which may cause ARS Pharma to operate its business in a more costly or otherwise adverse manner that was not anticipated.

From time to time, ARS Pharma may be required to license technologies relating to its therapeutic programs from additional third parties to further develop or commercialize ARS's product candidates. Should ARS Pharma be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell ARS Pharma's product candidates, such licenses may not be available to ARS Pharma on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of ARS's product candidates could cause ARS Pharma to abandon any related efforts, which could seriously harm its business and operations.

Any collaboration arrangements that ARS Pharma may enter into in the future may not be successful, which could adversely affect its ability to develop and commercialize its products.

Any future collaborations that ARS Pharma enters into may not be successful. The success of ARS Pharma's collaboration arrangements will depend heavily on the efforts and activities of its collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of ARS Pharma's products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with ARS Pharma's products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- ARS Pharma could grant exclusive rights to ARS Pharma's collaborators that would prevent ARS Pharma from collaborating with others;
- collaborators may not properly maintain or defend ARS Pharma's intellectual property rights or may use ARS Pharma's intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate ARS Pharma's intellectual property or proprietary information or expose ARS Pharma to potential liability;
- disputes may arise between ARS Pharma and a collaborator that causes the delay or termination of the research, development or commercialization of ARS Pharma's current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;

- collaborators may own or co-own intellectual property covering ARS Pharma's products that results from ARS Pharma's collaborating with them, and in such cases, ARS Pharma would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to ARS Pharma's Business Operations, Employee Matters and Managing Growth

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect ARS Pharma's business, including its nonclinical studies, clinical trials, third parties on whom ARS Pharma relies, ARS Pharma's supply chain, its ability to raise capital, its ability to conduct regular business and its financial results.

ARS Pharma is subject to risks related to public health crises such as the COVID-19 pandemic and the ongoing efforts to halt its spread. The pandemic and policies and regulations implemented by governments in response to the pandemic, often directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical service and supplies, has spiked, while demand for other goods and services has fallen. ARS Pharma has experienced certain impacts of the COVID-19 pandemic to date, including inability to conduct clinical trial site monitoring for certain earlier phase clinical trials and delays in completing clinical trials, bioanalytical sample analysis and study reports. There can be no guarantee ARS Pharma will not experience other impacts, such as being forced to further delay or pause enrollment, experiencing potential interruptions to its supply chain, facing difficulties or additional costs in enrolling patients in future clinical trials or being able to achieve full enrollment of its studies within the timeframes ARS Pharma anticipates, or at all.

The impact of the COVID-19 pandemic has been and may continue to be extensive in many aspects of society and could continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. The full extent to which the COVID-19 pandemic, including efforts to halt the pandemic, could ultimately impact ARS Pharma's business, nonclinical studies, clinical trials and financial results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including the rate and success of vaccination efforts, new strains of the virus for which current vaccinations may not be effective and new information which may emerge, among others. Other global health concerns could also result in social, economic, and labor instability in the countries in which ARS Pharma or the third parties with whom ARS Pharma engage operate.

In response to the COVID-19 pandemic, ARS Pharma has continued to take precautionary measures intended to help minimize the risk of the virus to ARS Pharma's employees, including closing or reducing access to ARS Pharma's executive offices and temporarily requiring employees to work remotely, suspending all non-essential travel for ARS Pharma's employees and discouraging employee attendance at industry events and in-person work-related meetings, all of which could negatively affect ARS Pharma's business.

While ARS Pharma has been working closely with ARS Pharma's third-party manufacturers, distributors and other partners to manage ARS Pharma's supply chain activities and mitigate potential disruptions to the production of *neffy* as a result of the COVID-19 pandemic, if, despite vaccination efforts, the COVID-19 pandemic persists for an extended period of time, there could be significant and material disruptions to ARS Pharma's supply chain and operations, and associated delays in the

manufacturing and supply of *neffy* and any future product candidates. Any such supply disruptions, including disruptions in procuring items that are essential for ARS Pharma's development activities and securing manufacturing slots for the products needed for such activities, could adversely impact ARS Pharma's ability to initiate and complete nonclinical studies or clinical trials and generate sales of and revenue from ARS Pharma's product candidates, if approved, which could have a material adverse effect on ARS Pharma's business, financial condition, results of operations and growth prospects.

The COVID-19 pandemic has affected and may in the future affect employees of third-party CROs located in affected geographies that ARS Pharma rely upon to carry out ARS Pharma's clinical trials. If the spread of the virus or any variant of the virus is not contained or increases, or if a new virus or pandemic emerges, ARS Pharma may experience additional disruptions that could severely impact ARS Pharma's business and clinical trials, including:

- delays or difficulties in ARS Pharma's commercialization efforts;
- delays or difficulties in enrolling patients in ARS Pharma's clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of sites or facilities serving as ARS Pharma's clinical trial sites and staff supporting the conduct of ARS Pharma's clinical trials, including ARS Pharma's trained therapists, or absenteeism that reduces site resources;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or national governments, employers and others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in ARS Pharma's clinical trials will acquire COVID-19 or another virus or illness while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from ARS Pharma's trials;
- limitations in employee resources that would otherwise be focused on conducting ARS Pharma's clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from regulatory authorities to initiate ARS Pharma's future clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct ARS Pharma's clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as neffy used in ARS Pharma's clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic or other pandemic which may require ARS Pharma to change the ways in which ARS Pharma's clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in nonclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and

- refusal of the FDA, the EMA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States, the EU or other relevant local geographies.

Any negative impact the COVID-19 pandemic or any future pandemic or similar disruption has on patient enrollment or treatment, or the development of *neffy* and any future product candidates, could cause costly delays to clinical trial activities, which could adversely affect ARS Pharma's ability to obtain regulatory approval for and to commercialize *neffy* and any future product candidates, if approved, increase ARS Pharma's operating expenses, which could have a material adverse effect on ARS Pharma's financial results. The COVID-19 pandemic has also in the past caused significant volatility in public equity markets and disruptions to the United States and global economies and any future pandemic or similar disruption could lead to further market dislocation. Any such increased volatility and economic dislocation may make it more difficult for ARS Pharma to raise capital on favorable terms, or at all. If ARS Pharma or any of the third parties with whom ARS Pharma engage were to experience renewed shutdowns or other business disruptions, ARS Pharma's ability to conduct its business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on its business and its results of operations and financial conditions. To the extent the COVID-19 pandemic or any future pandemic or similar disruption adversely affects ARS Pharma's business and financial results, it may also heighten many of the other risks described in this "*Risk Factors—Risk Factors Related to ARS Pharma*" section, such as those relating to the timing and completion of ARS Pharma's clinical trials and ARS Pharma's ability to obtain future financing.

ARS Pharma's success is highly dependent on its ability to attract and retain highly skilled executive officers and employees.

ARS Pharma's success depends, and will likely continue to depend, upon its ability to hire and retain the services of its current executive officers and its other highly qualified personnel. ARS Pharma has entered into employment agreements with each of ARS Pharma's executive officers but they may terminate their employment or engagement with ARS Pharma at any time. The loss of their services might impede the achievement of ARS Pharma's research, development and commercialization objectives.

ARS Pharma's ability to compete in the biotechnology and pharmaceuticals industries depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. ARS Pharma's industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in ARS Pharma's industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

ARS Pharma's industry has experienced a high rate of turnover in recent years. Competition to hire from this limited pool is intense, and ARS Pharma may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. ARS Pharma also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions.

ARS Pharma relies on consultants and advisors, including scientific and clinical advisors, to assist ARS Pharma in formulating ARS Pharma's research and development and commercialization strategy. ARS Pharma's consultants and advisors, which includes entities owned by ARS Pharma's executive officers and directors, may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to ARS Pharma. If ARS Pharma is unable to continue to attract and retain highly qualified personnel, ARS Pharma's ability to develop and commercialize *neffy* or any future product candidates will be limited.

ARS Pharma only has a limited number of employees to manage and operate its business.

As of June 30, 2022, ARS Pharma had nine full-time employees and two part-time employees. ARS Pharma's focus on the development of *neffy* requires ARS Pharma to optimize cash utilization and to manage and operate ARS Pharma's business in a highly efficient manner. ARS Pharma cannot assure you that it will be able to hire and/or retain adequate staffing levels to develop *neffy* or to run ARS Pharma's operations and/or to accomplish all of the objectives that ARS Pharma otherwise would seek to accomplish.

ARS Pharma's employees, independent contractors, consultants, current and future licensing and collaboration partners and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for ARS Pharma and harm its reputation.

ARS Pharma is exposed to the risk that its employees, independent contractors, consultants, current and future licensing and collaboration partners and CROs may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to ARS Pharma that violates:

- FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities; and
- laws that require the reporting of financial information or data accurately.

Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in ARS Pharma's nonclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to ARS Pharma's reputation. It is not always possible to identify and deter misconduct, and the precautions ARS Pharma takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting ARS Pharma from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, ARS Pharma is subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against ARS Pharma, and it is not successful in defending ourselves or asserting its rights, those actions could have a significant impact on ARS Pharma's business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of ARS Pharma's operations, any of which could have a material adverse effect on ARS Pharma's ability to operate its business and its results of operations.

ARS Pharma expects to expand its organization, and as a result, it may encounter difficulties in managing its growth, which could disrupt its operations.

ARS Pharma expects to experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to support ARS Pharma's public company operations. To manage these growth

activities, ARS Pharma must continue to implement and improve ARS Pharma's managerial, operational and financial systems, expand ARS Pharma's facilities and continue to recruit and train additional qualified personnel. ARS Pharma's management may need to devote a significant amount of its attention to managing these growth activities. Due to ARS Pharma's limited financial resources and the limited experience of ARS Pharma's management team in managing a company with such anticipated growth, ARS Pharma may not be able to effectively manage the expansion or relocation of its operations, retain key employees, or identify, recruit and train additional qualified personnel. ARS Pharma's inability to manage the expansion or relocation of its operations effectively may result in weaknesses in ARS Pharma's infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. ARS Pharma's expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of *neffy* for additional indications or future product candidates. If ARS Pharma is unable to effectively manage ARS Pharma's expected growth, its expenses may increase more than expected, its ability to generate revenues could be reduced and it may not be able to implement its business strategy, including the successful commercialization of *neffy* or any future product candidates.

Risks Related to the Combined Company

In determining whether you should vote approve the proposals contained in this proxy statement, you should carefully read the following risk factors in addition to the risks described above.

The combined company will need to raise additional financing in the future to fund its operations, which may not be available to it on favorable terms or at all.

Although we expect that the combined company will have approximately $265 million in cash, cash equivalents and marketable securities at Closing, which we expect will provide at least three years of operating runway, following such period of time, the combined company will require additional funds to continue the development and potential commercialization of *neffy* and future product candidates. The combined company's future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical studies and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance.

Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit the combined company's ability to achieve its business objectives. If the combined company raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely the rights of its common stockholders. Further, to the extent that the combined company raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, its stockholder's ownership interest in the combined company will be diluted. In addition, any debt financing may subject the combined company to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, the terms of the ARS Loan and Security Agreement contain restrictive covenants that may prevent the combined company from incurring additional indebtedness without Silicon Valley Bank's consent. If the combined company raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, the combined company may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Even if the combined

company were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to the combined company or its stockholders.

The market price of the combined company's common stock is expected to be volatile, and the market price of the common stock may drop following the Merger.

The market price of the combined company's common stock following the Merger could be subject to significant fluctuations. Market prices for securities of pre-commercial pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company's common stock to fluctuate include:

- the ability of the combined company to obtain regulatory approvals for its product candidates, and delays or failures to obtain such approvals;
- failure of any of the combined company's product candidates, if approved, to achieve commercial success;
- failure by the combined company to maintain its existing third-party license and supply agreements;
- failure by the combined company or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to the combined company's product candidates;
- any inability to obtain adequate supply of the combined company's product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by the combined company's competitors;
- failure to meet or exceed financial and development projections the combined company may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by the combined company or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the combined company's ability to obtain patent protection for its product candidates;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined company's business, or if they issue an adverse or misleading opinion regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of its common stock by the combined company or its stockholders in the future;

- trading volume of the combined company's common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of the combined company;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in the combined company's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. For example, following a decline in Silverback's stock price, a federal securities class action complaint was filed on November 5, 2021 against Silverback and certain of its officers and directors in the U.S. District for the Western District of Washington, captioned *Dresner v. Silverback Therapeutics, Inc.*, et al., Case No. 2:21-cv-01499, which alleges violations of (i) Sections 11 and 15 of the Securities Act; and (ii) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder. Defendants filed a motion to dismiss the action in May 2022 and the court has not yet issued a ruling. If not dismissed, settled or otherwise resolved prior to the Closing, the combined company will need to defend this action. Even if the combined company is successful in defending against this action or any similar claims that may be brought in the future, such litigation could result in substantial costs and a diversion of management's attention and resources, which could harm the combined company's business.

Additionally, a decrease in the stock price of the combined company may cause the combined company's common stock to no longer satisfy the continued listing standards of Nasdaq. If the combined company is not able to maintain the requirements for listing on Nasdaq, it could be delisted, which could have a materially adverse effect on its ability to raise additional funds as well as the price and liquidity of its common stock.

The combined company will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

The combined company will incur significant legal, accounting and other expenses that ARS Pharma did not incur as a private company, including costs associated with public company reporting requirements. The combined company will also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new requirements implemented by the SEC and Nasdaq. These rules and regulations are expected to increase the combined company's legal and financial compliance costs and to make some activities more time consuming and costly. For example, the combined company's management team will consist of the executive officers of ARS Pharma prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations also may make it difficult and expensive

for the combined company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for the combined company to attract and retain qualified individuals to serve on the combined company's board of directors or as executive officers of the combined company, which may adversely affect investor confidence in the combined company and could cause the combined company's business or stock price to suffer.

Delaware law and provisions in the combined company's amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of the combined company's common stock.

The combined company's status as a Delaware corporation and the anti-takeover provisions of the DGCL may discourage, delay or prevent a change in control by prohibiting the combined company from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to the combined company's stockholders. In addition, the combined company's amended and restated certificate of incorporation and amended and restated bylaws will contain provisions that may make the acquisition of the combined company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the combined company's board of directors;
- the ability of the combined company's board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of the combined company's board of directors to elect a director to fill a vacancy created by the expansion of the combined company's board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on the combined company's board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of the combined company's stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of the entire board of directors of the combined company, the chair of the combined company's board of directors or the combined company's chief executive officer, which could delay the ability of the combined company's stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of the combined company's amended and restated certificate of incorporation relating to the management of its business or its amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to the combined company's board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the combined company.

In addition, as a Delaware corporation, the combined company will be subject to Section 203 of the DGCL. These provisions may prohibit large stockholders, in particular those owning 15% or more

of the outstanding voting stock of the combined company, from merging or combining with the combined company for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, Silverback has not opted out of this provision, which will be applicable to the combined company following the Closing.

These and other provisions in the combined company's amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of the combined company's board of directors or initiate actions that are opposed by its then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving the combined company. The existence of these provisions could negatively affect the price of the combined company's common stock and limit opportunities for its stockholders to realize value in a corporate transaction.

The combined company's amended and restated certificate of incorporation will designate the state courts the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, and the federal district courts of the United States of America to be the exclusive forums for substantially all disputes between the combined company and its stockholders, which could limit the combined company's stockholders' ability to obtain a favorable judicial forum for disputes with the combined company or its directors, officers and employees.

The amended and restated certificate of incorporation of the combined company provides that, to the fullest extent permitted by law, unless the combined company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of the combined company; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of the combined company's current or former directors, officers or other employees to the combined company or its stockholders; (iii) any action or proceeding asserting a claim against the combined company or any of its current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, amended and restated certificate of incorporation of the combined company or the amended and restated bylaws of the combined company; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of the amended and restated certificate of incorporation of the combined company or the amended and restated bylaws of the combined company; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against the combined company or any of its directors, officers or other employees, governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, the amended and restated certificate of incorporation of the combined company will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal

court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, the combined company would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of its amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in the combined company's amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects.

These exclusive forum provisions may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the combined company or its directors, officers, or other employees, which may discourage lawsuits against the combined company and its directors, officers and other employees. If a court were to find either exclusive-forum provision in the combined company's amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, the combined company may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Silverback and ARS Pharma do not anticipate that the combined company will pay any cash dividends in the foreseeable future.

The current expectation is that the combined company will retain its future earnings, if any, to fund the development and growth of the combined company's business. As a result, capital appreciation, if any, of the common stock of the combined company will be its stockholders' sole source of gain, if any, for the foreseeable future.

An active trading market for the combined company's common stock may not develop and its stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for ARS Pharma's common stock. An active trading market for the combined company's shares of common stock may never develop or be sustained. If an active market for its common stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause the combined company's stock price to decline.

If existing stockholders of Silverback and ARS Pharma sell, or indicate an intention to sell, substantial amounts of the combined company's common stock in the public market after legal restrictions on resale discussed in this proxy statement lapse, the trading price of the common stock of the combined company could decline. Neither Silverback nor ARS Pharma is able to predict the effect that sales may have on the prevailing market price of the combined company's common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the combined company, its business or its market, its stock price and trading volume could decline.

The trading market for the combined company's common stock will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts

may elect not to provide research coverage of the combined company's common stock after the completion of the Merger, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, the combined company will not have any control over the analysts, or the content and opinions included in their reports. The price of the combined company's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of the combined company or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

If the combined company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

The combined company will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that the combined company maintain effective disclosure controls and procedures and internal control over financial reporting. The combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, ARS Pharma has never been required to test its internal controls within a specified period. This will require that the combined company incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. The combined company may experience difficulty in meeting these reporting requirements in a timely manner.

The combined company may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. The combined company's internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, the combined company may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

If the combined company fails to attract and retain management and other key personnel, it may be unable to continue to successfully develop or commercialize its product candidates or otherwise implement its business plan.

The combined company's ability to compete in the highly competitive pharmaceuticals industry depends on its ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. The combined company will be highly dependent on its management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of the combined company's product candidates, completion of its planned clinical trials, commercialization of its product candidates or in-licensing or acquisition of new assets and could impact negatively its ability to implement successfully its business plan. If the combined company loses the services of any of these individuals, it might not be able to

find suitable replacements on a timely basis or at all, and its business could be harmed as a result. The combined company might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

The combined company will be an "emerging growth company" and neither Silverback nor ARS Pharma can be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make the combined company's common stock less attractive to investors.

The combined company will be an "emerging growth company," as defined under the Jumpstart Our Business Startups Act (the "JOBS Act"). For so long as the combined company is an "emerging growth company," it is expected that it will take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Neither Silverback nor ARS Pharma can predict if investors will find the combined company's common stock less attractive, or the combined company less comparable to certain other public companies because it will rely on these exemptions. If some investors find the combined company's common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile.

Under the JOBS Act, "emerging growth companies" can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The combined company will have irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

The combined company's ability to use NOL carryforwards and certain other tax attributes may be limited.

Each of Silverback and ARS Pharma has incurred substantial losses during its history. Unused losses for the tax years beginning before January 1, 2018, will carry forward to offset future taxable income, if any, until such unused losses expire. Unused federal losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. In addition, both current and future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Code if the combined company undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. The Merger will result in an ownership change for Silverback. ARS Pharma's NOL carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on Silverback's, ARS Pharma's and the combined company's NOL carryforwards. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of Silverback's, ARS Pharma's, or the combined company's NOL carryforwards and other tax attributes, which could adversely affect the combined company's business, cash flow, financial condition or results of operations.

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This proxy statement and the documents incorporated by reference into this proxy statement contain forward-looking statements. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as it cannot be assured that the events or circumstances reflected in these statements will be achieved or will occur. You can identify forward-looking statements by the use of forward-looking terminology including "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "pro forma," "should," "will," "would," or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. For example, forward-looking statements include, but are not limited to statements about:

- expected timing, completion, effects and potential benefits of the Merger;
- statements of the plans, strategies and objectives of management with respect to the approval and closing of the Merger;
- Silverback's ability to solicit a sufficient number of proxies to approve matters related to the consummation of the Merger;
- the expected Exchange Ratio and relative ownership percentages of the stockholders of ARS Pharma and Silverback in the combined company following the Closing;
- the expected level of Silverback Net Cash at Closing;
- the expected name, ticker symbol, management team and board of directors of the combined company;
- any statements regarding future economic conditions or performance;
- Silverback's plans to divest its preclinical assets;
- research and development plans, including planned clinical trials, for *neffy*, including for additional indications;
- the design and potential benefits of *neffy*;
- ARS Pharma's plans to submit a supplemental NDA to the FDA and MAA to the EMA for *neffy* and the timing thereof;
- ARS Pharma's expectations regarding the timing for FDA review of its NDA submitted in the third quarter of 2022;
- the timing of the commercial launch of *neffy*, if approved, and the ability of the Merger to provide sufficient capital for such launch;
- the commercialization strategy for *neffy*;
- the size of the markets for *neffy* and any other product candidates, and the combined company's ability to serve those markets;
- the rate and degree of market acceptance of *neffy* and any other product candidates;
- regulatory developments in the United States and foreign countries;
- the safety, efficacy, and market success of competing therapies that are or become available;
- the combined company's ability to attract and retain key scientific and management personnel;

- the performance of our third-party service providers, including the combined company's contract research organizations, suppliers, and manufacturers;
- the combined company's ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- the combined company's ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- the combined company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of *neffy* or any future product candidate;
- the impact of the COVID-19 pandemic on the combined company's business and operations; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

For a discussion of the factors that may cause Silverback, ARS Pharma or the combined company's actual results, performance or achievements following the Closing to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, or for a discussion of risk associated with the ability of Silverback and ARS Pharma to complete the Merger and the effect of the Merger on the business of Silverback, ARS Pharma and the combined company following the completion of the Merger, see the section titled "*Risk Factors*" in this proxy statement. Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the SEC by Silverback. See the section titled "*Where You Can Find More Information*" in this proxy statement. There can be no assurance that the Merger will be completed, or if it is completed, that it will close within the anticipated time period or that the expected benefits of the Merger will be realized.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Silverback, ARS Pharma or the combined company following completion of the Merger could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement are current only as of the date on which the statements were made. Silverback and ARS Pharma do not undertake any obligation (and expressly disclaim any such obligation) to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as required by applicable law.

In addition, statements that "Silverback believes" or "ARS Pharma believes" and similar statements reflect Silverback's or ARS Pharma's beliefs and opinions on the relevant subject. These statements are based upon information available to Silverback or ARS Pharma, as the case may be, as of the date of this proxy statement, and while Silverback or ARS Pharma, as the case may be, believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and such statements should not be read to indicate that such party has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

THE VIRTUAL SPECIAL MEETING OF SILVERBACK'S STOCKHOLDERS

Date, Time and Place

The Silverback virtual special meeting will be held in a virtual meeting format only, via the internet and with no physical in-person meeting on November 4, 2022, at 10:00 a.m. Pacific Time, unless postponed or adjourned to a later date. The Silverback virtual special meeting can be accessed by visiting www.proxydocs.com/SBTX where you will be able to vote your shares and submit questions during the Silverback virtual special meeting webcast by logging in to the website listed above using the control number included in your proxy card. Online check-in will begin at 10:00 a.m. Pacific Time, and Silverback encourages you to allow ample time for the online check-in procedures.

This proxy statement is first being furnished to stockholders of Silverback on or about October 7, 2022. This proxy statement provides Silverback stockholders with information they need to know to be able to vote or instruct their vote to be cast at the Silverback virtual special meeting.

Purpose of the Silverback Virtual Special Meeting

The purpose of the Silverback virtual special meeting is to:

1. *Proposal No. 1 (Merger Proposal).* Approve (i) the issuance of shares of Silverback Common Stock or other securities of Silverback pursuant to the Merger, which will represent (or are convertible into) more than 20% of the shares of Silverback Common Stock outstanding immediately prior to the Merger, and (ii) the change of control resulting from the Merger, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), respectively; and

3. *Proposal No. 2 (Adjournment Proposal).* Approve a postponement or adjournment of the Silverback virtual special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal No. 1.

Silverback will transact no other business at the Silverback virtual special meeting except such business as may properly be brought before the Silverback virtual special meeting or any adjournment or postponement thereof.

Recommendation of the Silverback Board

The Silverback Board has unanimously determined that the Merger Proposal and the Adjournment Proposal are fair to, advisable for and in the best interests of Silverback and its stockholders. The Silverback Board recommends that Silverback's stockholders vote "**FOR**" each of Proposal Nos. 1 and 2.

Record Date and Voting Power

Only holders of record of Silverback Common Stock at the close of business on the record date, September 19, 2022, are entitled to notice of, and to vote at, the Silverback virtual special meeting. There were 8 holders of record of Silverback Common Stock at the close of business on the record date. At the close of business on the record date, 35,798,117 shares of Silverback Common Stock were issued and outstanding. Each share of Silverback Common Stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See the section titled "*Principal Stockholders of Silverback*" in this proxy statement for information regarding persons known to Silverback's management to be the beneficial owners of more than 5% of the outstanding shares of Silverback Common Stock.

Voting and Revocation of Proxies

The proxy accompanying this proxy statement is solicited on behalf of the Silverback Board for use at the Silverback virtual special meeting.

Only holders of record of Silverback Common Stock at the close of business on the record date will be entitled to notice of, and to vote at, the Silverback virtual special meeting or any adjournments or postponements thereof.

As of the close of business on the record date, there were 35,798,117 shares of Silverback Common Stock outstanding and entitled to vote at the Silverback virtual special meeting. Each share of Silverback Common Stock outstanding on the record date entitles the holder thereof to one vote on each proposal to be considered at the Silverback virtual special meeting.

Your vote is important. Silverback expects that many Silverback stockholders will not attend the Silverback virtual special meeting, and instead will be represented by proxy. Most Silverback stockholders have a choice of submitting a proxy to vote their shares via the internet by following the instructions posted at www.proxydocs.com/SBTX, by using the toll-free telephone number, or by returning a completed Silverback proxy card or voting instruction form. Please check your notice, proxy card or the information forwarded by your broker, bank or other nominee to see which options are available to you. These internet and telephone procedures have been designed to authenticate Silverback stockholders, to allow you to vote your shares, and to confirm that your instructions have been properly recorded.

You can revoke your proxy at any time before it is exercised by delivering a properly executed, later-dated proxy (including a proxy submitted by internet or telephone), by delivering a written revocation before the Silverback virtual special meeting or by voting at the Silverback virtual special meeting. Executing your proxy in advance will not limit your right to vote at the Silverback virtual special meeting if you decide to attend the Silverback virtual special meeting. However, if your shares are held in the name of a broker, bank or other nominee, you cannot vote at the Silverback virtual special meeting unless you have a legal proxy, executed in your favor, from the holder of record.

All shares entitled to vote and represented by properly executed proxies received prior to the Silverback virtual special meeting and not revoked will be voted at the Silverback virtual special meeting in accordance with your instructions. If you sign and return your proxy but do not indicate how your shares should be voted on a proposal, the shares represented by your proxy will be voted as the Silverback Board recommends for such proposal.

Subject to health concerns relating to COVID-19, which may require Silverback to implement alternative procedures to protect the health and welfare of Silverback's employees and stockholders, a complete list of Silverback stockholders entitled to vote at the Silverback virtual special meeting will be available for examination by any Silverback stockholder in the Corporate Secretary's Office at Silverback Therapeutics, Inc., 500 Fairview Ave. N, Suite 600, Seattle, Washington 98109, for purposes pertaining to the Silverback virtual special meeting, during ordinary business hours for a period of 10 days before the Silverback virtual special meeting, and at the Silverback virtual special meeting. A complete list of Silverback stockholders entitled to vote at the Silverback virtual special meeting will also be available for inspection during the Silverback virtual special meeting at www.proxydocs.com/SBTX, by logging in with your control number(s).

Quorum and Required Vote

The presence, virtually or by proxy, at the Silverback virtual special meeting of the holders of a majority of the shares of Silverback Common Stock outstanding and entitled to vote at the Silverback

virtual special meeting is necessary to constitute a quorum at the meeting. Abstentions and broker non-votes will be counted towards a quorum. Approval of Proposals Nos. 1 and 2 requires the affirmative vote of a majority of the votes cast virtually or by proxy at the Silverback virtual special meeting.

Proposal No. 1 is a condition to the consummation of the Merger. Therefore, the Merger cannot be consummated without the approval of Proposal No. 1. Proposal No. 2 is not a condition to the consummation of the Merger. Proposal No. 1 is not conditioned on Proposal No. 2 being approved.

As of immediately prior to the date of the Merger Agreement, the directors and executive officers of Silverback and other stockholders who signed the Silverback Support Agreements beneficially owned approximately 31% of the outstanding shares of Silverback Common Stock entitled to vote at the Silverback virtual special meeting. Pursuant to the Silverback Support Agreements, each such director, executive officer and stockholder has agreed, solely in his, her or its capacity as a stockholder of Silverback, to be present (virtually or by proxy) at the Silverback virtual special meeting to vote all shares of Silverback Common Stock owned by him, her or it as of the record date in favor of Proposal Nos. 1 and 2. Additionally, each such stockholder has agreed, solely in his, her or its capacity as a stockholder of Silverback, to vote against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and against any acquisition proposal involving a third party.

Voting by Holders of Record

If you were the record holder of your shares of Silverback Common Stock as of the record date, you may vote your shares of Silverback Common Stock at the Silverback virtual special meeting via the virtual meeting website. Any Silverback stockholder can attend the Silverback virtual special meeting by visiting www.proxydocs.com/SBTX, where stockholders may vote and submit questions during the Silverback virtual special meeting webcast. Additionally, you may submit your proxy authorizing the voting of your shares of Silverback Common Stock at the Silverback virtual special meeting by mail, by telephone or via the internet.

Voting via Proxies Submitted by the Internet or by Telephone

To vote through the internet, go to www.proxydocs.com/SBTX to complete an electronic proxy card. You will be asked to provide the company number and control number from the enclosed proxy card.

To vote over the telephone, dial toll-free (866) 355-8664 using a touch-tone phone and follow the recorded instructions. You will be asked to provide the company number and control number from the enclosed proxy card.

Voting via Proxies Submitted by Mail

As an alternative to submitting your proxy via the internet or by telephone, you may submit your proxy by mail.

To vote using the proxy card, simply complete, sign and date the enclosed proxy card and return it promptly in the envelope provided. If you return your signed proxy card to us before the Silverback virtual special meeting, we will vote your shares as you direct.

Treatment of Abstentions; Failure to Vote

For purposes of the Silverback virtual special meeting, an abstention occurs when a Silverback stockholder attends the Silverback virtual special meeting, virtually or by proxy, but abstains from

voting. If a Silverback stockholder is not present at the Silverback virtual special meeting and does not respond by proxy, it will have no effect on the vote count for such proposal. Abstentions and broker non-votes (if applicable) will have no effect on the outcome of Proposal Nos. 1 and 2 but will be used to determine whether a quorum is present at the Silverback virtual special meeting.

Attendance at the Silverback Virtual Special Meeting and Voting at the Silverback Virtual Special Meeting

You or your authorized proxy may attend the Silverback virtual special meeting if you were a registered or beneficial stockholder of Silverback Common Stock as of the Silverback record date. A summary of the information you need to attend the Silverback virtual special meeting online is provided below:

- To participate, vote or submit questions during the Silverback virtual special meeting via live webcast, you must register in advance at www.proxydocs.com/SBTX prior to the meeting and provide the control number as set forth in the proxy card or voting instruction form at www.proxydocs.com/SBTX. Upon completing your registration, you will receive further instructions via email, including unique links to access the Silverback virtual special meeting and to submit questions in advance of the Silverback virtual special meeting.
- Any stockholder may listen to the Silverback virtual special meeting and participate live via webcast at www.proxydocs.com/SBTX. The webcast will begin at 10:00 a.m. Pacific Time on November 4, 2022.
- Stockholders may vote and submit questions during the Silverback virtual special meeting via live webcast.
- To enter the Silverback virtual special meeting, please have your control number which is available on your proxy card or the instructions that accompanied your proxy materials. If you do not have your control number, you will be able to listen to the meeting only and you will not be able to vote or submit questions during the meeting.
- Instructions on how to connect to and participate in the Silverback virtual special meeting via the internet, including how to demonstrate proof of stock ownership, are posted at www.proxydocs.com/SBTX.

If we experience technical difficulties during the Silverback virtual special meeting (e.g., a temporary or prolonged power outage), we will determine whether the Silverback virtual special meeting can be promptly reconvened (if the technical difficulty is temporary) or whether the Silverback virtual special meeting will need to be reconvened on a later day (if the technical difficulty is more prolonged). In any situation, we will promptly notify stockholders of the decision via www.proxydocs.com/SBTX. We will have technicians ready to assist you with any technical difficulties you may have accessing the virtual meeting website. If you encounter any difficulties accessing the virtual meeting website during the check-in or meeting time, please call the technical support number that will be posted on the virtual meeting website log-in page at www.proxydocs.com/SBTX.

Please note that you will not be able to attend the Silverback virtual special meeting in person. In light of the ongoing developments relating to the ongoing COVID-19 pandemic and to protect the health of Silverback stockholders, management, employees and the community, the Silverback virtual special meeting will be held virtually conducted via live audio webcast. You will be able to attend the Silverback virtual special meeting by visiting www.proxydocs.com/SBTX and entering your control number as further explained in the accompanying proxy card. Silverback recommends that you log in at least 15 minutes before the Silverback virtual special meeting to ensure you are logged in when the meeting starts.

If you own shares in street name through an account with a bank, broker or other nominee, please send proof of your Silverback share ownership as of the Silverback record date (for example, a brokerage firm account statement or a "legal proxy" from your intermediary) along with your registration request. If you are not sure what proof to send, check with your intermediary.

If your shares are registered in your name with Silverback's stock registrar and transfer agent, American Stock Transfer & Trust Company, LLC, no proof of ownership is necessary because Silverback can verify your ownership.

Solicitation of Proxies; Expenses of Solicitation

The Silverback Board is soliciting proxies for the Silverback virtual special meeting from its stockholders. Silverback will bear a portion of the cost of the solicitation of proxies, including preparation, assembly and delivery, as applicable, of this proxy statement, the Silverback proxy card and any additional materials furnished to Silverback stockholders. Proxies may be solicited by directors, officers and a small number of Silverback's regular employees by mail, email, in person and by telephone, but such persons will not receive any additional compensation for these activities.

Tabulation of Votes

Silverback will appoint Mediant Communications, Inc. ("Mediant") to serve as the Inspector of Election for the Silverback virtual special meeting. Mediant will independently tabulate affirmative and negative votes and abstentions.

Adjournments

Subject to certain restrictions contained in the Merger Agreement, the Silverback virtual special meeting may be adjourned to allow additional time for obtaining additional proxies. No notice of an adjourned meeting need be given if the time and place thereof are announced at the Silverback virtual special meeting at which the adjournment was taken unless: the adjournment is for more than 30 days, in which case a notice of the adjourned meeting will be given to each Silverback stockholder of record entitled to vote at the Silverback virtual special meeting; or if, after the adjournment, a new record date for determination of Silverback stockholders entitled to vote is fixed for the adjourned meeting, in which case the Silverback Board will fix as the record date for determining Silverback stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of Silverback stockholders entitled to vote at the adjourned meeting, and will give notice of the adjourned meeting to each Silverback stockholder of record as of such record date.

At any adjourned meeting, all proxies will be voted in the same manner as they would have been voted at the original convening of the Silverback virtual special meeting, except for any proxies that have been effectively revoked or withdrawn prior to the adjourned meeting.

Other Matters

As of the date of this proxy statement, the Silverback Board does not know of any business to be presented at the Silverback virtual special meeting other than as set forth in the notice accompanying this proxy statement. If any other matters should properly come before the Silverback virtual special meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

Assistance and Additional Information

If you need assistance with submitting a proxy to vote your shares via the internet, by telephone or by completing your Silverback proxy card, or have questions regarding the Silverback virtual special meeting, please contact our proxy solicitor:

MacKenzie Partners, Inc.
1407 Broadway, 27th Floor
New York, NY 10018
(800) 322-2885
proxy@mackenziepartners.com

Your vote is very important regardless of the number of shares of Silverback Common Stock that you own and the matters to be considered at the Silverback virtual special meeting are of great importance to the stockholders of Silverback. Accordingly, you are urged to read and carefully consider the information contained in or incorporated by reference into this proxy statement and promptly submit your proxy via the internet or by telephone or complete, date, sign and promptly return the enclosed proxy card or voting instruction form in the enclosed postage-paid envelope. If you submit your proxy via the internet or by telephone, you do not need to return the enclosed proxy card.

Please vote your shares via the internet or by telephone, or sign, date and return the enclosed proxy card or voting instruction form promptly to ensure that your shares can be represented, even if you otherwise plan to attend the Silverback virtual special meeting.

THE MERGER

This section and the section titled "The Merger Agreement" in this proxy statement describe the material aspects of the Merger, including the Merger Agreement. While Silverback believes that this description covers the material terms of the Merger and the Merger Agreement, it may not contain all of the information that is important to you. You should carefully read this entire proxy statement for a more complete understanding of the Merger and the Merger Agreement, including the Merger Agreement attached as Annex A, the fairness opinion of SVB Securities LLC attached as Annex B, and the other documents to which you are referred herein. See the section titled "Where You Can Find More Information" in this proxy statement.

Background of the Merger

As part of the ongoing consideration and evaluation of its long-term prospects and strategies, the Silverback Board frequently reviews, with Silverback's senior management and outside advisors, strategic and financial alternatives considering developments in Silverback's business, the sectors in which it competes, the economy generally and financial markets, all with the goal of enhancing value for its stockholders. As part of this process, from time to time, members of Silverback's senior management and/or its advisors have engaged in business development and/or strategic discussions with industry participants, including the acquisition of strategic assets and strategic in-licensing.

On March 11, 2022, there was a regularly scheduled meeting of the Silverback Board, with representatives of management and Cooley LLP ("Cooley"), outside legal counsel to Silverback, also attending. At this meeting, the Silverback Board reviewed the clinical data observed to date for Silverback's lead oncology programs SBT6050, together with the overall clinical development plans for the SBT6050 and SBT6290 programs. Given the limited drug activity and the level of adverse events observed in the clinical trials to date, the Silverback Board also discussed alternative clinical development strategies available to Silverback in the event that the Silverback Board determined to discontinue the two programs following receipt of additional clinical data. Following these discussions, the Silverback Board directed management to continue to evaluate potential in-licensing opportunities and alternative strategic transactions potentially available to Silverback, together with potential steps to preserve and extend cash runway.

Following the meeting of the Silverback Board held on March 11, 2022, Silverback's senior management analyzed the benefits and drawbacks of discontinuing the SBT6050 and SBT6290 programs, and conducted a review of Silverback's pipeline and strategic options, as well as its likely cash runway under multiple scenarios. Silverback's senior management met with individual members of the Silverback Board and discussed management's recommendations that Silverback proceed with a strategic reprioritization, including the discontinuation of the SBT6050 and SBT6290 programs and a reduction in force to be implemented for the purpose of extending Silverback's cash runway.

On March 28, 2022, the Silverback Board held a special teleconference meeting, with representatives of Silverback's senior management and Cooley attending, to discuss Silverback's projected cash runway, preclinical and clinical pipeline, and strategic options. At the meeting, the Silverback Board approved management's recommendation to focus resources on the development of SBT8230 for chronic hepatitis B virus and Silverback's preclinical pipeline by discontinuing development of Silverback's SBT6050 and SBT6290 oncology programs and by restructuring the company workforce to reduce headcount by 27%.

On March 31, 2022, Silverback issued a press release announcing the decision to focus its resources on SBT8230 and Silverback's preclinical pipeline by discontinuing its oncology programs and by implementing a reduction in force of 27%. Silverback also reported $319.1 million in cash, cash equivalents, and investments as of December 31, 2021, which was estimated to provide runway into the second half of 2026 following the strategic reprioritization.

Starting the first week of April 2022, Silverback's senior management increased its efforts on a target list of companies for a potential strategic transaction, including a reverse merger, and to begin outreach. Silverback's senior management focused on merger candidates meeting one or more of certain characteristics, including adjacency to Silverback's technology, competitive differentiation, regulatory risk, potential valuation consideration relative to the opportunity, commercial potential, and meaningful near-term catalysts to achieve value appreciation within six to 18 months using Silverback's cash on hand, in addition to the counterparty's cash, without requiring significant post-transaction dilution to Silverback's stockholders (the "Criteria"). In preparing the Criteria and contemplating appropriate merger candidates, Silverback sought input from SVB Securities because of its relationship and familiarity with Silverback and its business from its role as a joint book-running manager in Silverback's initial public offering, and its qualifications, reputation, experience and expertise as a transaction advisor for reverse mergers in the biopharmaceutical industry.

On April 3, 2022, Silverback's Chief Executive Officer, Dr. Laura Shawver, had an introductory teleconference meeting with the Chief Financial Officer of Company A, a private near-clinical company, who reached out unsolicited following the Silverback press release and was interested in the potential for a reverse merger.

On April 4, 2022, following Silverback's senior management's assessment that Company A potentially met most of the Criteria, Dr. Shawver and the Chief Executive Officer of Company A had a follow up teleconference meeting to discuss an overview of Company A.

On April 5, 2022, Dr. Shawver received an unsolicited call from a non-director investor in Company B, a private near-clinical company and portfolio company of a fund with a representative on the Silverback Board, who inquired about the potential for a reverse merger.

On April 8, 2022, following Silverback's senior management's assessment that Company B potentially met most of the Criteria, Dr. Shawver had an introductory conversation with the Chief Executive Officer of Company B who provided an overview of their pipeline and capabilities.

On April 9, 2022, Silverback entered into a mutual confidential disclosure agreement, which did not contain a standstill provision or a don't ask, don't waive clause, with Company A.

On April 12, 2022, Silverback's senior management shared the formulated Criteria and a refined preliminary target list of 16 merger candidates that potentially met most of the Criteria, which included Company A and Company B, with the Chair of the Silverback Board.

On April 13, 2022, Silverback's senior management shared with the Silverback Board the same preliminary list of reverse merger candidates. On the same day, Silverback's senior management also had a teleconference meeting with a representative of Company A, who provided a more detailed overview of its business, pipeline, and capabilities. On the same day, Silverback also entered into a mutual confidential disclosure agreement, which did not contain a standstill provision or a don't ask, don't waive clause, with Company B.

Between April 13, 2022 and April 22, 2022, Dr. Shawver held four teleconference meetings with Company B's Chief Executive Officer to discuss Company B's pipeline, due diligence questions, and potential synergies with Silverback's pipeline and programs.

On April 16, 2022, Silverback's senior management were introduced, by representatives of SVB Securities, to Company C, a clinical-stage private company with a pipeline that was adjacent to Silverback's preclinical programs.

On April 17, 2022, Dr. Shawver held a teleconference meeting with the Chief Executive Officer of Company C who provided an overview of Company C's pipeline and capabilities.

On April 19, 2022, Silverback's senior management met with representatives of Company A in person at Silverback's headquarters in Seattle. Representatives of Company A provided their perspective on a post-closing ownership split, verbally suggesting a split of 75% and 25% for Company A and Silverback equity holders, respectively, on a fully diluted basis. These proposed terms implied a post-deal valuation greater $950 million. Company A indicated that it had flexibility with respect to the treatment of Silverback's legacy assets.

On April 22, 2022, there was a verbal discussion between Dr. Shawver and Company B's Chief Executive Officer regarding terms of a potential reverse merger, including a potential post-closing ownership split of 48% and 52% for Silverback and Company B equity holders, respectively, on a fully diluted basis. The proposed terms implied a post-deal valuation of $625 million which, in the case of Silverback, included the value of certain of its legacy assets that could be retained by the combined company.

On April 22, 2022, the Silverback Board held a special teleconference meeting, with representatives of Silverback's senior management and Cooley attending, to discuss strategic options for Silverback, including remaining as a standalone company with a limited pipeline build focusing on SBT8230 and preclinical programs, a strategic reorganization, including a strategic merger or sale of the company, and the potential to build the pipeline through asset in-licensing. Silverback's senior management team provided an update on its ongoing outreach process, including an update on the discussions with Company A, Company B and Company C and shared an updated list of 36 potential reverse merger targets that potentially met most of the Criteria. Silverback's senior management also reviewed detailed assessments of Company A, Company B and Company C, including each company's pre-clinical and clinical stage programs, potential valuation consideration relative to the opportunity, commercial potential of each company, meaningful near-term catalysts to achieve value appreciation within six to 18 months using Silverback's cash contribution, in addition to the counterparty's cash, without requiring significant post-transaction dilution to Silverback's stockholders, and, to the extent available, the value that each would potentially place on Silverback's assets, and the anticipated post-closing ownership split between such company's and Silverback's equity holders. The Silverback Board provided guidance to Silverback's senior management to continue its outreach to reverse merger candidates in addition to Company A, Company B and Company C and to continue its diligence efforts. The Silverback Board also approved engaging a financial advisor for a reverse merger process and requested Silverback's senior management engage a financial advisor experienced in reverse mergers. Silverback's senior management provided a summary of the discussions it had with four financial advisors, including SVB Securities. The Silverback Board authorized management to engage SVB Securities to act as Silverback's financial advisor given SVB Securities' relationship and familiarity with Silverback and its business from its role as a joint book-running manager in Silverback's initial public offering, and its qualifications, reputation, experience and expertise as a transaction advisor for reverse mergers in the biopharmaceutical industry.

On April 23, 2022, Company B granted Silverback access to its data room and on April 26, 2022, Silverback provided Company B with a list of diligence questions related to Company B's pipeline, clinical development plans, the competitive landscape, regulatory and commercial considerations.

On April 25, 2022, Dr. Shawver held a teleconference meeting with the Chief Executive Officer of Company A to discuss, among other things, Company A's proposal with respect to a potential private placement alongside a reverse merger.

On April 28, 2022, Company B presented a corporate overview to Silverback's senior management at a teleconference meeting, covering in detail, their pipeline, capabilities, and answers to Silverback's data room diligence questions.

Between May 2, 2022 and May 10, 2022, Silverback's senior management continued due diligence of Company B.

On May 2, 2022, Silverback executed a mutual confidential disclosure agreement, which did not contain a standstill provision or a don't ask, don't waive clause, with Company C.

On May 5, 2022, Silverback's senior management had a teleconference with representatives of Company C who presented a corporate overview, covering in detail, its pipeline and capabilities. That same day, SVB Securities sent Silverback a draft engagement letter to engage SVB Securities as Silverback's financial advisor in connection with a potential reverse merger transaction.

On May 8, 2022 and May 10, 2022, Dr. Shawver had introductory calls with a director from ARS Pharma who provided an overview of ARS Pharma. ARS Pharma was first introduced to Dr. Shawver in November of 2021 by a member of the ARS Board at an industry conference. ARS Pharma was subsequently reintroduced to Silverback by SVB Securities.

On May 9, 2022, after Silverback's senior management assessed ARS Pharma as potentially meeting most of its Criteria, including near term value inflection points and the potential for the Silverback stockholders to have minimal near-term dilution, Silverback executed a mutual confidential disclosure agreement, which did not contain a standstill provision or a don't ask, don't waive clause, with ARS Pharma.

On May 10, 2022, Dr. Shawver had an introductory call with the Chief Executive Officer of Company D following an unsolicited e-mail on May 9th from its Chief Executive Officer and a follow-up e-mail from one of its directors. After Silverback's senior management assessed Company D, a clinical stage company, as meeting most of the Criteria, a mutual confidential disclosure agreement, which did not contain a standstill provision or a don't ask, don't waive clause, was executed with Company D on the same date.

On May 11, 2022, Company B sent a non-binding proposal for a reverse merger that reflected a 57.5% and 43.5% post-closing ownership split for Company B and Silverback equity holders, respectively, on a fully diluted basis based on respective valuations of $325 million and $245 million and assuming Silverback's cash balance at closing is $240 million, which would be adjusted for Silverback's actual net cash at closing. The proposal allowed for the sale, spinoff or other separation of Silverback's two preclinical programs (SBT8230 for cHBV and CD40-GC) prior to the closing of the proposed merger.

On May 12, 2022, Company D's management team met with Silverback's senior management team via teleconference to provide an overview of their pipeline and capabilities, and Silverback was subsequently granted access to Company D's data room, and following review of its contents, Silverback provided a list of follow-up due diligence questions to Company D on May 19, 2022.

Between May 13 and May 24, 2022 Silverback's senior management had several discussions with representatives of Company C, including with respect to follow-up questions to their corporate overview presentation and Company C expressed that it would expect a post-closing ownership split for Company C equity holders in excess of 50%.

On May 16, 2022, Company D sent Silverback a non-binding term sheet for a reverse merger that reflected a 57% and 43% post-closing ownership split for Company D and Silverback equity holders, respectively, on a fully diluted basis based on respective valuations of $350 million and $265 million and assuming Silverback's net cash at closing is $250 million, which would be adjusted for Silverback's actual net cash at closing. The term sheet allowed Silverback to monetize certain of its legacy assets, technology and intellectual property.

On May 17, 2022, Silverback's senior management had a teleconference with ARS Pharma where a detailed review of ARS Pharma's business and its near-term commercial asset was provided to Silverback's senior management. Later that day, Silverback received a non-binding letter of interest from ARS Pharma for a reverse merger that reflected a 65.4% and 34.6% post-closing ownership split for ARS Pharma and Silverback equity holders, respectively, on a fully diluted basis based on respective valuations of $472.5 million and $250 million and assuming Silverback's net cash at closing is $235 million, which would be adjusted based on Silverback's actual net cash at closing. The proposal did not include any plans for Silverback's legacy assets other than stating that the combined company would not include any of Silverback's legacy assets.

Later that same day, at a special teleconference meeting, the Silverback Board met, with representatives of Silverback's senior management, Cooley and SVB Securities also attending, to review the status of the strategic process. Representatives of SVB Securities presented an overview of the proposals received from Company B, Company D and ARS Pharma, and Silverback's senior management provided a detailed analysis of such companies and their proposals. Following an extensive discussion, the Silverback Board directed SVB Securities to continue to introduce Silverback to additional promising reverse merger targets.

On May 18, 2022, a member of Silverback's senior management team had an in-person meeting with representatives of Company D and discussed Company D's scientific approach, pipeline, and potential synergies between the two companies.

On May 19, 2022, the Silverback Board discussed the formation of a Transaction Committee comprised of Saqib Islam and Jonathan Root (the "Transaction Committee"), each of whom is a non-executive, independent director, and has transactional experience, to assist Silverback's senior management in the strategic review, which was formally authorized and ratified by unanimous written consent on May 26, 2022. The Silverback Board tasked the Transaction Committee and Silverback's senior management with recommending a strategic path following review of all potential strategic options, including strategic mergers and acquisitions, asset acquisitions and sales, remaining a standalone company pursuing a limited pipeline focusing on SBT8230 and preclinical programs, and liquidation to distribute available cash.

That same day, Silverback hosted Company D in person at its headquarters for a presentation to discuss pipeline, capabilities, and potential synergies between Silverback and Company D.

Later that day, Dr. Shawver had a phone call with a director of ARS Pharma as a follow-up to the corporate overview and Dr. Shawver informed the director of ARS Pharma of Silverback's intent to hire a commercial consultant to conduct further diligence. On the same day SVB Securities also sent out process letters or verbally communicated to 12 potential reverse merger targets, all of which were identified as having potential to meet most of the Criteria, including ARS Pharma, Company A and Company C, requesting initial proposals by May 27, 2022.

On May 21, 2022, Silverback executed the engagement letter with SVB Securities.

On May 23, 2022, at a special teleconference meeting, the Transaction Committee met, with representatives of Silverback's senior management, Cooley and SVB Securities also attending, to discuss the status of the strategic process, the potential targets and make a decision regarding next steps. Silverback's senior management presented an overview and analysis of a potential liquidation and dissolution of Silverback and SVB Securities provided an overview of various considerations the Transaction Committee should take into account in considering various strategic transactions, including acquisitions by larger public companies and reverse merger transactions with private companies, and also provided an overview of ARS Pharma, Company B and Company D, which were viewed by

Silverback's senior management as the most attractive reverse merger candidates based upon the Criteria, and the potential relative valuations for Silverback and such potential targets based upon the proposals received to date. Following an extensive discussion, the Transaction Committee directed SVB Securities to reach out to ARS Pharma, Company B and Company D to continue discussions and diligence.

Between May 23, 2022 and June 6, 2022, Silverback and ARS Pharma conducted additional diligence on each other.

On May 24, 2022, Company A submitted a non-binding indication of interest for a reverse merger that reflected a post-closing ownership split ranging between 62-66% and 34-38% for Company A and Silverback stockholders, respectively, based on a valuation for Company A between $410-$475 million and assuming Silverback's net cash at closing is $250 million and excluding any shares issued in a private placement which would be additionally dilutive to Silverback stockholders. The proposal contemplated a concurrent private placement and allowed Silverback to spin-off its technology, assets and employees to a new entity and fund it with a portion of Silverback's cash on hand. On the same day, Company C submitted a non-binding indication of interest for a reverse merger that reflected a 39.2% and 60.8% post-closing ownership split for Company C and Silverback stockholders, respectively, based on relative valuations of $185 million and $287.5 million and assuming Silverback's net cash at closing is $250 million and included a proposed value of Silverback's preclinical programs. The proposal contemplated the possibility of using available funds to advance Silverback's pipeline programs following the merger.

On May 30, 2022, Dr. Shawver had a teleconference meeting with the Chief Executive Officer and a director of Company D to discuss the development and business plans for Company D.

Between May 18, 2022 and June 2, 2022, Silverback's senior management engaged in detailed due diligence of ARS Pharma's clinical, regulatory and CMC data and plans. Silverback hired an experienced commercial advisor to assess the market opportunity and commercial launch plan feasibility of ARS Pharma's lead product candidate, *neffy*. Silverback also conducted informational calls with commercial and regulatory key opinion leaders.

On June 2, 2022, ARS Pharma and Company B each presented a corporate overview to the Transaction Committee and Silverback's senior management.

On June 3, 2022, Dr. Shawver had a teleconference meeting with the Chief Executive Officer of Company D indicating concerns with certain fundamental aspects of its programs and to discuss the planned follow-up due diligence regarding the same.

During the week of June 6, 2022, Silverback conducted additional due diligence calls with independent key opinion leaders within indications being pursued by Company D. Following this scientific due diligence, Silverback's senior management made the decision not to move forward with Company D in the process due to its belief that the other reverse merger targets represented a superior opportunity relative to Company D when considering clinical risk, competitive differentiation, regulatory risk and the potential valuation consideration, and communicated this decision to Company D.

On June 6, 2022, at a special teleconference meeting, the Transaction Committee met, with representatives of Silverback's senior management, Cooley and SVB Securities also attending, to review strategic options including a reverse merger, based on proposals received to date, an updated analysis on remaining a standalone company pursuing a limited pipeline focusing on SBT8230 and preclinical programs, and an updated liquidation analysis. Silverback's senior management provided its

assessment based on extensive diligence, including input from key opinion leaders and consultants that were knowledgeable in disease areas, regulatory strategies, and commercial market opportunities presented. Representatives from SVB Securities provided a preliminary financial assessment of the proposals made by ARS Pharma and Company B. At this meeting, the Transaction Committee, in consultation with Silverback's senior management, determined, based upon an assessment of the Criteria, including the completion of NDA-enabling studies, that *neffy* is a near-term commercial asset with a sizable potential market and efficient commercialization plan, that ARS Pharma was the most promising reverse merger candidate, and viewed as superior to the other candidates with respect to potential valuation consideration relative to the opportunity, commercial potential, lower clinical risk relative to the other earlier stage reverse merger candidates and meaningful near-term catalysts to achieve value appreciation within six to 18 months using Silverback's cash on hand, in addition to the counterparty's cash. The Transaction Committee discussed proposed amendments to the ARS Pharma proposal including adding a provision that would allow Silverback to divest its legacy assets, board representation on the combined company's board of directors roughly reflective of the post-closing equity split, proposing lock-up agreements for certain ARS Pharma and Silverback stockholders, an exclusivity provision, a more detailed definition of Silverback net cash, excluding out-of-the money Silverback options in the fully diluted share count for purposes of the post-closing ownership calculation and requiring a high percentage of ARS Pharma stockholders to sign support agreements. Following the discussion of the revised proposal and for the foregoing reasons, the Transaction Committee unanimously recommended that Silverback proceed with ARS Pharma, with Company B as the backup candidate and directed Silverback's senior management to seek best and final offers from ARS Pharma and Company B. Following the meeting, Silverback's senior management and SVB Securities contacted ARS Pharma and Company B with a request to provide their best and final offer and provided related guidance.

On June 8, 2022, ARS Pharma submitted an updated letter of intent with improved terms that reflected an approximately 62.1% to 63% and 37.0% to 37.9% post-closing ownership split for ARS Pharma and Silverback equity holders, respectively, on a fully diluted basis, reflecting relative valuations of $435 million and $255-$265 million and assuming Silverback's net cash at closing was between $240 million to $250 million, the ability for Silverback to sell its preclinical assets prior to the closing and any cash proceeds received prior to closing being added on a dollar-for-dollar basis to Silverback's net cash at closing, proposing a nine member board of directors with six designees from ARS Pharma and three designees from Silverback, proposing that Silverback stockholders representing no less than 51% of the voting securities of Silverback and certain to be identified major investors of ARS Pharma and the continuing executive officers and directors of the combined company enter into lock-up agreements for a period of 180 days following the closing of the proposed merger, a binding 45 day exclusivity provision, a detailed definition of Silverback net cash, requiring stockholders representing no less than 51% of the voting securities of Silverback to enter into support agreements to vote in favor of the proposed merger, proposing that the definitive agreement include customary deal protections such as no-shop provisions and fiduciary outs for both parties, and adding a condition to ARS Pharma's obligation to consummate the proposed merger that Silverback net cash at closing be between $240 million and $250 million. The revised letter of intent was shared with the Transaction Committee and the Transaction Committee directed Silverback's senior management to further negotiate the letter of intent to improve the terms.

On June 9, 2022, Company B submitted a revised non-binding proposal with improved terms that reflected a 52.5% and 47.5% post-closing ownership split for Company B and Silverback equity holders, respectively, on a fully diluted basis reflecting relative valuations of $271 million and $250 million and assuming Silverback's net cash at closing is $240 million. Company C, in response to guidance from Dr. Shawver that their proposal was not competitive, also submitted a revised non-binding indication of interest with improved terms that reflected a 33.7% and 66.3% post-closing ownership split for Company C and Silverback equity holders, respectively, on a fully diluted basis reflecting relative valuations of $146.3 million and $287.5 million.

On June 10, 2022, SVB Securities delivered to ARS Pharma a revised draft of the ARS Pharma letter of intent which included the terms approved by the Transaction Committee, including a 63.5% and 36.5% post-closing ownership split for ARS Pharma and Silverback equity holders, respectively, on a fully diluted basis using the treasury stock method and excluding out-of-the-money options of Silverback and assuming Silverback's net cash at closing is $235 million, which was subject to adjustment based on Silverback's actual net cash at closing, clarifying Silverback's ability to divest its legacy assets includes assignments, licenses or other transfers in one or more transactions prior to or concurrently with the closing and any proceeds received or due from such asset sales being credited to Silverback's net cash at closing, reducing the number of Silverback stockholders that would execute support agreements and lock-up agreements to 25% of the outstanding voting securities of Silverback and requiring that ARS Pharma stockholders representing at least 75% of the outstanding voting securities of ARS Pharma deliver support agreements, reducing the exclusivity period to 30 days, with an option to extend for 15 days by mutual agreement, and a more detailed definition of Silverback net cash, limiting the availability of a fiduciary out to Silverback, and removing the minimum Silverback net cash condition.

On June 10, 2022, Inceptive Law ("Inceptiv"), outside legal counsel to ARS Pharma, sent a revised draft of the ARS Pharma letter of intent to Cooley, which added a condition to ARS Pharma's obligation to consummate the proposed merger that Silverback net cash at closing be between $210 million and $255 million.

Between April 5, 2022, and June 10, 2022, Silverback's senior management and SVB Securities developed a list of 54 clinical and near-clinical stage publicly traded and private biopharmaceutical companies to be targeted for evaluation and proactive outreach. Of the 54 private and public companies evaluated during this process, 13 companies executed mutual confidential disclosure agreements with Silverback, none of which contained a standstill provision or a don't ask, don't waive clause, 12 companies were selected to receive process letters or verbally asked to submit proposals. Of these 12 companies, nine companies submitted a proposal.

On June 10, 2022, the Silverback Board held a regularly scheduled meeting by teleconference, with representatives from Silverback's senior management, Cooley, and SVB Securities also attending. Silverback's senior management provided an overview of the strategic process undertaken to date and representatives from Cooley advised the Silverback Board as to its fiduciary duties. The Transaction Committee recommended to the Silverback Board that Silverback pursue a reverse merger with ARS Pharma based on scientific evaluation, competitive differentiation, regulatory risk, potential valuation consideration relative to the opportunity, commercial potential and commercial launch plan feasibility, meaningful near-term catalysts to achieve value appreciation using Silverback's cash contribution, in addition to ARS Pharma's own cash, estimated to be approximately $40 million as of May 17, 2022, including based on input from Mark Watrous, an independent consultant with over 25 years of experience in drug launch and commercialization. Mr. Watrous was a separate advisor from SVB Securities, who was hired to provide an independent assessment of ARS Pharma's commercial opportunity and *neffy* launch plan feasibility, and to participate in due diligence calls with ARS Pharma management. Representatives from SVB Securities advised the Silverback Board regarding the key terms of the revised ARS Pharma proposal and a preliminary discounted cash flow analysis for the transaction with ARS Pharma, including the notational value per share to the Silverback stockholders and various assumptions and qualifications to such analysis. Silverback's senior management also presented the alternative strategic options available to Silverback, including a liquidation and distribution of available cash and remaining a standalone entity. The Silverback Board reviewed the potential reverse merger with ARS Pharma versus other strategic options available to Silverback, including continuing as a standalone entity or liquidation and distribution of available cash. At the meeting, representatives of SVB Securities provided disclosure that SVB Securities had previously served as an advisor to ARS Pharma in a potential transaction unrelated to the current transaction, but

did not receive any fees relating to such relationship. Following discussion, the Silverback Board unanimously approved the Transaction Committee's recommendation to proceed with advancing a reverse merger with ARS Pharma. Silverback and ARS Pharma finalized and executed the letter of intent on June 10, 2022, which included a binding exclusivity provision for 30 days, with the option to extend for 15 days upon mutual agreement.

Following such execution, Company A, Company B and Company C were contacted by Silverback's senior management and were informed that Silverback would not be moving forward with them in the process.

On June 17, 2022, Cooley shared an initial draft of the merger agreement with Inceptiv, which included a proposed termination fee payable by Silverback to ARS Pharma of $6 million if ARS Pharma terminated the merger agreement under certain circumstances. That same day, Dr. Shawver and a director from ARS Pharma met to discuss, among other topics, the potential composition of the combined company's board of directors.

On June 22, 2022, Cooley shared initial drafts of the form of lock-up agreement, Silverback support agreement and ARS Pharma support agreement.

On June 24, 2022, Silverback's senior management team identified 21 potential purchasers for its preclinical asset CD40-GC and began outreach with certain of these identified parties.

On June 27, 2022, Inceptiv sent revised drafts of the form of lock-up agreement, Silverback support agreement and ARS Pharma support agreement and the agreements were subsequently negotiated and finalized.

On June 28, 2022, Inceptiv sent Cooley a revised draft of the merger agreement, which included, among other things, expanding the circumstances in which a termination fee would by payable by Silverback to ARS Pharma, increasing the termination fee payable by Silverback to ARS Pharma to $20 million and requiring Silverback to reimburse ARS Pharma for up to $2.5 million in expenses if the merger agreement is terminated under certain circumstances. That same day, Silverback and ARS Pharma along with each of their respective independent auditors and legal counsel held a teleconference meeting to discuss diligence, ARS Pharma's audited financial statements and other deliverables and a proposed signing timeline.

On June 29, 2022, Silverback was granted access to ARS Pharma's virtual data room.

On July 1, 2022, ARS Pharma was granted access to Silverback's virtual data room. That same day, Dr. Shawver and Richard Lowenthal, the Chief Executive Officer, of ARS Pharma held a telephonic meeting to discuss the open issues in the merger agreement, including related to the termination fee payable to ARS Pharma by Silverback if the merger agreement was terminated under certain circumstances, the requirement of Silverback to reimburse ARS Pharma for up to $2.5 million in expenses if the merger agreement was terminated under certain circumstances, the definition of ARS Pharma Material Adverse Effect, the instances in which Silverback would be required to seek ARS Pharma's consent for any Asset Dispositions and the definition of Silverback Net Cash.

On July 6, 2022, Silverback's senior management provided a summary of the primary open issues in ARS Pharma's revised merger agreement to the Transaction Committee and sought guidance on how to respond to ARS Pharma. On July 7, 2022, Cooley sent a revised draft of the merger agreement to Inceptiv which included the guidance of the Transaction Committee. The revised draft proposed a bifurcated termination fee of $6 million or $10 million payable to ARS Pharma by Silverback if the merger agreement was terminated under certain circumstances, removed the

requirement of Silverback to reimburse ARS Pharma for up to $2.5 million in expenses if the merger agreement was terminated under certain circumstances, a more limited definition of ARS Pharma Material Adverse Effect, a limited ARS Pharma consent right for any Asset Dispositions and a definition of Silverback Net Cash that limited deductions and expanded additions to such calculation.

On July 9, 2022, Inceptiv sent Cooley a revised draft of the merger agreement, which included, among other things, a note that Silverback's proposal regarding the bifurcated termination fees was an open discussion point and reinserting the requirement of Silverback to reimburse ARS Pharma for up to $2.5 million in transaction fees if the merger agreement was terminated under certain circumstances.

On July 11, 2022, representatives from Cooley, Silverback's senior management, outside litigation counsel to ARS Pharma and ARS Pharma's management held a teleconference meeting to discuss due diligence matters related to Silverback's outstanding stockholder litigation. That same day, Dr. Shawver and Mr. Lowenthal held a telephonic meeting to discuss the major outstanding issues in the merger agreement, including related to the termination fee payable to ARS Pharma by Silverback if the merger agreement was terminated under certain circumstances, the requirement of Silverback to reimburse ARS Pharma for up to $2.5 million in expenses if the merger agreement was terminated under certain circumstances, the definition of ARS Pharma Material Adverse Effect and the definition of Silverback Net Cash. On that call, the parties agreed, subject to approval from their respective boards of directors, to, among other things, Silverback's proposal regarding the bifurcated termination fee payable to ARS Pharma, that Silverback would reimburse ARS Pharma for up to $1.5 million in limited circumstances, a more limited definition of ARS Pharma Material Adverse Effect and a definition of Silverback Net Cash that expanded and limited certain deductions and additions to such calculation. Following approval from the Transaction Committee, Cooley sent a revised draft of the merger agreement to Inceptiv.

On July 13, 2022, representatives from Cooley, Silverback's senior management, outside intellectual property counsel to ARS Pharma and ARS Pharma's senior management held a teleconference meeting to discuss due diligence matters related to ARS Pharma's intellectual property portfolio.

From July 11 to July 20, 2022, the parties continued to work through open due diligence requests, exchanged drafts of each party's disclosure schedules and drafts of the merger agreement and engaged in related discussions to finalize the transaction documents.

On July 20, 2022, at a special teleconference meeting of the Silverback Board, with representatives of Silverback's senior management, Cooley and SVB Securities also attending, the Silverback Board reviewed the strategic process and ARS Pharma's proposal. At this meeting, representatives of SVB Securities reviewed its financial analysis of the consideration proposed to be paid by Silverback in the Merger. Following this review, SVB Securities rendered to the Silverback Board its oral opinion that, as of July 20, 2022, and based upon and subject to the various assumptions made, and the qualifications and limitations upon the review undertaken by SVB Securities in preparing its opinion, the Exchange Ratio proposed to be paid by Silverback pursuant to the terms of the Merger Agreement was fair, from a financial point of view, to Silverback. SVB Securities subsequently confirmed its oral opinion by delivery of a written opinion dated July 20, 2022. Also, at this meeting, representatives of Cooley advised the Silverback Board regarding its fiduciary duties in connection with approving the Merger, reviewed the key terms of the Merger Agreement and the Contemplated Transactions and the lock-up agreements, Silverback Support Agreement and ARS Pharma Support Agreement. Silverback's senior management also presented an updated analysis of the liquidation and distribution of available cash scenario. The Silverback Board engaged in discussions relating to ARS Pharma, its business, the terms of the Merger Agreement and the Contemplated Transactions and the other strategic options available to Silverback.

Following discussion of the Merger Agreement and the Contemplated Transactions, including the factors described in the section titled "*The Merger—Silverback Reasons for the Merger,*" the Silverback Board unanimously (i) determined that the Merger and the other Contemplated Transactions are fair to, advisable and in the best interests of Silverback and its stockholders, (ii) approved and declared advisable the Merger Agreement and the Contemplated Transactions including the issuance of shares of Silverback common stock to the stockholders of ARS Pharma and the change of control of Silverback, and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that the stockholders of Silverback vote to approve Proposal Nos. 1 and 2.

On July 21, 2022, representatives of Silverback, Merger Sub and ARS Pharma executed the definitive Merger Agreement. Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of Silverback and ARS Pharma delivered the Silverback Support Agreements and ARS Pharma Support Agreements, respectively. Immediately following the execution of the Merger Agreement, ARS Pharma delivered the unanimous written consent of the ARS Pharma Board approving the Merger Agreement, the Merger and the Contemplated Transactions and the ARS Pharma Stockholder Written Consent approving the ARS Pharma Stockholder Matters. Later that afternoon, the execution of the Merger Agreement was publicly announced and representatives from Silverback and ARS Pharma held a conference call with investors.

Following an analysis of the independence of each proposed member of the combined company's board of directors, Silverback, Merger Sub and ARS Pharma executed the First Amendment to the Merger Agreement, dated August 11, 2022, pursuant to which the size of the combined company's board of directors was increased to eleven members, with eight designees of ARS Pharma and three designees of Silverback, in order meet the board of director independence requirements under the Nasdaq listing rules.

In July 2022, Silverback's senior management team began a process to divest its legacy pipeline. As of September 1, 2022, Silverback's senior management identified 51 potential targets to acquire aspects of the company's legacy pipeline, including SBT8230, Silverback's monoclonal antibody library, discovery-stage programs, and next-generation linker technology. Of these 51 potential targets, 23 companies entered confidentiality agreements, and 10 companies engaged in diligence of Silverback's legacy pipeline.

On September 19, 2022, Silverback verbally agreed to non-binding terms and conditions with respect to the sale of its Nectin4 monoclonal antibody, for a one-time payment of $325,000, and the process of drafting and negotiating an acquisition agreement is ongoing. On September 30, 2022, Silverback entered into a non-binding term sheet to sell certain patent applications and rights related to its next-generation linker technology for a one-time payment of $200,000, and the process of drafting and negotiating an acquisition agreement is ongoing. As of October 4, 2022, Silverback is actively engaged in term-sheet discussions regarding assets relating to SBT8230 for a one-time payment of €12,000,000. There can be no assurance that the terms of any of the foregoing proposed sale transactions including the proposed consideration will not change and that any sale agreement will ever be executed or, if executed, will be executed or consummated in a timely manner to be included in the determination of the Silverback Net Cash.

Silverback Reasons for the Merger

At a meeting held on July 20, 2022, among other things, the Silverback Board unanimously (i) determined that the Merger and the other Contemplated Transactions are fair to, advisable and in the best interests of Silverback and its stockholders, (ii) approved and declared advisable the Merger Agreement and the Contemplated Transactions, including the issuance of shares of Silverback common stock to the stockholders of ARS Pharma and the change of control of Silverback, and

(iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that the stockholders of Silverback vote to approve Proposal Nos. 1 and 2.

The Silverback Board considered the following reasons in reaching its conclusion to approve the Merger Agreement and the Merger, all of which the Silverback Board viewed as supporting its decision to approve the Merger with ARS Pharma:

- the Silverback Board, with the assistance of its advisors, undertook a comprehensive and thorough process of reviewing and analyzing potential strategic options, including strategic mergers and acquisitions, asset acquisitions, in-licensing and sales, remaining a standalone company pursuing a limited pipeline focusing on SBT8230 and preclinical programs, and a liquidation to distribute available cash, to identify the opportunity that would, in the Board's opinion, create the most value for Silverback's stockholders;
- the Silverback Board's belief, after a thorough review of strategic alternatives and discussions with Silverback senior management, financial advisors and legal counsel, that the Merger is more favorable to Silverback's stockholders than the potential value that might have resulted from other strategic options available to Silverback;
- the Silverback Board's belief, based in part on scientific, regulatory and commercial diligence and an analysis process conducted over several weeks by Silverback's management and reviewed with the Silverback Board, that *neffy* is a near-term commercial asset with a sizable potential market and efficient commercialization plan and may create value for the stockholders of the combined company and an opportunity for Silverback's stockholders to participate in the potential growth of the combined company;
- based on review with the management of Silverback, the current plans of ARS Pharma for developing and potentially commercializing *neffy* outside the U.S., expanding ARS Pharma's pediatric labeling with *neffy* and examining and potentially developing *neffy* to target other conditions beyond Type I allergic reactions, to confirm the likelihood that the combined company would possess sufficient financial resources to allow the management team to focus on such plans;
- the possibility that the combined company would be able to take advantage of the potential benefits resulting from the combination of Silverback's public company structure with ARS Pharma's business to raise additional funds in the future;
- the strength of the balance sheet of the combined company, which includes the cash that ARS Pharma currently holds in addition to the cash that Silverback is expected to have in connection with the consummation of the Merger, which would give the combined company an estimated operating runway of at least three years and, assuming *neffy* is approved by the FDA, is expected to provide funding through the commercial launch of *neffy* in the United States;
- the fact that the combined company will be led by an experienced industry chief executive officer and a team many of whom have first-hand experience leading the development and commercial efforts for approved nasal spray products, as well as extensive drug development, research and development, business, and regulatory expertise, and a board of directors with representation from the current Silverback Board and ARS Pharma Board; and
- the Silverback Board's belief that, as a result of arm's length negotiations with ARS Pharma, Silverback and its representatives negotiated the most favorable Exchange Ratio for Silverback stockholders that ARS Pharma was willing to agree to, and that the terms of the Merger Agreement include the most favorable terms to Silverback in the aggregate to which ARS Pharma was willing to agree;
- the opinion of SVB Securities, rendered orally to the Silverback Board on July 20, 2022 (and subsequently confirmed in writing as of July 20, 2022), that, as of such date and based upon

and subject to the various assumptions made, and the qualifications and limitations upon the review undertaken by SVB Securities in preparing its opinion, the Exchange Ratio proposed to be paid by Silverback pursuant to the terms of the Merger Agreement was fair, from a financial point of view, to Silverback, as more fully described below under the caption "*The Merger—Opinion of Silverback's Financial Advisor*."

The Silverback Board also reviewed various reasons impacting the financial condition, results of operations and prospects of Silverback, including:

- the risks associated with Silverback remaining a standalone company pursuing a limited pipeline focusing on SBT8230 and preclinical programs including liquidity needs and cash-burn related to, among other things, funding Silverback's development pipeline.
- the risks associated with SBT8230 becoming a commercially viable program due to the nature of development in HBV requiring combination treatment, the competitive landscape among HBV therapies, and the inherent technical risks of early-stage programs;
- the risks associated with early preclinical assets and the timelines for beginning clinical development and demonstrating clinical proof-of-concept and potentially demonstrating activity.
- the risks associated with building Silverback's pipeline with more near-term clinical assets through asset in-licensing;
- the risks associated with out-licensing assets, the risk that the programs may be too early for licensing or if they could be licensed, not achieving milestones with Silverback's partnered programs due to technical challenges, Silverback's partner's shift in strategic priorities, or other reasons;
- the risks and delays associated with, and uncertain value and costs to Silverback's stockholders of, liquidating Silverback, including, without limitation, the uncertainties of continuing cash burn while contingent liabilities are resolved and uncertainty of timing of release of cash until contingent liabilities are resolved; and
- the fact that the estimated return to stockholders of Silverback in a potential liquidation of Silverback would result in a payment of approximately $5.47 per share of Silverback Common Stock assuming, among other things, a liquidation date of November 30, 2022.

The Silverback Board also reviewed the terms and conditions of the Merger Agreement and the Contemplated Transactions, as well as the safeguards and protective provisions included therein intended to mitigate risks, including:

- the initial estimated Exchange Ratio used to establish the number of shares of Silverback Common Stock to be issued to ARS Pharma's stockholders in the Merger was determined based on the relative valuations of Silverback and ARS Pharma, and thus the relative percentage ownership of Silverback's stockholders and ARS Pharma's stockholders immediately following the completion of the Merger is subject to change based on the amount of Silverback Net Cash at Closing to the extent it is greater than or less than $240 million, subject to a floor of $210 million and a ceiling of $255 million;
- a dollar-for-dollar adjustment to Silverback Net Cash for amounts received by Silverback for the timely sale of its legacy assets if successful;
- the limited number and nature of the conditions to ARS Pharma's obligation to consummate the Merger and the limited risk of non-satisfaction of such conditions as well as the likelihood that the Merger will be consummated on a timely basis;
- the requirement that ARS Pharma provide Silverback with FDA confirmation of the submission for an NDA for *neffy* 2.0 mg as a condition to Silverback's obligation to consummate the Merger;

- the respective right of, and limitation on, Silverback under the Merger Agreement to consider certain unsolicited Acquisition Proposals under certain circumstances should Silverback receive a Superior Offer;
- the reasonableness of the potential termination fee of $6 million or $10 million, and related reimbursement of certain transaction expenses capped at $1.5 million, which could become payable by Silverback to ARS Pharma if the Merger Agreement is terminated in certain circumstances;
- the support agreements, pursuant to which certain directors, officers and stockholders of Silverback and ARS Pharmaceuticals have agreed, solely in their capacity as stockholders of Silverback and ARS Pharma, respectively, to vote all of their shares of Silverback Common Stock or ARS Pharmaceuticals Capital Stock in favor of the approval or adoption, respectively, of the Merger Agreement and the Contemplated Transactions;
- the agreement of ARS Pharma to provide the written consent of ARS Pharma's stockholders necessary to adopt the Merger Agreement thereby approving the Merger and the other Contemplated Transactions within one business day of the date of the Merger Agreement and the actual receipt of such written consent; and
- the belief that the terms of the Merger Agreement, including the parties' representations, warranties and covenants, and the conditions to their respective obligations, are reasonable under the circumstances.

In the course of its deliberations, the Silverback Board also considered a variety of risks and other countervailing factors related to entering into the Merger, including:

- the $6 million or $10 million termination fee payable by Silverback to ARS Pharma upon the termination of the Merger Agreement in certain circumstances, the $6 million termination fee payable by ARS Pharma to Silverback upon the termination of the Merger Agreement in certain circumstances, up to $1.5 million in expense reimbursement payable by Silverback to ARS Pharma in the event of a termination of the Merger Agreement due to the failure of Silverback's stockholders to approve the Merger Proposal, and the potential effect of the fees in deterring other potential acquirers from proposing an alternative transaction that may be more advantageous to Silverback's stockholders;
- the substantial expenses to be incurred in connection with the Merger, including the costs associated with any related litigation;
- the likelihood of disruptive stockholder litigation following announcement of the Merger;
- the possible volatility, at least in the short term, of the trading price of Silverback Common Stock resulting from the announcement of the Merger;
- the risk that the Merger might not be consummated in a timely manner or at all and the potential adverse effect of the public announcement of the Merger or delay or failure to complete the Merger on the reputation of Silverback;
- the likely detrimental effect on Silverback's cash position, stock price and ability to initiate another process and to successfully complete an alternative transaction should the Merger not be completed;
- the risk to Silverback's business, operations and financial results in the event that the Merger is not consummated, including the diminution of Silverback's cash and the significant challenges associated with the need to raise additional capital through the public or private sale of equity securities;

- the strategic direction of the combined company following the completion of the Merger, which will be determined by a board of directors initially comprised of a majority of the directors designated by ARS Pharma; and
- various other risks associated with the combined company and the Merger, including those described in the section titled "*Risk Factors*."

In view of the wide variety of reasons considered in connection with its evaluation of the Merger and the complexity of these matters, the Silverback Board did not find it useful to attempt, and did not attempt, to quantify, rank or otherwise assign relative weights to these reasons. In considering the reasons described above, individual members of the Silverback Board may have given different weight to different reasons. The Silverback Board conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, Silverback's management team and the legal and financial advisors of Silverback, and considered the reasons overall to be favorable to, and to support, its determination.

Opinion of Silverback's Financial Advisor

Introduction

Silverback retained SVB Securities as its financial advisor in connection with the Merger and the other Contemplated Transactions. In connection with this engagement, the Silverback Board requested that SVB Securities evaluate the fairness, from a financial point of view, to Silverback of the Exchange Ratio proposed to be paid by Silverback pursuant to the terms of the Merger Agreement. On July 20, 2022, SVB Securities rendered to the Silverback Board its oral opinion, which was subsequently confirmed by delivery of a written opinion dated July 20, 2022 that, as of such date and based upon and subject to the various assumptions made, and the qualifications and limitations and upon the review undertaken by SVB Securities in preparing its opinion, the Exchange Ratio proposed to be paid by Silverback pursuant to the terms of the Merger Agreement was fair, from a financial point of view, to Silverback. In providing its opinion, SVB Securities noted that the Exchange Ratio is subject to certain adjustments set forth in the Merger Agreement, and SVB Securities expressed no opinion as to any such adjustments.

The full text of the written opinion of SVB Securities, dated July 20, 2022, which describes the assumptions made and the qualifications and limitations upon the review undertaken by SVB Securities in preparing its opinion, is attached as Annex B to this proxy statement and is incorporated herein by reference. The summary of the written opinion of SVB Securities set forth below is qualified in its entirety by the full text of the written opinion attached hereto as Annex B to this proxy statement. **SVB Securities' financial advisory services and opinion were provided for the information and assistance of the Silverback Board (in their capacity as directors and not in any other capacity) in connection with and for purposes of the Silverback Board's consideration of the Merger and the opinion of SVB Securities addressed only the fairness, from a financial point of view, as of the date thereof, to Silverback of the Exchange Ratio proposed to be paid by Silverback pursuant to the terms of the Merger Agreement. The opinion of SVB Securities did not address any other term or aspect of the Merger Agreement or the Merger and does not constitute a recommendation to any stockholder of Silverback as to whether or how such holder should vote with respect to the merger or otherwise act with respect to the Merger or any other matter.**

The full text of the written opinion of SVB Securities should be read carefully in its entirety for a description of the assumptions made and limitations upon the review undertaken by SVB Securities in preparing its opinion.

In connection with rendering the opinion described above and performing its related financial analyses, SVB Securities reviewed, among other things:

- a draft of the Merger Agreement, dated July 20, 2022;
- Silverback's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed by Silverback with the SEC on March 31, 2022;
- Silverback's Quarterly Report on form 10-Q for the quarterly period ended March 31, 2022, as filed by Silverback with the SEC;
- certain Current Reports on Form 8-K, as filed by Silverback with, or furnished by Silverback to, the SEC;
- certain internal information, primarily related to expense forecasts, relating to the business, operations, earnings, cash flow, assets, liabilities and prospects of Silverback, as furnished to SVB Securities by the management of Silverback; and
- certain internal information relating to the business, operations, earnings, cash flow, assets, liabilities and prospects of the Company, including the Financial Projections (as defined below), and as modified furnished to SVB Securities, by the management of Silverback for purposes of SVB Securities' analysis, as described below under "*The Merger—Certain Unaudited Financial Projections*, which are referred to in this summary of the opinion of SVB Securities as the "Financial Projections", and which are collectively referred to in this summary of the opinion of SVB Securities as the "Internal Data".

SVB Securities also conducted discussions with members of the senior management of Silverback and ARS Pharma and their respective advisors and representatives regarding their assessment of the Internal Data as well as the past and current business, operations, financial condition and prospects of each of Silverback and ARS Pharma. In addition, SVB Securities reviewed the historical trading prices and trading activity for the Silverback common stock. Furthermore, SVB Securities reviewed certain financial data for ARS Pharma and compared that data to similar publicly available market, financial and other data for certain other companies, the securities of which are publicly traded, that SVB Securities believed to be comparable in certain respects to ARS Pharma. SVB Securities also conducted such other financial studies and analyses and took into account such other information as SVB Securities deemed appropriate.

SVB Securities assumed, without independent verification or any responsibility therefor, the accuracy and completeness of the financial, legal, regulatory, tax, accounting and other information supplied to, discussed with, or reviewed by SVB Securities for purposes of its opinion and, with Silverback's consent, SVB Securities relied upon such information as being complete and accurate. In that regard, SVB Securities was advised by Silverback, and assumed, at Silverback's direction, that the Internal Data (including, without limitation, the Financial Projections) were reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of Silverback and ARS Pharma as to the matters covered thereby and SVB Securities relied, at Silverback's direction, on the Internal Data for purposes of SVB Securities' analysis and its opinion. SVB Securities expressed no view or opinion as to the Internal Data (including, without limitation, the Financial Projections) or the assumptions on which they were based. In addition, at Silverback's direction, SVB Securities did not make any independent evaluation or appraisal of any of the assets or liabilities (contingent, derivative, off-balance-sheet or otherwise) of Silverback or ARS Pharma, nor was SVB Securities furnished with any such evaluation or appraisal, and SVB Securities was not asked to conduct, and did not conduct, a physical inspection of the properties or assets of Silverback or ARS Pharma.

SVB Securities assumed, at Silverback's direction, that the final executed Merger Agreement would not differ in any respect material to SVB Securities' analysis or its opinion from the last draft of

the merger agreement reviewed by SVB Securities. SVB Securities also assumed, at Silverback's direction, that the representations and warranties made by ARS Pharma and Silverback and Merger Sub in the Merger Agreement and the related agreements were and would be true and correct in all respects material to SVB Securities' analysis. SVB Securities also assumed, at Silverback's direction, that the Merger would be consummated on the terms set forth in the Merger Agreement and in accordance with all applicable laws and other relevant documents or requirements, without delay or the waiver, modification or amendment of any term, condition or agreement, the effect of which would be material to SVB Securities' analysis or SVB Securities' opinion and that, in the course of obtaining the necessary governmental, regulatory and other approvals, consents, releases and waivers for the Merger, no delay, limitation, restriction, condition or other change would be imposed, the effect of which would be material to SVB Securities' analysis or SVB Securities' opinion. SVB Securities did not evaluate and did not express any opinion as to the solvency or fair value of Silverback or ARS Pharma, or their respective abilities to pay their obligations when they come due, or as to the impact of the Merger on such matters, under any state, federal or other laws relating to bankruptcy, insolvency, or similar matters. SVB Securities is not a legal, regulatory, tax or accounting advisor, and SVB Securities expressed no opinion as to any legal, regulatory tax or accounting matters.

The opinion of SVB Securities expressed no view as to, and did not address, Silverback's underlying business decision to proceed with or effect the Merger, or the relative merits of the Merger as compared to any alternative business strategies or transactions that might be available to Silverback or in which Silverback might engage. The opinion of SVB Securities was limited to and addressed only the fairness, from a financial point of view, as of the date of its opinion, to Silverback of the Exchange Ratio proposed to be paid by Silverback pursuant to the terms of the Merger Agreement. SVB Securities was not asked to, nor did it express any view on, and its opinion did not address, any other term or aspect of the Merger Agreement or the other Contemplated Transactions, including, without limitation, the structure or form of the Merger or the other Contemplated Transactions, or any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with or otherwise contemplated by the Merger or the other Contemplated Transactions, including, without limitation, the fairness of the Merger or any other term or aspect of the Merger to, or any consideration to be received in connection therewith by, or the impact of the Merger on, the holders of any other class of securities, creditors or other constituencies of Silverback or any other party. In addition, SVB Securities expressed no view or opinion as to the fairness (financial or otherwise) of the amount, nature or any other aspect of any compensation to be paid or payable to any of the officers, directors or employees of Silverback or any other party, or class of such persons in connection with the Merger or the other Contemplated Transactions, whether relative to the Exchange Ratio to be paid by Silverback pursuant to the terms of the Merger Agreement or otherwise. The opinion of SVB Securities was necessarily based on financial, economic, monetary, currency, market and other conditions and circumstances as in effect on, and the information made available to SVB Securities as of, the date of its written opinion, and SVB Securities does not have any obligation or responsibility to update, revise or reaffirm its opinion based on circumstances, developments or events occurring after the date of its opinion. SVB Securities' opinion does not constitute a recommendation to any stockholder of Silverback as to whether or how such stockholder should vote with respect to the merger or otherwise act with respect to the transaction or any other matter.

SVB Securities' financial advisory services and its opinion were provided for the information and assistance of the Silverback Board (in their capacity as directors and not in any other capacity) in connection with and for purposes of its consideration of the Merger and the other Contemplated Transactions. SVB Securities' opinion was approved by the SVB Securities LLC Fairness Opinion Review Committee.

Summary of Financial Analyses

The following is a summary of the material financial analyses prepared by SVB Securities and reviewed with the Silverback Board in connection its opinion, which was delivered orally to the Silverback Board on July 20, 2022 and subsequently confirmed in its written opinion, dated July 20, 2022. For purposes of the analyses described below, SVB Securities was directed to rely upon the Internal Data, including the Financial Projections. The summary set forth below does not purport to be a complete description of the financial analyses performed or factors considered by, and underlying the opinion of, SVB Securities, nor does the order of the analyses described below represent the relative importance or weight given to those analyses by SVB Securities. The preparation of a fairness opinion is a complex analytical process involving various determinations as to the most appropriate and relevant methods of financial analysis and the application of those methods to the particular circumstances and, therefore, a fairness opinion is not readily susceptible to summary description. In arriving at its opinion, SVB Securities did not draw, in isolation, conclusions from or with regard to any factor or analysis that it considered. Accordingly, SVB Securities believes that its analyses must be considered as a whole and that selecting portions of such analyses and factors without considering all analyses and factors, could create a misleading or incomplete view of the processes underlying SVB Securities' financial analyses and its opinion.

SVB Securities may have deemed various assumptions more or less probable than other assumptions, so the reference ranges resulting from any particular portion of the analyses summarized below should not be taken to be the view of SVB Securities as to the actual value of Silverback. Some of the summaries of the financial analyses set forth below include information presented in tabular format. In order to fully understand the financial analyses, the tables must be read together with the text of each summary, as the tables alone do not constitute a complete description of the financial analyses performed by SVB Securities. In its analyses, SVB Securities made numerous assumptions with respect to industry performance, general business and economic conditions and other matters, many of which are beyond the control of Silverback or any other parties to the Merger and the other Contemplated Transactions. None of Silverback, ARS Pharma, Merger Sub, SVB Securities or any other person assumes responsibility if future results are materially different from those discussed. Any estimates contained in these analyses are not necessarily indicative of actual values or predictive of future results or values, which may be significantly more or less favorable than as set forth below. In addition, analyses relating to the value of Silverback or ARS Pharma do not purport to be appraisals or reflect the prices at which these companies may actually be sold. Accordingly, the assumptions and estimates used in, and the results derived from, the financial analyses are inherently subject to substantial uncertainty. Except as otherwise noted, the following quantitative information, to the extent that it is based on market data, is based on market data as it existed on or before July 20, 2022 and is not necessarily indicative of current market conditions.

SVB Securities' financial analyses and opinion were only one of many factors taken into consideration by the Silverback Board in its evaluation of the Merger, as described under "*The Merger—Silverback Reasons for the Merger.*" Consequently, the analyses described above should not be viewed as determinative of the views of the Silverback Board or management of Silverback with respect to the Exchange Ratio or as to whether the Silverback Board would have been willing to determine that a different Exchange Ratio was fair. The Exchange Ratio, as well as the type of consideration payable in the Merger, was determined through arm's-length negotiations between Silverback and ARS Pharma and was approved by the Silverback Board. SVB Securities provided advice to Silverback during these negotiations. However, SVB Securities did not recommend any specific Exchange Ratio or other financial terms to Silverback or the Silverback Board or that any specific Exchange Ratio or other financial terms constituted the only appropriate consideration for the Merger.

In preparing its analysis, SVB Securities took into account that the Exchange Ratio contained in the Merger Agreement is calculated by attributing equity values of $255,000,000 and $435,000,000 to Silverback and ARS Pharma, respectively, subject to certain adjustments set forth in the Merger Agreement. SVB Securities expressed no opinion as to any such adjustments.

Valuation Analysis – Discounted Cash Flow

A discounted cash flow analysis is a traditional valuation methodology used to derive a valuation of an asset or set of assets by calculating the "present value" of estimated future cash flows of the asset or set of assets. "Present value" refers to the current value of future cash flows or amounts and is obtained by discounting those future cash flows or amounts by a discount rate that takes into account assumptions and estimates of risk, the opportunity cost of capital, expected returns and other appropriate factors, and then adding the present value equivalent of the terminal value of the business at the end of the applicable projection period. SVB Securities performed a discounted cash flow analysis to calculate the estimated present value of the stand-alone, unlevered, after-tax free cash flows that ARS Pharma was forecasted to generate from January 1, 2023 through December 31, 2038, which unlevered, after-tax free cash flows were derived from the Financial Projections on which SVB Securities relied. SVB Securities estimated the net present value of unlevered, after-tax free flows after fiscal year 2038 by assuming an annual decline of 30% of such cash flows in perpetuity. These cash flows were discounted to present value as of January 1, 2023, using a discount rate ranging from 11% to 13%, determined based on SVB Securities' professional judgment and experience. In performing its discounted cash flow analysis, SVB Securities adjusted for cash balances, and relied on the Financial Projections at the direction of Silverback management. At the direction of Silverback management, SVB Securities did not account for the estimated cash flow impact of any net operating loss carryforwards or other tax attributes that may be available to ARS Pharma nor any cash flows for the period of the Financial Projections for sales of products outside of the United States.

This analysis resulted in an implied equity value for ARS Pharma of approximately $845 million to $1.045 billion and a corresponding implied exchange ratio of approximately 2.3985x to 2.9617x.

Additional Factors Observed by SVB Securities – ARS Pharma Valuation Analysis – Selected Public Companies

As additional factors not part of its financial analyses but noted for reference purposes, SVB Securities reviewed publicly available information relating to the market capitalization of certain U.S.-listed publicly-traded companies whose lead product is being marketed or is in regulatory development, selected based on SVB Securities' professional judgment and experience. These companies, which are referred to as the Selected Companies, were:

Company	Lead Relevant Program	Indication	Equity Value (in millions)	Enterprise Value (in millions)	EV/Rev Multiples 2023	EV/Rev Multiples 2024
Biohaven Pharmaceutical Holding Company Ltd	Nurtec ODT	Acute Treatment of Migraine	$ 6,340 (1)	$ 6,441	5.4x	3.8x
Intra-Cellular Therapies, Inc.	Caplyta	Schizophrenia	5,530	4,758	10.9	6.9
Harmony Biosciences Holdings, Inc.	Wakix	Excessive daytime sleepiness associated with narcolepsy	3,276	3,243	5.5	4.2
Axsome Therapeutics, Inc.	Sunosi; AXS-05	EDS associated with narcolepsy or OSA; Major depressive disorder	1,840	1,853	8.6	4.2
Revance Therapeutics, Inc.	Daxibotulinumtoxin A	Glabellar (frown) lines	1,241	1,340	6.1	3.4
Aurinia Pharmaceuticals Inc.	Lupkynis	Active lupus nephritis	1,439	1,020	4.3	2.5

(1) Equity value disregards impact of pending transaction with Pfizer Inc., announced on May 10, 2022.

SVB Securities noted that although such companies had certain financial and operating characteristics that could be considered similar to those of ARS Pharma, including but not limited to a focus on companies which recently began commercial sales of their products or which would likely commercialize their products in the near term as well as other operating metrics, none of the companies had the same management, make-up, technology, size or mix of businesses as ARS Pharma and, accordingly, there were inherent limitations on the applicability of such companies to the valuation analysis of ARS Pharma. Additionally, while some of the Selected Companies are commercial stage companies and ARS Pharma is a pre-commercial stage company, SVB Securities considered these Selected Companies because of their similarities to the business, industry, market opportunity and pipeline of ARS Pharma, including by focusing on companies which recently began commercial sales of their products or which would likely commercialize their products in the near term. An analysis of selected companies, including determining the Selected Companies, is not purely quantitative; rather it involves complex consideration and judgments, including factors that could affect the public trading values of the companies reviewed. Accordingly, SVB Securities made qualitative judgments, based on its experience and professional judgment, concerning differences between the operational, business and/or financial characteristics of ARS Pharma and potential selected companies, in determining the Selected Companies as well as to provide a context in which to consider the results of the selected company analysis, which analysis was included as an additional factor not part of its financial analyses and only noted for reference purposes.

SVB Securities calculated the aggregate enterprise value of each of the Selected Companies based upon the closing price of the common stock of each Selected Company on July 19, 2022 and the fully-diluted number of shares outstanding, using the treasury stock method. SVB Securities then calculated the enterprise values as multiples of estimated revenues for the years 2023 and 2024, based on publicly available information. SVB Securities then applied the Financial Forecasts for the years 2025 and 2026, discounted to 2023 and 2024, respectively, assuming a 12% discount rate based on an estimate of ARS Pharma's weighted-average cost of capital. SVB Securities then added ARS Pharma's estimated net cash at closing of $30.0 million and applied a 20% illiquidity discount to reach an adjusted equity value for ARS Pharma. SVB Securities compared these adjusted equity valuations to the proposed ARS Pharma valuation of $435 million based on the proposed valuation and ownership ratio in the Merger Agreement and also compared the resulting implied exchange ratio range of 1.3567x to 1.9480x to the Exchange Ratio. The results of this analysis are summarized as follows:

	Adj. Equity Value 2023 (in millions)	Adj. Equity Value 2024 (in millions)
25th Percentile	$ 473	$ 558
75th Percentile	687	666

General

SVB Securities LLC is a full-service securities firm engaged in securities trading and brokerage activities as well as investment banking and financial advisory services. SVB Securities has provided certain investment banking services to Silverback from time to time, for which it has received compensation. In the past two years, SVB Securities served as a joint book-running manager for Silverback's December 2020 initial public offering, for which it received fees of approximately $6.1 million, and SVB Securities and its affiliates have not engaged in any investment banking activities with ARS Pharma. In the ordinary course of business, SVB Securities and its affiliates have in the past provided, currently are providing and may in the future provide investment banking and commercial banking services to Silverback, ARS Pharma or their respective affiliates and would expect to receive customary fees for the rendering of such services. In the ordinary course of their trading and brokerage activities, SVB Securities or its affiliates have in the past and may in the future hold

positions, for their own account or the accounts of their customers, in equity, debt or other securities of Silverback, ARS Pharma or their respective affiliates.

Consistent with applicable legal and regulatory requirements, SVB Securities has adopted policies and procedures to establish and maintain the independence of its research department and personnel. As a result, SVB Securities' research analysts may hold views, make statements or investment recommendations and/or publish research reports with respect to Silverback and the Merger and other participants in the Merger that differ from the views of SVB Securities' investment banking personnel.

The Silverback Board selected SVB Securities to act as Silverback's financial advisor in connection with the Merger based on SVB Securities' qualifications, reputation, experience and expertise in the biopharmaceutical industry, its knowledge of and involvement in recent transactions in the biopharmaceutical industry and its relationship and familiarity with Silverback and its business. SVB Securities is an internationally recognized investment banking firm that has substantial experience in transactions similar to the Merger and the other transactions contemplated by the Merger Agreement.

In connection with SVB Securities' services as financial advisor to Silverback, Silverback has agreed to pay SVB Securities an aggregate fee of $2.75 million, $1.0 million of which became payable upon the rendering by SVB Securities of the opinion on July 20, 2022 and the remainder of which is payable contingent upon consummation of the Merger. In addition, Silverback has agreed to reimburse certain of SVB Securities' expenses arising, and to indemnify SVB Securities against certain liabilities that may arise, out of SVB Securities' engagement. The terms of the fee arrangement between SVB Securities and Silverback, which are customary in transactions of this nature, were negotiated at arm's length between SVB Securities and Silverback, and the Silverback Board was aware of the arrangement, including the fact that a significant portion of the fee payable to SVB Securities is contingent upon the completion of the Merger and the other transactions contemplated by the Merger Agreement.

Certain Unaudited Financial Projections

As a matter of course, Silverback does not publicly disclose long-term projections of future financial results due to the inherent unpredictability and subjectivity of underlying assumptions and estimates. However, in connection with the Silverback Board's evaluation of the Merger, preliminary internal financial projections for ARS Pharma were prepared by the management of ARS Pharma and provided to the management of Silverback, and then adjusted by the management of Silverback (such adjusted projections, the "Financial Projections") solely for use by SVB Securities in connection with the rendering of its fairness opinion and performing its related financial analyses, as described below under "*The Merger—Opinion of the Silverback Financial Advisor*." A summary of the Financial Projections is set forth below.

The inclusion of the Financial Projections should not be deemed an admission or representation by Silverback, SVB Securities, ARS Pharma or any of their respective officers, directors, affiliates, advisors, or other representatives with respect to such Financial Projections. The Financial Projections are not included to influence your views on the Merger and are summarized in this proxy statement solely to provide stockholders access to certain non-public information considered by the Silverback Board in connection with its evaluation of the Merger and provided to Silverback's financial advisor, SVB Securities, to assist with its financial analyses as described in the section titled "*The Merger—Opinion of the Silverback Financial Advisor*." The information from the Financial Projections should be evaluated, if at all, in conjunction with the historical financial statements and other information regarding ARS Pharma in this proxy statement.

The Financial Projections were not prepared with a view toward public disclosure, nor were they prepared with a view toward compliance with published guidelines of the SEC, the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information, or GAAP. Neither the independent registered public accounting firm of Silverback nor ARS Pharma nor any other independent accountant has audited, reviewed, compiled, examined or performed any procedures with respect to the accompanying unaudited prospective financial information for the purpose of its inclusion herein, and accordingly, neither the independent registered public accounting firm of Silverback nor ARS Pharma nor any other independent accountant expresses an opinion or provides any form of assurance with respect thereto for the purpose of this proxy statement. The Ernst & Young LLP reports incorporated by reference in this proxy statement relate to the previously issued financial statements of Silverback. These reports, as well as the reports related to ARS Pharma included herein, do not extend to the Financial Projections and should not be read to do so.

The Financial Projections include unlevered free cash flow, total adjusted revenue and earnings before interest and taxes ("EBIT"), which are "non-GAAP financial measures" which are financial performance measures that are not calculated in accordance with GAAP. Non-GAAP financial measures should not be viewed as a substitute for GAAP financial measures and may be different from non-GAAP financial measures used by other companies. Furthermore, there are limitations inherent in non-GAAP financial measures because they exclude charges and credits that are required to be included in a GAAP presentation. Accordingly, non-GAAP financial measures should be considered together with, and not as an alternative to, financial measures prepared in accordance with GAAP. The SEC rules, which otherwise would require a reconciliation of a non-GAAP financial measure to a GAAP financial measure, do not apply to non-GAAP financial measures provided to a board of directors or financial advisors in connection with a proposed business combination transaction such as the Merger if the disclosure is included in a document such as this proxy statement to comply with requirements under state laws, including case law. The Financial Projections were provided to SVB Securities in order for it to render its Opinion and to the Silverback Board in connection with its consideration of the Contemplated Transactions and other strategic alternatives, and we believe we have an obligation to disclose such projections under Delaware law, including applicable case law, in order to provide a fair summary of certain of the financial analyses and substantive work of SVB Securities and because the Financial Projections were relied upon by the Silverback Board in connection with its consideration of the Contemplated Transactions and other strategic alternatives. In addition, reconciliations of non-GAAP financial measures to a GAAP financial measure were not provided to or relied upon by the SVB Securities in connection with rendering its Opinion with respect to the Merger, as further described in the section titled "*The Merger—Opinion of the Silverback Financial Advisor*." Accordingly, Silverback has not provided a reconciliation of the financial measures included in the Financial Projections to the relevant GAAP financial measures.

The financial projections prepared by ARS Pharma and supplied to Silverback were prepared solely for internal use as part of ARS Pharma's ongoing strategic planning processes and are subjective in many respects. As a result, the Financial Projections, are susceptible to multiple interpretations and periodic revisions based on actual experience and business developments. Although ARS Pharma and Silverback believe their respective assumptions to be reasonable, all financial projections are inherently uncertain, and ARS Pharma and Silverback expect that differences will exist between actual and projected results. Although presented with numerical specificity, the Financial Projections reflect numerous variables, estimates, and assumptions made by ARS Pharma's and Silverback's respective management at the time the initial financial projections were prepared by ARS Pharma and adjusted by Silverback, and also reflect general business, economic, market, and financial conditions and other matters, all of which are difficult to predict and many of which are beyond ARS Pharma's and Silverback's control. In addition, the Financial Projections cover multiple years, and this information by its nature becomes subject to greater uncertainty with each successive year.

Accordingly, there can be no assurance that the estimates and assumptions made in preparing the Financial Projections will prove accurate or that any of the Financial Projections will be realized.

The Financial Projections included certain assumptions relating to, among others things, ARS Pharma's and Silverback's respective expectations, which may not prove to be accurate, relating to the business, earnings, cash flow, assets, liabilities and prospects of ARS Pharma, industry metrics and the regulatory and commercial probability of success and expenses adjusted on the basis thereof.

The Financial Projections assume, among other things, (i) that *neffy* will only be available to the United States market, (ii) that *neffy* will launch in the third quarter of 2023 for the emergency treatment of Type I allergic reactions, and (iii) the potential benefit from net operating loss generation and usage are excluded from the discounted cash flow analysis. The assumption that *neffy* will launch in the third quarter of 2023 for the emergency treatment of Type I allergic reactions was based on ARS Pharma's belief as of May 2022, as communicated to Silverback, that it intended to submit an NDA for *neffy* to the FDA in the third quarter of 2022. Based on an anticipated NDA submission by ARS Pharma at the end of the third quarter of 2022 and ARS Pharma's assumption that the FDA would grant a standard (non-priority) review for such NDA submission, ARS anticipated a potential approval of *neffy* by the FDA in July 2023. The launch of *neffy* was assumed by ARS and Silverback to occur shortly after receipt of such FDA approval in the third quarter of 2023.

The Financial Projections are subject to many risks and uncertainties and you are urged to review the section titled "*Risk Factors*" for a description of risk factors relating to the Merger and ARS Pharma's business. You should also read the section titled "*Cautionary Note Concerning Forward-Looking Statements*" for additional information regarding the risks inherent in forward-looking information such as the Financial Projections.

The inclusion of the Financial Projections herein should not be regarded as an indication that Silverback, SVB Securities, ARS Pharma or any of their respective affiliates or representatives considered or consider the Financial Projections to be necessarily indicative of actual future events, and the Financial Projections should not be relied upon as such. The Financial Projections do not take into account any circumstances or events occurring after the date they were prepared. Silverback and the combined company do not intend to, and disclaim any obligation to, update, correct, or otherwise revise the Financial Projections to reflect circumstances existing or arising after the date the Financial Projections were generated or to reflect the occurrence of future events, even in the event that any or all of the assumptions or other information underlying the Financial Projections are shown to be in error. Furthermore, the Financial Projections do not take into account the effect of any failure of the Merger to be consummated and should not be viewed as accurate or continuing in that context.

In light of the foregoing factors and the uncertainties inherent in financial projections, stockholders are cautioned not to place undue reliance, if any, on the Financial Projections.

The following table, which is subject to the financial projection statements above, presents (in millions) a summary of the Financial Projections, which represent the preliminary internal financial projections for ARS Pharma as such financial projections were adjusted by the management of Silverback solely for use by SVB Securities in connection with the rendering of its Opinion and performing related financial analysis and made available to the Silverback Board.

Years	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038
Total Adjusted Revenue	$ 14	$ 57	$ 133	$240	$396	$513	$571	$633	$699	$769	$846	$910	$956	$1,003	$1,054	$1,106
EBIT[1]	($81)	($100)	($ 54)	$ 118	$175	$236	$263	$291	$321	$354	$389	$419	$440	$ 462	$ 485	$ 509
Unlevered Free Cash Flow[2]	($81)	($104)	($ 62)	$ 76	$ 114	$163	$189	$209	$231	$255	$280	$303	$321	$ 337	$ 354	$ 371

(1) Equal to total adjusted revenue less cost of goods sold, research and development expenses, sales and marketing expense, and general and administrative expense.

(2) Unlevered free cash flow is defined as EBIT, less taxes and less changes in net working capital. Unlevered free cash flow did not include the potential benefit from net operating loss generation and usage.

Interests of the Silverback Directors and Executive Officers in the Merger

In considering the recommendation of the Silverback Board with respect to the approval of the Merger Agreement, the Merger and the issuance of shares of Silverback Common Stock as contemplated by the Merger Agreement, and the other matters to be acted upon by the Silverback stockholders at the Silverback virtual special meeting, the Silverback stockholders should be aware that certain current and former members of the Silverback Board and current and former executive officers of Silverback have interests in the Merger that may be different from, or in addition to, the interests of the Silverback stockholders. These interests relate to or arise from, among other things, change in control and severance benefits to which each of Silverback's named executive officers would become entitled to in the event of termination of their employment under certain circumstances, as specified below under "*—Merger-Related Compensation of Executive Officers*."

The Silverback Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the Merger Agreement and the Merger, and to recommend, as applicable, that Silverback's stockholders approve the proposals to be presented to Silverback's stockholders for consideration at the Silverback virtual special meeting as contemplated by this proxy statement.

Ownership Interests

As of June 30, 2022, Silverback's directors and executive officers (including affiliates) beneficially owned, in the aggregate approximately 30% of the outstanding shares of Silverback Common Stock. Approval of Proposals Nos. 1 and 2 requires the affirmative vote of a majority of the votes cast virtually or by proxy at the Silverback virtual special meeting. Certain officers and directors of Silverback, and their affiliates, have also entered into support agreements in connection with the Merger. For a more detailed discussion of the support agreements, please see the section titled "*Agreements Related to the Merger.*"

Silverback Options and Restricted Stock Units

As of June 30, 2022, Silverback's directors and executive officers, including any director or executive officer who served in such capacity since the beginning of the last fiscal year, collectively held unvested stock options to purchase 2,993,191 shares of Silverback Common Stock, vested stock options to purchase 1,699,222 shares of Silverback Common Stock and unvested restricted stock units covering 266,614 shares of Silverback Common Stock. All outstanding and unexercised options to purchase shares of Silverback Common Stock and all outstanding and unvested restricted stock units will remain effective and outstanding to the extent they are not forfeited or, for restricted stock units, accelerated (and settled) in connection with the Merger.

Under the terms of Silverback's non-employee director compensation policy and each of the non-employee director stock option agreements, any unvested stock options held by a non-employee director will accelerate and vest in full upon the Closing. Under the terms of Silverback's Change in Control and Severance Benefit Plan (the "Severance Plan"), Silverback stock options and restricted stock units held by Silverback's executive officers are subject to accelerated vesting, which is described in the section below titled "*—Merger-Related Compensation of Executive Officers*."

The following table presents certain information concerning the outstanding Silverback stock options and restricted stock units held by each of Silverback's directors and executive officers as of

June 30, 2022, including any director or executive officer who served in such capacity since the beginning of the last fiscal year:

Name	Number of Vested Options Held	Weighted Average Exercise Price of Vested Options ($)	Number of Unvested Options Held	Weighted Average Exercise Price of Unvested Options ($)	Number of Unvested Restricted Stock Units
Executive Officers					
Laura Shawver, Ph.D.[1]	640,595	8.66	1,251,532	8.29	95,607
Valerie Odegard, Ph.D.[2]	344,846	9.69	572,372	10.63	61,639
Jonathan Piazza[3]	148,664	12.07	414,281	8.60	54,941
Naomi Hunder, M.D.[4]	201,611	10.69	422,932	9.81	54,427
Non-Employee Directors					
Peter Thompson, M.D.	34,135	24.44	37,135	12.85	—
Vickie L. Capps	34,202	24.43	37,203	12.86	—
Robert Hershberg, M.D., Ph.D.	111,867	11.78	67,258	12.79	—
Saqib Islam, J.D.	84,347	14.33	69,101	11.99	—
Maria Koehler, M.D., Ph.D.	10,416	55.51	32,584	27.15	—
Andrew Powell, J.D.	54,404	17.45	51,658	10.32	—
Jonathan Root, M.D.	34,135	24.44	37,135	12.85	—
Thilo Schroeder, Ph.D.[5]	—	—	—	—	—

(1) Dr. Shawver is no longer serving as an executive officer of Silverback.
(2) Dr. Odegard is no longer serving as an executive officer of Silverback.
(3) Mr. Piazza is no longer serving as an executive officer of Silverback.
(4) Dr. Hunder is no longer serving as an executive officer of Silverback.
(5) Dr. Schroeder did not stand for reelection on the Silverback Board and his term ended at the 2022 Annual Meeting of Silverback's stockholders.

Merger-Related Compensation of Executive Officers

In November 2020, the Silverback Board approved the Severance Plan, which became effective on December 3, 2020. The Severance Plan and the individual agreement with each participant in the Severance Plan (the "Participation Agreements") provide for severance benefits, including in connection with a "change in control" (as defined in the Severance Plan), for certain of our employees, including our executive officers, subject to execution and effectiveness of a release of claims.

The Severance Plan and the Participation Agreements with our executive officers provide that, in the event of an involuntary termination, which is either a termination without "cause" (not including death or "disability") or a resignation for "good reason" (each, as defined in the Severance Plan), that occurs during the time period commencing three months prior to the to the closing of a change in control and ending 12 months following the closing of such change in control (which will occur at Closing) (such a termination, a "Change in Control Termination" and such period, the "Change in Control Period"): (i) Dr. Shawver will be entitled to a lump sum cash payment equal to 24 months of her base salary, a lump sum cash payment equal 200% of her annual target cash bonus for the year in which her termination occurs, a lump sum cash payment equal to a prorated portion of her target annual cash bonus for the year in which her termination occurs, up to 18 months of continued group health plan benefits, and a lump sum payment in an amount equal to the premiums required to continue her group health plan benefits for an additional six months; and (ii) our other executive officers will each be entitled to a lump sum cash payment equal to 18 months of the executive officer's base salary, 150% of the executive officer's annual target cash bonus for the year in which the executive officer's termination occurs, a lump sum cash payment equal to a prorated portion of the executive officer's target annual cash bonus for the year in which the executive officer's termination

occurs, up to 18 months of continued group health plan benefits, and, other than for Mr. Piazza, 100% accelerated vesting of all outstanding stock options and other stock awards held by the executive officer. Additionally, pursuant to the terms of the Severance Plan and their participation agreements, all stock options and other stock awards held by Dr. Shawver and Mr. Piazza will automatically vest in full upon the closing of a change in control (whether or not Dr. Shawver or Mr. Piazza experience an involuntary termination in connection with such change in control).

Effective upon the signing of the Merger Agreement, the Silverback Board approved certain amendments to the compensation arrangement of certain employees (the "Severance Amendments"), including Silverback's executive officers, pursuant to which (i) certain employees, including any named executive officer of Silverback who experiences, or is deemed to experience, a Change in Control Termination, will be eligible to receive an extension of the post-termination exercise period of the applicable employee's stock options from three months to 12 months following a qualifying termination of service; and (ii) the executive officers of Silverback will be eligible to receive severance benefits under the Severance Plan as if they each experience a Change in Control Termination, regardless of whether such executive officer's actual termination date occurs during the Change in Control Period, subject to such executive officer's execution and delivery of an effective general release of claims in favor of Silverback and satisfaction of all other requirements set forth in the Severance Plan.

The amount of severance payable to our executive officers may be reduced under applicable agreements or otherwise in light of adverse tax consequences under Sections 280G and 4999 of the Code.

Indemnification and Insurance

For a discussion of the indemnification and insurance provisions related to the Silverback directors and officers under the Merger Agreement, please see the section titled "*The Merger Agreement—Other Agreements—Director Indemnification and Insurance*."

Structure

Under the Merger Agreement, Merger Sub, a wholly owned subsidiary of Silverback formed in connection with the Merger, will merge with and into ARS Pharma, with ARS Pharma surviving as a wholly owned subsidiary of Silverback. Substantially concurrent with the completion of the Merger, Silverback will be renamed "ARS Pharmaceuticals, Inc." and expects to trade on The Nasdaq Global Market under the symbol "SPRY."

Executive Officers of the Combined Company Following the Merger

Immediately following the Merger, the executive management team of the combined company is expected to be comprised of the following individuals with such additional officers as may be added by ARS Pharma or the combined company:

Name	Position with the Combined Company	Current Position
Richard Lowenthal, M.S., MSEL	President and Chief Executive Officer	President and Chief Executive Officer of ARS Pharma
Kathleen Scott	Chief Financial Officer	Chief Financial Officer of ARS Pharma
Sarina Tanimoto, M.D., M.B.A.	Chief Medical Officer	Chief Medical Officer of ARS Pharma
Eric Karas	Chief Commercial Officer	Chief Commercial Officer of ARS Pharma
Justin Chakma	Chief Business Officer	Chief Business Officer of ARS Pharma

Directors of the Combined Company Following the Merger

At the Effective Time, the combined company is expected to initially have an eleven member board of directors, comprised of (a) Richard Lowenthal, M.S., MSEL, Pratik Shah, Ph.D., Peter Kolchinsky, Ph.D., Rajeev Dadoo, Ph.D., Brenton L. Saunders, Phillip Schneider, Michael Kelly and Jonathan Leff, each as an ARS Pharma designee, and (b) Laura Shawver, Ph.D., Peter A. Thompson, M.D. and Saqib Islam, J.D., each as a Silverback designee, until their respective successors are duly elected or appointed and qualified or their earlier death, resignation or removal.

The aforementioned board of directors will have an audit committee, a compensation committee and a nominating and corporate governance committee, in accordance with the Nasdaq rules. All of Silverback's current directors, other than Dr. Shawver, Dr. Thompson and Mr. Islam, are expected to resign from their positions as directors of Silverback, effective as of the Effective Time.

Merger Consideration and Exchange Ratio

For a discussion of the merger consideration and the Exchange Ratio, please see the section titled "*The Merger Agreement—Merger Consideration and Exchange Ratio.*"

Effective Time of the Merger

The Merger will be completed as promptly as practicable (but no later than the second business day) after all of the conditions to Closing are satisfied or waived, including the approval of the stockholders of Silverback, unless earlier terminated in accordance with the terms of the Merger Agreement. For more information on termination rights, see the section titled "*The Merger Agreement—Termination and Termination Fees.*" The Merger is anticipated to occur after the Silverback virtual special meeting, which is further described in the section titled "*The Virtual Special Meeting of Silverback's Stockholders*." Silverback and ARS Pharma cannot predict the exact timing of the Closing because it is subject to various conditions.

Regulatory Approvals Required for the Merger

Under the Merger Agreement, Silverback and ARS Pharma have agreed to use reasonable best efforts to obtain all regulatory approvals required to consummate the Merger and the other Contemplated Transactions.

Under the HSR Act and the rules promulgated thereunder, certain acquisitions may not be completed until information has been furnished to the Antitrust Division of the U.S. Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), and the applicable HSR Act waiting period has expired or been terminated. The waiting period under the HSR Act for the Merger is 30 calendar days following the parties' filings of their respective HSR Act notification and report forms (which period is extended to the next business day if the 30th day falls on a Saturday, Sunday, or federal holiday), unless the waiting period is terminated earlier or extended through the issuance of a request for additional information. The Merger is subject to the provisions of the HSR Act and therefore cannot be completed until each of Silverback and ARS Pharma file a notification and report form with the DOJ and the FTC under the HSR Act and the applicable waiting period has expired or been terminated. Silverback and ARS Pharma made the necessary filings with the DOJ and the FTC on August 4, 2022. The waiting period with respect to the notification and report forms filed under the HSR Act expired at 11:59 p.m., Eastern Time, on September 6, 2022.

At any time before or after consummation of the Merger, notwithstanding the termination or expiration of the waiting period under the HSR Act, the DOJ or the FTC could take such action under

the antitrust laws as either deem necessary or desirable in the public interest, including seeking to enjoin the completion of the Merger, seeking divestiture of substantial assets of the parties, or requiring the parties to license or hold separate assets or modify or terminate existing relationships and contractual rights, or to impose a restriction, requirement, or limitation on the operation of the business. At any time before or after the completion of the Merger, and notwithstanding the termination or expiration of the waiting period under the HSR Act, state or foreign jurisdictions could also take such action under antitrust law as they deems necessary or desirable. Such action could include seeking to enjoin the completion of the Merger or seeking divestiture of substantial assets of the parties. Private parties may also seek to take legal action under the antitrust laws under certain circumstances. We cannot be certain that a challenge to the Merger will not be made or that, if a challenge is made, we will prevail.

Material U.S. Federal Income Tax Consequences of the Merger

This summary is based upon current provisions of the Code, existing Treasury regulations, judicial decisions, and published rulings and administrative pronouncements of the IRS, all in effect as of the date hereof and all of which are subject to differing interpretations or change. Any such change or differing interpretation, which may be retroactive, could alter the tax consequences to ARS Pharma stockholders as described in this summary.

This discussion applies only to ARS Pharma stockholders who hold their ARS Pharma Capital Stock as a “capital asset” within the meaning of Section 1221 of the Code, and does not address all U.S. federal income tax consequences relevant to an ARS Pharma stockholder. In addition, it does not address consequences relevant to ARS Pharma stockholders that are subject to particular U.S. or non-U.S. tax rules, including, without limitation to ARS Pharma stockholders that are:

- brokers, dealers or traders in securities; banks; insurance companies; other financial institutions; mutual funds;
- real estate investment trusts; regulated investment companies; tax-exempt organizations or governmental organizations;
- pass-through entities such as partnerships, S corporations, disregarded entities for federal income tax purposes and limited liability companies (and investors therein);
- persons who are not U.S. holders (as defined below);
- subject to the alternative minimum tax provisions of the Code;
- persons who hold their shares as part of a hedge, wash sale, synthetic security, conversion transaction, or other integrated transaction;
- persons that have a functional currency other than the U.S. dollar;
- traders in securities who elect to apply a mark-to-market method of accounting;
- persons who hold shares of ARS Pharma Capital Stock that may constitute “qualified small business stock” under Section 1202 of the Code or as “Section 1244 stock” for purposes of Section 1244 of the Code;
- persons who elect to apply the provisions of Section 1400Z-2 to any gains realized in the Merger;
- persons who acquired their shares of ARS Capital Stock in a transaction subject to the gain rollover provisions of Section 1045 of the Code;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to ARS Pharma Capital Stock being taken into account in an “applicable financial statement” (as defined in the Code);

- persons deemed to sell ARS Pharma Capital Stock under the constructive sale provisions of the Code;
- persons who acquired their shares of ARS Pharma Capital Stock pursuant to the exercise of options or otherwise as compensation or through a tax-qualified retirement plan or through the exercise of a warrant or conversion rights under convertible instruments; and
- certain expatriates or former citizens or long-term residents of the United States.

ARS Pharma stockholders subject to particular U.S. or non-U.S. tax rules that are described in this paragraph are urged to consult their own tax advisors regarding the consequences to them of the Merger.

If an entity that is treated as a partnership for U.S. federal income tax purposes holds ARS Pharma Capital Stock, the U.S. federal income tax treatment of a partner in the partnership will depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. If you are a partnership or a partner of a partnership holding ARS Pharma Capital Stock or any other person not addressed by this discussion, you should consult your tax advisors regarding the tax consequences of the Merger.

In addition, the following discussion does not address: (a) the tax consequences of transactions effectuated before, after or at the same time as the Merger, whether or not they are in connection with the Merger, including, without limitation, transactions in which shares of ARS Pharma Capital Stock are acquired or disposed of other than in exchange for shares of Silverback Common Stock in the Merger; (b) the tax consequences to holders of options or warrants issued by ARS Pharma which are assumed in connection with the Merger; (c) the tax consequences of the ownership of shares of Silverback Common Stock following the Merger; (d) any U.S. federal non-income tax consequences of the Merger, including estate, gift or other tax consequences; (e) any state, local or non-U.S. tax consequences of the Merger; or (f) the Medicare contribution tax on net investment income.

Definition of "U.S. Holder"

For purposes of this discussion, a "U.S. holder" is a beneficial owner of ARS Pharma Capital Stock that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation or any other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- a trust if either (i) a court within the United States is able to exercise primary supervision over the administration of such trust, and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) are authorized or have the authority to control all substantial decisions of such trust, or (ii) the trust was in existence on August 20, 1996 and has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes; or
- an estate, the income of which is subject to U.S. federal income tax regardless of its source.

Treatment of U.S. Holders in the Merger

If the Merger qualifies as a reorganization under Section 368(a) of the Code, ARS Pharma stockholders will not recognize gain or loss upon the exchange of their ARS Pharma Capital Stock for Silverback Common Stock. ARS Pharma stockholders will obtain a basis in the Silverback Common Stock they receive in the Merger equal to their basis in the ARS Pharma Capital Stock exchanged

therefor. The holding period of the shares of Silverback Common Stock received by an ARS Pharma stockholder in the Merger will include the holding period of the shares of ARS Pharma Capital Stock surrendered in exchange therefor.

If the Merger does not qualify as a reorganization within the meaning of Section 368(a) of the Code, then each U.S. holder will be treated as exchanging its ARS Pharma Capital Stock in a fully taxable transaction in exchange for Silverback Common Stock. U.S. holders of ARS Pharma Capital Stock generally will recognize capital gain or loss in such exchange equal to the difference between (i) the sum of the fair market value of the Silverback Common Stock received in the Merger and (ii) such holder's tax basis in the ARS Pharma Capital Stock surrendered in the Merger. The aggregate tax basis of a U.S. holder in the Silverback Common Stock received in the Merger will equal its fair market value at the Effective Time, and the holding period of Silverback Common Stock received in the Merger will begin on the day after the Effective Time of the Merger.

For purposes of the above discussion of the bases and holding periods for shares of ARS Pharma Capital Stock acquired by ARS Pharma stockholders at different times for different prices, such ARS Pharma stockholders must calculate their gains and losses and holding periods separately for each identifiable block of such ARS Pharma Capital Stock exchanged in the Merger.

Information Reporting

Each U.S. holder who receives shares of Silverback Common Stock in the Merger is required to retain permanent records pertaining to the Merger, and make such records available to any authorized IRS officers and employees. Such records should specifically include information regarding the amount, basis, and fair market value of all transferred property, and relevant facts regarding any liabilities assumed or extinguished as part of such reorganization. U.S. holders who owned immediately before the Merger at least one percent (by vote or value) of the total outstanding stock of ARS Pharma or securities of ARS Pharma with a basis of $1,000,000 or more are required to attach a statement to their tax returns for the year in which the Merger is consummated that contains the information listed in Treasury Regulation Section 1.368-3(b). Such statement must include the U.S. holder's tax basis in such holder's ARS Pharma Capital Stock surrendered in the Merger, the fair market value of such stock, the date of the Merger and the name and employer identification number of each of ARS Pharma and Silverback. U.S. holders are urged to consult with their tax advisors to comply with these rules.

Holders of ARS Pharma Capital Stock are urged to consult their tax advisors regarding the U.S. federal income tax consequences of the Merger in light of their personal circumstances and the consequences to them under state, local and non-U.S. tax laws and other federal tax laws.

Nasdaq Stock Market Listing

Silverback Common Stock currently is listed on The Nasdaq Global Market under the symbol "SBTX." Silverback has agreed to use commercially reasonable efforts (i) to maintain its existing listing on Nasdaq until the Effective Time and obtain approval of the listing of the combined company on Nasdaq, (ii) to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Silverback Common Stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance), and (iii) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial Nasdaq Listing Application for the Silverback Common Stock on Nasdaq and to cause such listing application to be conditionally approved prior to the Effective Time.

In addition, under the Merger Agreement, each of ARS Pharma's and Silverback's obligation to complete the Merger is subject to the satisfaction or waiver by each of the parties, at or prior to the Closing, of various conditions, including that the shares of Silverback Common Stock to be issued in the Merger have been approved for listing (subject to official notice of issuance) on Nasdaq as of the Closing.

If the Nasdaq Listing Application is accepted, Silverback anticipates that the common stock of the combined company will be listed on the Nasdaq Global Market following the Closing under the trading symbol "SPRY."

Anticipated Accounting Treatment

The Merger will be accounted for as a reverse recapitalization under GAAP. For accounting purposes, ARS Pharma is considered to be acquiring Silverback in this transaction. This determination was primarily based on the expectations that, immediately following the Merger: (i) ARS Pharma stockholders will own a substantial majority of the voting rights; (ii) ARS Pharma will designate a majority (eight of eleven) of the initial members of the board of directors of the combined organization; and (iii) ARS Pharma's executive management team will become the management of the combined company. Accordingly, for accounting purposes, the Merger will be treated as the equivalent of ARS Pharma issuing stock to acquire the net assets of Silverback. Apart from cash and cash equivalents and other highly liquid assets, the other assets and liabilities being acquired are expected to be nominal. At the close of the Merger, the net assets of Silverback will be recorded at their acquisition-date fair value in the financial statements of ARS Pharma and the reported operating results prior to the Merger will be those of ARS Pharma.

Appraisal Rights and Dissenters' Rights

Under the DGCL, Silverback stockholders are not entitled to appraisal rights in connection with the Merger.

ARS Pharma stockholders are entitled to statutory appraisal rights in connection with the Merger under Section 262 of the DGCL and under Chapter 13 of the California Corporations Code. One of the conditions to Silverback's obligation to consummate the Merger is that no stockholders of ARS Pharma shall have exercised statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of California Corporations Code with respect to their shares of ARS Pharma Capital Stock.

As of the date of the Merger Agreement, ARS Pharma stockholders representing approximately 83% of the outstanding shares of ARS Capital Stock immediately prior to the date of the Merger Agreement waived any statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of California Corporations Code with respect to their shares of ARS Pharma Capital Stock.

THE MERGER AGREEMENT

The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached as Annex A to this proxy statement and is incorporated by reference. The Merger Agreement has been attached to this proxy statement to provide you with information regarding its terms. It is not intended to provide any other factual information about Silverback, ARS Pharma or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the Merger and the terms and conditions of the Merger Agreement.

The Merger Agreement contains representations and warranties that Silverback and Merger Sub, on the one hand, and ARS Pharma, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if such statements made in the representations and warranties prove to be incorrect. In addition, the assertions made in the representations and warranties are qualified by the information in confidential disclosure schedules exchanged by the parties in connection with the signing of the Merger Agreement. While Silverback and ARS Pharma do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about Silverback, ARS Pharma or Merger Sub, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between Silverback and Merger Sub on the one hand, and ARS Pharma on the other hand, and are modified by the disclosure schedules.

Structure

Under the Merger Agreement, Merger Sub, a wholly owned subsidiary of Silverback formed in connection with the Merger, will merge with and into ARS Pharma, with ARS Pharma surviving as a wholly owned subsidiary of Silverback. Substantially concurrent with the completion of the Merger, Silverback will be renamed “ARS Pharmaceuticals, Inc.” and expects to trade on The Nasdaq Global Market under the symbol “SPRY.”

Completion and Effectiveness of the Merger

The Merger will be completed as promptly as practicable (but no later than the second business day) after all of the conditions to Closing are satisfied or waived, including the approval of the stockholders of Silverback, unless earlier terminated in accordance with the terms of the Merger Agreement. For more information on termination rights, see the section titled “*The Merger Agreement—Termination and Termination Fees.*” The Merger is anticipated to occur after the Silverback virtual special meeting, which is further described in the section titled “*The Virtual Special Meeting of Silverback’s Stockholders*.” Silverback and ARS Pharma cannot predict the exact timing of the Closing because it is subject to various conditions.

Merger Consideration and Exchange Ratio

Merger Consideration

At the Effective Time, each share of ARS Pharma Capital Stock outstanding immediately prior to the Effective Time and after giving effect to the Preferred Stock Conversion (excluding shares held as

treasury stock by ARS Pharma or held or owned by Silverback, Merger Sub or any subsidiary of Silverback or ARS Pharma and dissenting shares) will be automatically converted solely into the right to receive a number of validly issued, fully paid and nonassessable shares of Silverback Common Stock equal to the Exchange Ratio.

No fractional shares of Silverback Common Stock will be issued in connection with the Merger, and no certificates or scrip for any such fractional shares will be issued. Any fractional shares of Silverback Common Stock that a holder of ARS Pharma Capital Stock would otherwise be entitled to receive will be aggregated with all fractional shares of Silverback Common Stock issuable to such holder and any remaining fractional shares will be rounded up to the nearest whole share.

Exchange Ratio

The Exchange Ratio formula is derived based upon an ARS Pharma fixed valuation of $435 million and a Silverback Equity Value of $255 million and is subject to certain adjustments, including based upon Silverback Net Cash at Closing.

Immediately following the Merger, assuming Silverback Net Cash at Closing is $240 million, the pre-Merger equity holders of ARS Pharma are expected to hold approximately 63% of the outstanding shares of Silverback Common Stock and the pre-Merger equity holders of Silverback are expected to hold approximately 37% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method. As currently anticipated, the Exchange Ratio is expected to be approximately 1.2441. The "Exchange Ratio" is the quotient obtained by dividing (a) (i) the ARS Pharma Valuation divided by (ii) the ARS Pharma Outstanding Shares by (b) (i) the Silverback Valuation divided by (ii) the Silverback Outstanding Shares, in which:

- "ARS Pharma Valuation" means $435 million.
- "ARS Pharma Outstanding Shares" means the total number of shares of ARS Pharma Capital Stock outstanding immediately prior to the Effective Time after giving effect to the Preferred Stock Conversion, expressed on a fully-diluted basis and using the treasury stock method, but assuming, without limitation or duplication, (i) the exercise of all ARS Pharma stock options and ARS Pharma warrants, in each case outstanding as of immediately prior to the Effective Time, and (ii) the issuance of shares of ARS Pharma Capital Stock in respect of all other outstanding options, restricted stock awards, warrants or rights to receive such shares, whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger (but excluding any shares of ARS Pharma Capital Stock reserved for issuance other than with respect to outstanding ARS Pharma warrants or ARS Pharma stock options under the ARS 2018 Plan as of immediately prior to the Effective Time).
- "Silverback Equity Value" means $255 million.
- "Silverback Outstanding Shares" means, subject to, among other things, certain stock dividends, subdivisions, reclassifications, recapitalizations, splits, combinations or exchanges of shares or other like changes occurring prior to the Effective Time and the exclusion of out-of-the money Silverback stock options, the total number of shares of Silverback Common Stock outstanding immediately prior to the Effective Time expressed on a fully-diluted basis and using the treasury stock method, but assuming, without limitation or duplication, the issuance of shares of Silverback Common Stock in respect of all Silverback stock options, Silverback restricted stock units, and other outstanding options, warrants or rights to receive such shares, in each case, outstanding as of immediately prior to the Effective Time (assuming cashless exercise using the volume weighted average closing trading price of the Silverback Common Stock on Nasdaq for the five consecutive trading days ending five trading days

immediately prior to the date upon which the Merger becomes effective), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger, (but excluding any shares of Silverback Common Stock reserved for issuance other than with respect to outstanding Silverback stock options and Silverback restricted stock units as of immediately prior to the Effective Time and as set forth above). No out-of-the-money Silverback stock options will be included in the total number of shares of Silverback Common Stock outstanding for purposes of determining the Silverback Outstanding Shares.

- "Silverback Valuation" means (i) if Silverback Net Cash is greater than $240 million, the sum of (x) the Silverback Equity Value *plus* (y) the amount by which, up to $15 million, Silverback Net Cash exceeds $240 million, (ii) if Silverback Net Cash is equal to $240 million, the Silverback Equity Value, or (iii) if Silverback Net Cash is less than $240 million, the sum of (x) the Silverback Equity Value, *minus* (y) the amount by which $240 million exceeds Silverback Net Cash.
- "Silverback Net Cash" means, without duplication, (a) the sum of Silverback's cash and cash equivalents, marketable securities, accounts, interest and other receivables, deposits and short and long term investments, in each case as of the Anticipated Closing Date, determined in a manner consistent with the manner in which such items were historically determined and in accordance with the financial statements (including any related notes) contained or incorporated by reference in the unaudited balance sheet of Silverback as of March 31, 2022 included in Silverback's Report on Form 10-Q for the quarterly period ended March 31, 2022, as filed with the SEC (the "Silverback Balance Sheet"), *minus* (b) the sum of Silverback's short and long term liabilities accrued at Closing, in each case as of the Anticipated Closing Date and determined in a manner consistent with the manner in which such items were historically determined and in accordance with the financial statements (including any related notes) contained or incorporated by reference in the Silverback Balance Sheet (including the Transaction Expenses payable by Silverback to the extent unpaid as of the Closing but excluding any lease liabilities to the extent they are contractually mitigated through a commercially reasonable sub-leasing arrangement), *minus* (c) the cash cost of any unpaid change of control payments or severance, termination or similar payments pursuant to a contract that are or become due to any current or former employee, director or independent contractor of Silverback in connection with the Closing, *minus* (d) to the extent unpaid at Closing, the cost of the D&O Tail Policy (as defined below) purchased pursuant to Section 5.7(d) of the Merger Agreement, *plus* (e) prepaid expenses and receivables that will be utilized by Silverback and/or the surviving company on and following the Closing, *plus* (f) expenses paid, or liabilities incurred, prior to the Closing, that will be covered by Silverback's D&O insurance in excess of the deductible, and *plus* (g) any net cash proceeds due to Silverback substantially concurrently with the Closing from any Asset Dispositions (as defined below) or, as mutually agreed in good faith, otherwise in connection with any Asset Disposition.

The following table illustrates how the Exchange Ratio and post-Merger equity ownership of ARS Pharma's pre-Merger equity holders and Silverback's pre-Merger equity holders may change if Silverback Net Cash is between $255 million and $210 million at Closing, in each case calculated as of July 20, 2022.

Silverback Net Cash at Closing ($ in millions)	Exchange Ratio	Post-Merger Ownership	
		ARS Pharma Equity Holders	Silverback Equity Holders
$210	1.4015	66%	34%
$215	1.3725	65%	35%
$220	1.3447	65%	35%
$225	1.3181	64%	36%
$230	1.2924	64%	36%
$235	1.2678	64%	36%
$240	1.2441	63%	37%
$245	1.2216	63%	37%
$250	1.1998	62%	38%
$255	1.1788	62%	38%

Treatment of ARS Pharma Stock Options

Under the terms of the Merger Agreement, each option to purchase shares of ARS Pharma Common Stock that is outstanding and unexercised immediately prior to the Effective Time, whether or not vested, will be converted into and become an option to purchase shares of Silverback Common Stock. Silverback will assume the ARS 2018 Plan and all such ARS Pharma stock options in accordance with the terms of the ARS 2018 Plan and the terms of the stock option agreement by which such option is evidenced.

Accordingly, from and after the Effective Time: (i) each outstanding ARS Pharma stock option assumed by Silverback may be exercised solely for shares of Silverback Common Stock; (ii) the number of shares of Silverback Common Stock subject to each outstanding ARS Pharma stock option assumed by Silverback will be determined by multiplying (A) the number of shares of ARS Pharma Common Stock that were subject to such ARS Pharma stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Silverback Common Stock; (iii) the per share exercise price for the Silverback Common Stock issuable upon exercise of each ARS Pharma stock option assumed by Silverback will be determined by dividing (A) the per share exercise price of Silverback Common Stock subject to such ARS Pharma stock option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any ARS Pharma stock option assumed by Silverback will continue in full force and effect and the term, exercisability, vesting schedule, accelerated vesting provisions, and any other provisions of such ARS Pharma stock option will otherwise remain unchanged; provided, however, that the Silverback Board or a committee thereof will succeed to the authority and responsibility of the ARS Pharma Board or any committee thereof with respect to each ARS Pharma stock option assumed by Silverback.

Treatment of ARS Pharma Warrants

Under the terms of the Merger Agreement, each warrant to purchase shares of ARS Pharma Common Stock that is outstanding and unexercised immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion), will be converted into and become a warrant to purchase shares of Silverback Common Stock and Silverback will assume each ARS Pharma warrant in accordance with its terms.

Accordingly, from and after the Effective Time: (i) each outstanding ARS Pharma warrant assumed by Silverback may be exercised solely for shares of Silverback Common Stock; (ii) the number of shares of Silverback Common Stock subject to each outstanding ARS Pharma warrant assumed by Silverback will be determined by multiplying (A) the number of shares of ARS Pharma Common Stock that were subject to such ARS Pharma warrant, as in effect immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion), by (B) the Exchange Ratio, and rounding the resulting number up to the nearest whole number of shares of Silverback Common Stock; (iii) the per share exercise price for the Silverback Common Stock issuable upon exercise of each ARS Pharma warrant assumed by Silverback will be determined by dividing (A) the per share exercise price of Silverback Common Stock subject to such ARS Pharma warrant as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any ARS Pharma warrant assumed by Silverback will continue in full force and effect and the term and other provisions of such ARS Pharma warrant will otherwise remain unchanged.

Treatment of Silverback Stock Options and Restricted Stock Units

All outstanding and unexercised options to purchase shares of Silverback Common Stock and all outstanding and unvested restricted stock units will remain effective and outstanding to the extent they are not forfeit or, for restricted stock units, accelerated (and settled) in connection with the Merger. As of June 30, 2022, there were outstanding options to purchase up to an aggregate of 8,649,255 shares of Silverback Common Stock and unvested restricted stock units covering 745,675 shares of Silverback Common Stock. As of June 30, 2022, Silverback's current executive officers and directors collectively owned outstanding options to purchase an aggregate of 4,692,413 shares of Silverback Common Stock and unvested restricted stock units covering 266,614 shares of Silverback Common Stock.

Directors and Executive Officers of the Combined Company Following the Merger

The Merger Agreement provides that the parties will use reasonable best efforts and take all necessary action so that immediately after the Effective Time, the Silverback Board is comprised of eleven members, with eight such members designated by ARS Pharma and three such members designated by Silverback. Mr. Lowenthal will serve as the President and Chief Executive Officer of the combined company. For more information about the directors and executive officers of the combined company following the Merger, please see the sections titled "*The Merger—Executive Officers of the Combined Company Following the Merger*" and "*The Merger—Directors of the Combined Company Following the Merger.*"

Conditions to the Completion of the Merger

The obligations of each party to consummate the Merger and the Contemplated Transactions are subject to the satisfaction or, to the extent permitted by applicable law, the written waiver by each of the parties, at or prior to the Closing, of the following conditions:

- there must not have been any temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Contemplated Transactions issued by any court of competent jurisdiction or other governmental body of competent jurisdiction and that remains in effect, and no law may have made the consummation of the Contemplated Transactions illegal;
- the Silverback stockholders must have approved the issuance of Silverback Common Stock or other securities of Silverback that represent (or are convertible into) more than 20% of the shares of Silverback Common Stock outstanding immediately prior to the Merger to the holders

of ARS Pharma Capital Stock, ARS Pharma stock options and ARS Pharma warrants in connection with the Contemplated Transactions and the change of control of Silverback resulting from the Contemplated Transactions, in each case pursuant to the Nasdaq rules;

- ARS Pharma must have delivered an action by written consent (the "ARS Pharma Stockholder Written Consent") by (a) the holders of a majority of the issued and outstanding shares of ARS Pharma Common Stock; (b) the holders of a majority of the issued and outstanding shares of ARS Pharma Common Stock and ARS Pharma Preferred Stock, voting together as a single class with each holder of shares of ARS Pharma Preferred Stock having the number of votes equal to the number of shares of ARS Pharma Common Stock into which such shares of ARS Pharma Preferred Stock could be converted; (c) the holders of a majority of the issued and outstanding shares of ARS Pharma Preferred Stock, voting together as a separate class on an as-if-converted to ARS Pharma Common Stock basis, which majority must include the holders of a majority of the issued and outstanding shares of ARS Pharma's Series D Preferred Stock, on an as-if-converted to ARS Pharma Common Stock basis; (d) solely with respect to the termination of the Amended and Restated Voting Agreement, by and among ARS Pharma and certain of its stockholders (the "Voting Agreement"), the holders of a majority of the Key Holder Shares (as defined in the Voting Agreement); and (e) solely with respect to the termination of the Amended and Restated Right of First Refusal and Co-Sale Agreement, by and among ARS Pharma and certain of its stockholders (the "ROFR Agreement"), the holders of a majority of the Key Holder Stock (as defined in the ROFR Agreement) (collectively, the "Required ARS Pharma Stockholder Vote"): (i) adopting and approving the Merger Agreement and the Contemplated Transactions, (ii) electing the automatic conversion of each share of ARS Pharma Preferred Stock into shares of ARS Pharma Common Stock immediately prior to the Effective Time in accordance with the relevant provisions of ARS Pharma's organizational documents, (iii) approving the termination of certain investor agreements among ARS Pharma and its stockholders, including the Voting Agreement, the ROFR Agreement and the Amended and Restated Investors Rights Agreement, by and among ARS Pharma and certain of its stockholder (collectively, the "ARS Pharma Investor Agreements"), (iv) acknowledging that the approval given thereby is irrevocable and that such stockholder is aware of its rights to demand appraisal, or assert any dissenters' rights, for its shares pursuant to Section 262 of the DGCL and Chapter 13 of the California Corporations Code and that such stockholder has received and read a copy of Section 262 of the DGCL and Section 13 of the California Corporations Code and (v) acknowledging that by such stockholder's approval of the Merger such stockholder is not entitled to appraisal rights and thereby waives any right to receive payment of the fair value of its shares of ARS Capital Stock under the DGCL or the California Corporations Code (collectively, the "ARS Pharma Stockholder Matters");
- existing shares of Silverback Common Stock must have been continually listed on Nasdaq as of and from the date of the Merger Agreement through the Closing Date and the shares of Silverback Common Stock to be issued pursuant to the Merger Agreement must have been approved for listing (subject to official notice of issuance) on Nasdaq as of the Closing;
- the waiting period applicable to the consummation of the Contemplated Transactions under the HSR Act, and any extensions thereof, must have expired or been terminated; and
- Silverback Net Cash must have been finally determined.

In addition, the obligation of Silverback and Merger Sub to consummate the Merger is further subject to the satisfaction or waiver of the following conditions:

- the representations and warranties of ARS Pharma set forth in the Merger Agreement under sections 2.1 (Due Organization; Subsidiaries), 2.3 (Authority; Binding Nature of Agreement), 2.4 (Vote Required), 2.6(a) and (c) (Capitalization) and 2.21 (No Financial Advisors) must have

been true and correct in all material respects as of the date of the Merger Agreement and must be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties must have been true and correct in all material respects as of such date);

- the representations and warranties of ARS Pharma set forth in the Merger Agreement (other than the ARS Pharma representations are warranties listed above) must have been true and correct as of the date of the Merger Agreement and must be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have an ARS Pharma Material Adverse Effect (as defined below) (without giving effect to any references therein to any ARS Pharma Material Adverse Effect or other materiality qualifications) or (b) for those representations and warranties which address matters only as of a particular date (which representations must have been true and correct, subject to the qualifications set forth in the preceding clause (a), as of such particular date);
- ARS Pharma must have performed and complied with in all material respects all agreements and covenants required to be performed or complied with by it under the Merger Agreement at or prior to the Effective Time;
- Silverback must have received from ARS Pharma (i) an officer's certificate certifying (x) that certain conditions set forth in the Merger Agreement have been duly satisfied and (y) that the information set forth in an allocation certificate delivered by ARS Pharma containing information regarding ARS Pharma's capitalization is true and accurate in all respects; and (ii) a copy of such allocation certificate;
- Silverback must have received (i) an original signed statement from ARS Pharma that ARS Pharma is not, and has not been at any time during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a "United States real property holding corporation," as defined in Section 897(c)(2) of the Code, conforming to the requirements of Treasury Regulations Section 1.1445-2(c)(3) and 1.897-2(h), and (ii) an original signed notice to be delivered to the Internal Revenue Service ("IRS") in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), together with written authorization for Silverback to deliver such notice to the IRS on behalf of ARS Pharma following the Closing, each dated as of the Closing Date, duly executed by an authorized officer of ARS Pharma, and in form and substance reasonably acceptable to Silverback;
- ARS Pharma must not have experienced an ARS Pharma Material Adverse Effect since the date of the Merger Agreement that is continuing;
- the ARS Pharma Investor Agreements must have been terminated;
- ARS Pharma must not have more than 10 stockholders who have not executed an investor questionnaire certifying that such stockholder is an "accredited investor" pursuant to Regulation D promulgated under the Securities Act, and any such non-accredited stockholders either alone or with such stockholder's purchaser representative(s) must have such knowledge and experience in financial and business matters that such stockholder is capable of evaluating the merits and risks of the Merger;
- the ARS Pharma Stockholder Written Consent executed by certain officers, directors and stockholders of ARS Pharma must be in full force and effect;
- the stockholders of ARS Pharma must not have exercised statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of the California Corporations Code with respect to their shares of ARS Pharma Capital Stock;

- Silverback must have received from ARS Pharma FDA confirmation of submission for a New Drug Application for *neffy* 2.0 mg; and
- Silverback must have received duly executed copies of the required Lock-Up Agreements from certain executive officers, directors and stockholders of ARS Pharma, each of which must be in full force and effect as of the Closing.

In addition, the obligation of ARS Pharma to complete the Merger is further subject to the satisfaction or waiver of the following conditions:

- the representations and warranties of Silverback and Merger Sub set forth in the Merger Agreement under sections 3.1(a) (Due Organization; Subsidiaries), 3.3 (Authority; Binding Nature of Agreement), 3.4 (Vote Required), 3.6(a) and (c) (Capitalization) and 3.22 (No Financial Advisors) must have been true and correct in all material respects as of the date of the Merger Agreement and must be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties must have been true and correct in all material respects as of such date);
- the representations and warranties of Silverback and Merger Sub set forth in the Merger Agreement (other than the Silverback and Merger Sub representations and warranties listed above) must have been true and correct as of the date of the Merger Agreement and must be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have a Silverback Material Adverse Effect (as defined below) (without giving effect to any references therein to any Silverback Material Adverse Effect or other materiality qualifications) or (b) for those representations and warranties which address matters only as of a particular date (which representations must have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date);
- Silverback and Merger Sub must have performed or complied with in all material respects all of their agreements and covenants required to be performed or complied with by each of them under the Merger Agreement at or prior to the Effective Time;
- ARS Pharma must have received from Silverback (i) an officer's certificate confirming that certain conditions of the Merger Agreement have been duly satisfied; (ii) a certificate containing information regarding Silverback's capitalization; (iii) a written resignation executed by the officers and directors of Silverback who will not continue as officers or directors of Silverback after the Closing; and (iv) the Silverback closing financial certificate certifying Silverback Net Cash as of the Anticipated Closing Date, a draft of which must have been provided at least five business days prior to the Closing, which certificate will be accompanied by such supporting documentation, information and calculations as are reasonably requested by ARS Pharma to verify and determine the information contained therein;
- Silverback must not have experienced a Silverback Material Adverse Effect since the date of the Merger Agreement that is continuing;
- Silverback Net Cash, as finally determined, must not be less than $210 million nor greater than $255 million (subject to Silverback's right to declare a dividend to its stockholders for the amount of Silverback Net Cash that exceeds $255 million); and
- ARS Pharma must have received a copy of the required Lock-Up Agreements from certain executive officers, directors and stockholders of Silverback, each of which must be in full force and effect as of the Closing.

"Silverback Material Adverse Effect" means any effect, change, event, circumstance or development (collectively, "Effect") that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of Silverback; *provided*, *however*, that Effects resulting from the following will not be taken into account in determining whether there has been a Silverback Material Adverse Effect: (a) general business or economic conditions generally affecting the industry in which Silverback operates, (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions, (c) changes in financial, banking or securities markets, (d) any change in the stock price or trading volume of Silverback Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Silverback Common Stock may be taken into account in determining whether a Silverback Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (e) the failure of Silverback to meet internal or analysts' expectations or projections or the results of operations of Silverback; (f) any change in, or any compliance with or action taken for the purpose of complying with, any law or GAAP (or interpretations of any law or GAAP), (g) resulting from the announcement of the Merger Agreement or the pendency of the Contemplated Transactions, (h) the Asset Dispositions, (i) any reduction in the amount of Silverback's cash and cash equivalents as a result of expenditures made by Silverback related to wind-down activities of Silverback associated with the termination of its research and development activities (including the termination of ongoing contractual obligations relating to Silverback current products or product candidates), or (j) resulting from the taking of any action required to be taken by the Merger Agreement, except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting Silverback relative to other similarly situated companies in the industries in which Silverback operates.

"ARS Pharma Material Adverse Effect" means any Effect that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of ARS Pharma or its Subsidiaries, taken as a whole; *provided*, *however*, that Effects resulting from the following will not be taken into account in determining whether there has been an ARS Pharma Material Adverse Effect: (a) general business or economic conditions generally affecting the industry in which ARS Pharma and its Subsidiaries operate, (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions, (c) changes in financial, banking or securities markets, (d) any change in, or any compliance with or action taken for the purpose of complying with, any law or GAAP (or interpretations of any law or GAAP), (e) resulting from the announcement of the Merger Agreement or the pendency of the Contemplated Transactions, or (f) resulting from the taking of any action required to be taken by the Merger Agreement, except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting ARS Pharma and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which ARS Pharma and its Subsidiaries operate.

Calculation of Silverback Net Cash

At least 10 calendar days prior to the Silverback virtual special meeting, Silverback and ARS Pharma will agree upon the anticipated date for Closing (the "Anticipated Closing Date"). At least five calendar days prior to the Anticipated Closing Date, Silverback will deliver to ARS Pharma a schedule (the "Net Cash Schedule") setting forth, in reasonable detail, Silverback's good faith, estimated calculation of Silverback Net Cash as of the Anticipated Closing Date, prepared and certified by an officer of Silverback, together with the relevant work papers and back-up materials used or useful in

preparing the Net Cash Schedule as reasonably requested by ARS Pharma. Within three calendar days after delivery of the Net Cash Schedule (the "Response Date"), ARS Pharma will have the right to dispute any part of the Net Cash Schedule by delivering a written notice to that effect to Silverback (a "Dispute Notice"). Any Dispute Notice will identify in reasonable detail the nature of any proposed revisions to the Silverback Net Cash calculation.

If on or prior to the Response Date, ARS Pharma (i) notifies Silverback in writing that it has no objections to the Silverback Net Cash calculation or (ii) fails to deliver a Dispute Notice, then the Silverback Net Cash calculation as set forth in the Net Cash Schedule will be deemed to have been finally determined for purposes of the Merger Agreement and to represent Silverback Net Cash at the Anticipated Closing Date for purposes of the Merger Agreement.

If ARS Pharma delivers a Dispute Notice on or prior to the Response Date, then representatives of both parties will promptly meet and attempt in good faith to resolve the disputed item(s) and negotiate an agreed-upon determination of Silverback Net Cash, which agreed upon Silverback Net Cash amount will be deemed to have been finally determined for purposes of the Merger Agreement and to represent the Silverback Net Cash, at the Anticipated Closing Date for purposes of the Merger Agreement.

If representatives of Silverback and ARS Pharma are unable to negotiate an agreed-upon determination of Silverback Net Cash, at the Anticipated Closing Date, within three calendar days after delivery of the Dispute Notice (or such other period as Silverback and ARS Pharma may mutually agree upon), then Silverback and ARS Pharma will jointly select an independent auditor of recognized national standing (the "Accounting Firm") to resolve any remaining disagreements as to the Silverback Net Cash calculation. Silverback will promptly deliver to the Accounting Firm the work papers and back-up materials used in preparing the Net Cash Schedule, and Silverback and ARS Pharma will use commercially reasonable efforts to cause the Accounting Firm to make its determination within 10 calendar days of accepting its selection. Silverback and ARS Pharma will be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; *provided, however*, that no such presentation or discussion will occur without the presence of a representative of each of Silverback and ARS Pharma. The determination of the Accounting Firm will be limited to the disagreements submitted to the Accounting Firm. The determination of the amount of Silverback Net Cash, made by the Accounting Firm will be deemed to have been finally determined for purposes of the Merger Agreement and to represent Silverback Net Cash, at the Anticipated Closing Date for purposes of the Merger Agreement, and the parties will delay the Closing until the resolution of the Silverback Net Cash calculation. The fees and expenses of the Accounting Firm will be allocated between Silverback and ARS Pharma in the same proportion that the disputed amount of Silverback Net Cash that was unsuccessfully disputed by such party (as finally determined by the Accounting Firm) bears to the total disputed amount of Silverback Net Cash, (and for the avoidance of doubt such fees and expenses of the Accounting Firm allocated to Silverback will reduce Silverback Net Cash). If the determination of Silverback Net Cash at the Anticipated Closing Date and the resolution of the matter is done in accordance with this paragraph, the parties will not be required to determine Silverback Net Cash, again even though the Closing may occur later than the Anticipated Closing Date, except that either party may request a re-determination of Silverback Net Cash if the Closing date is more than five business days after the Anticipated Closing Date.

Potential Asset Disposition

Silverback is entitled, but under no obligation, to separate into a new company or sell, transfer, assign or otherwise divest its preclinical assets to a third party in one or a series of transactions prior to, concurrently with, or immediately following the Closing (the "Asset Dispositions"); *provided, however*, that Silverback will notify ARS Pharma at least five business days prior to entering into any

agreement with respect to any Asset Disposition, provide copies of all written agreements or documents with respect to such sale and provide ARS Pharma with an opportunity to provide comments to such documents, which comments will be considered by Silverback in good faith, *provided, however,* that the inclusion or exclusion of such ARS Pharma comments will be at the sole discretion of Silverback after having considered such comments in good faith and engaging in good faith discussions with the ARS Pharma regarding the same; and *provided further, however*, that any such Asset Disposition that would create any material post-disposition liabilities for Silverback following the Closing will require, to the extent consistent with applicable laws, the written consent of ARS Pharma, not to be unreasonably withheld, delayed or conditioned. If the Asset Dispositions are not completed prior to, concurrently with, or immediately following the Closing, Silverback's preclinical assets will be retained by Silverback and the value of such assets will have no impact on the calculation of the Exchange Ratio.

Representations and Warranties

The Merger Agreement contains customary representations and warranties of the parties. ARS Pharma represents and warrants to the following matters:

- Due Organization; Subsidiaries
- Organizational Documents
- Authority; Binding Nature of Agreement
- Vote Required
- Non-Contravention; Consents
- Capitalization
- Financial Statements
- Absence of Changes
- Absence of Undisclosed Liabilities
- Title to Assets
- Real Property; Leasehold
- Intellectual Property
- Agreements, Contracts and Commitments
- Compliance; Permits; Restrictions
- Legal Proceedings; Orders
- Tax Matters
- Employee and Labor Matters; Benefit Plans
- Environmental Matters
- Insurance
- No Financial Advisors
- Transactions with Affiliates
- Anti-Bribery
- Disclaimer of Other Representations and Warranties

Silverback and Merger Sub represent and warrant to the following matters:

- Due Organization; No Subsidiaries
- Organizational Documents
- Authority; Binding Nature of Agreement
- Vote Required
- Non-Contravention; Consents
- Capitalization
- SEC Filings; Financial Statements
- Absence of Changes
- Absence of Undisclosed Liabilities
- Title to Assets
- Real Property; Leasehold
- Intellectual Property
- Agreements, Contracts and Commitments
- Compliance; Permits
- Legal Proceedings; Orders
- Tax Matters
- Employee and Labor Matters; Benefit Plans
- Environmental Matters
- Transactions with Affiliates
- Insurance
- No Financial Advisors
- Anti-Bribery
- Valid Issuance
- Opinion of Financial Advisor
- Disclaimer of Other Representations and Warranties

The representations and warranties of ARS Pharma, Silverback and Merger Sub contained in the Merger Agreement or any certificate or instrument delivered pursuant to the Merger Agreement will terminate at the Effective Time.

Non-Solicitation

Both Silverback and ARS Pharma are prohibited by the terms of the Merger Agreement, other than, in the case of Silverback, with respect to any Asset Disposition, from (i) soliciting, initiating or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any Acquisition Proposal (as defined below) or Acquisition Inquiry (as defined below) or taking any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnishing any non-public information regarding such party to any person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engaging in discussions or negotiations with any person with respect to any Acquisition Proposal or Acquisition Inquiry;

(iv) approving, endorsing or recommending any Acquisition Proposal; (v) executing or entering into any letter of intent or any contract contemplating or otherwise relating to any Acquisition Transaction (as defined below) (other than, in the case of Silverback, a confidentiality agreement permitted as described below); or (vi) publicly proposing to do any of the foregoing.

Pursuant to the terms of the Merger Agreement, each of Silverback and ARS Pharma agreed to immediately cease and cause to be terminated any existing discussions, negotiations and communications with any person relating to any Acquisition Proposal or Acquisition Inquiry as of the date of the Merger Agreement and request the destruction or return of any of such party's nonpublic information.

Subject to certain restrictions and prior to obtaining the approval of the Merger Proposal by the Required Silverback Stockholder Vote (as defined below), Silverback may furnish non-public information regarding Silverback to, and enter into discussions or negotiations with, any person in response to an unsolicited *bona fide* Acquisition Proposal by such person, which the Silverback Board determines in good faith, after consultation with its outside financial advisors and outside legal counsel, constitutes, or could be reasonably likely to result in, a Superior Offer (as defined below) (and is not withdrawn) if: (A) neither Silverback nor any of its representatives have breached the non-solicitation restrictions in the Merger Agreement in any material respect, (B) the Silverback Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action could be reasonably likely to be inconsistent with the fiduciary duties of the Silverback Board under applicable law; (C) Silverback receives from such person an executed confidentiality agreement containing provisions, in the aggregate, at least as favorable to it as those contained in the confidentiality agreement entered into between Silverback and ARS Pharma in connection with the Merger; and (D) substantially contemporaneously with furnishing any such nonpublic information to such person, Silverback furnishes such nonpublic information to the ARS Pharma (to the extent such information has not been previously furnished to ARS Pharma).

If Silverback or ARS Pharma or any of their respective representatives, receives an Acquisition Proposal or Acquisition Inquiry during the period following the date of the Merger Agreement through the Closing, then such party will promptly (and in no event later than one business day after such party becomes aware of such Acquisition Proposal or Acquisition Inquiry) advise the other party orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the person making or submitting such Acquisition Proposal or Acquisition Inquiry and the material terms thereof) and, in the case of Silverback, provide a copy of any written Acquisition Proposal or Acquisition Inquiry to ARS Pharma. Each party will keep the other party reasonably informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and any material modification thereto.

"Acquisition Inquiry" means, with respect to a party, an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by ARS Pharma, on the one hand, or Silverback, on the other hand, to the other party) that would reasonably be expected to lead to an Acquisition Proposal.

"Acquisition Proposal" means, with respect to a party, any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of ARS Pharma or any of its affiliates, on the one hand, or by or on behalf of Silverback or any of its affiliates, on the other hand, to the other party) contemplating or otherwise relating to or which would reasonably be interpreted to lead to any Acquisition Transaction with such party, other than the Asset Dispositions.

"Acquisition Transaction" means any transaction or series of related transactions (other than the Asset Dispositions) involving:

- any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction: (i) in which a party is a constituent entity; (ii) in which a person or "group" (as defined in the Exchange Act and the rules promulgated thereunder) of persons directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of a party or any of its subsidiaries; or (iii) in which a party or any of its subsidiaries issues securities representing more than 20% of the outstanding securities of any class of voting securities of such party or any of its subsidiaries; or
- any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of a party and its subsidiaries, taken as a whole.

"Superior Offer" means an unsolicited bona fide written Acquisition Proposal (with all references to 20% in the definition of Acquisition Transaction being treated as references to greater than 50% for these purposes) that: (a) was not obtained or made as a direct or indirect result of a breach of (or in violation of) the Merger Agreement; and (b) is on terms and conditions that the Silverback Board determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation thereof), as well as any written offer by the other party to the Merger Agreement to amend the terms of the Merger Agreement, and following consultation with its outside legal counsel and outside financial advisors, if any, are more favorable, from a financial point of view, to Silverback's stockholders than the terms of the Contemplated Transactions.

Silverback Stockholder Meeting

Promptly as reasonably practicable after the resolution of SEC staff comments and the filing of the definitive proxy statement related to the approval of the Merger, Silverback will take all action necessary under applicable law to call, give notice of and hold the a special meeting of the Silverback stockholders for the purpose of seeking approval of (i) the Merger Proposal, (ii) in accordance with Section 14A of the Exchange Act and the applicable SEC rules issued thereunder, seeking advisory approval of a proposal to Silverback's stockholders for a non-binding, advisory vote to approve certain compensation that may become payable to Silverback's named executive officers in connection with the completion of the Merger, if applicable, and (iii) any other proposals the parties deem necessary or desirable to consummate the Contemplated Transactions (together with the proposal set forth in the foregoing clause (ii), the "Other Stockholder Proposals").

The Silverback virtual special meeting will be held as promptly as practicable after filing the definitive proxy statement related to the approval of the Merger. Silverback will take reasonable measures to ensure that all proxies solicited in connection with the Silverback virtual special meeting are solicited in compliance with all applicable law. If, on or before the date of the Silverback virtual special meeting, Silverback reasonably believes that it (i) will not receive proxies sufficient to obtain the required approvals of the Merger Proposal (the "Required Silverback Stockholder Vote"), whether or not a quorum would be present or (ii) will not have sufficient shares of Silverback Common Stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Silverback virtual special meeting, Silverback may postpone or adjourn the Silverback special meeting as long as the date of the Silverback virtual special meeting is not postponed or adjourned more than an aggregate of 60 calendar days in connection with any postponements or adjournments.

Silverback agreed that, subject to certain exceptions in the Merger Agreement: (i) the Silverback Board will recommend that the holders of Silverback Common Stock vote to approve the Merger

Proposal and the Other Stockholder Proposals, (ii) this proxy statement will include a statement to the effect that the Silverback Board recommends that Silverback's stockholders vote to approve the Merger Proposal (the recommendation of the Silverback Board with respect to the Merger Proposal being referred to as the "Silverback Board Recommendation") and the Other Stockholder Proposals; and (iii) the Silverback Board Recommendation will not be withheld, amended, withdrawn or modified (and the Silverback Board will not publicly propose to withhold, amend, withdraw or modify the Silverback Board Recommendation) in a manner adverse to ARS Pharma (the actions set forth in the foregoing clause (iii), collectively, a "Silverback Board Adverse Recommendation Change").

The terms of the Merger Agreement provide that if at any time prior to the approval of Merger Proposal by the Required Silverback Stockholder Vote, Silverback receives a written Acquisition Proposal (which did not arise out of a material breach of the non-solicitation provisions of the Merger Agreement) from any person that has not been withdrawn and after consultation with outside legal counsel, the Silverback Board determines, in good faith, that such Acquisition Proposal is a Superior Offer, the Silverback Board may make a Silverback Board Adverse Recommendation Change or terminate the Merger Agreement to enter into a definitive agreement with respect to such Superior Offer, if and only if all of the following apply: (A) the Silverback Board determines in good faith, after consultation with Silverback's outside legal counsel, that the failure to do so would be reasonably likely to be inconsistent with the fiduciary duties of the Silverback Board to Silverback's stockholders under applicable law; (B) Silverback has given ARS Pharma prior written notice of its intention to consider making a Silverback Board Adverse Recommendation Change or terminate the Merger Agreement to enter into a definitive agreement with respect to such Superior Offer at least three business days prior to making any such Silverback Board Adverse Recommendation Change or termination (a "Silverback Determination Notice") (which notice will not constitute a Silverback Board Adverse Recommendation Change); and (C) (1) Silverback provided to ARS Pharma a summary of the material terms and conditions of the Acquisition Proposal in accordance with the Merger Agreement, (2) Silverback has given ARS Pharma three business days after the Silverback Determination Notice to propose revisions to the terms of the Merger Agreement or make another proposal and has made its representatives reasonably available to negotiate in good faith with ARS Pharma (to the extent ARS Pharma desires to negotiate) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by ARS Pharma, if any, after consultation with outside legal counsel, the Silverback Board determines, in good faith, that such Acquisition Proposal is a Superior Offer and that the failure to make the Silverback Board Adverse Recommendation Change or terminate the Merger Agreement to enter into a definitive agreement with respect to such Superior Offer would be reasonably likely to be inconsistent with the fiduciary duties of the Silverback Board to Silverback's stockholders under applicable law. The provisions of the Merger Agreement described in this paragraph also apply to any material change to the facts and circumstances relating to such Acquisition Proposal and require a new Silverback Determination Notice, except that the references to three business days will be deemed to be two business days.

The terms of the Merger Agreement also provide that, other than in connection with an Acquisition Proposal, the Silverback Board may make a Silverback Board Adverse Recommendation Change in response to a Silverback Change in Circumstance (as defined below), if and only if: (A) the Silverback Board determines in good faith, after consultation with the Silverback's outside legal counsel, that the failure to do so would be reasonably likely to be inconsistent with the fiduciary duties of the Silverback Board to Silverback's stockholders under applicable law; (B) Silverback has given ARS Pharma a Silverback Determination Notice at least three business days prior to making any such Silverback Board Adverse Recommendation Change; and (C) (1) Silverback has specified the Silverback change in circumstance in reasonable detail, (2) Silverback has given ARS Pharma three business days after the Silverback Determination Notice to propose revisions to the terms of the Merger Agreement or make another proposal, and has made its representatives reasonably available to negotiate in good faith with ARS Pharma with respect to such proposed revisions or other proposal,

if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by ARS Pharma, if any, after consultation with outside legal counsel, the Silverback Board determines, in good faith, that the failure to make the Silverback Board Adverse Recommendation Change in response to such Silverback change in circumstance would be reasonably likely to be inconsistent with the fiduciary duties of the Silverback Board to Silverback's stockholders under applicable law. The provisions of the Merger Agreement described in this paragraph also apply to any material change to the facts and circumstances relating to such Silverback change in circumstance and require a new Silverback Determination Notice, except that the references to three business days will be deemed to be two business days.

A "Silverback Change in Circumstance" means a change in circumstances (other than an Acquisition Proposal) that affects the business, assets or operations of Silverback that occurs or arises after the date of the Merger Agreement that was neither known to Silverback or the Silverback Board nor reasonably foreseeable on, or prior to, the date of the Merger Agreement.

ARS Pharma Stockholder Action by Written Consent

The Merger Agreement contemplates that, as promptly as reasonably practicable after the date of the Merger Agreement, and in any event no later than one business day after the date of the Merger Agreement, ARS Pharma will obtain the ARS Pharma Stockholder Written Consent which contains the Required ARS Pharma Stockholder Vote. In addition, certain officers, directors and stockholders of ARS Pharma which represent at least 75% of the voting securities of ARS Pharma will execute such ARS Pharma Stockholder Written Consent and will execute an investor questionnaire, with no more than 10 of such officers, directors and stockholders representing that they are not "accredited investors" as defined in Regulation D promulgated under the Securities Act.

As promptly as reasonably practicable after the date of the Merger Agreement, and in any even no later than three business days after the date of the Merger Agreement or such date as the parties mutually agree, ARS Pharma will prepare, with the cooperation of Silverback, and cause to be mailed, distributed or otherwise made available to its stockholders that did not execute the ARS Pharma Stockholder Written Consent an information statement requirements of Rule 502(b) of Regulation D promulgated under the Securities Act.

ARS Pharma agreed that: (i) the ARS Pharma Board will recommend that the ARS Pharma stockholders vote to approve the ARS Pharma Stockholder Matters and will use reasonable best efforts to solicit such approval certain officers, directors and stockholders of ARS Pharma which represent at least 75% of the voting securities of ARS Pharma within one business day after the Merger Agreement (the recommendation of the ARS Pharma Board that ARS Pharma's stockholders vote to adopt and approve the ARS Pharma Stockholder Matters being referred to as the "ARS Pharma Board Recommendation"); and (ii) the ARS Pharma Board Recommendation will not be withdrawn or modified (and the ARS Pharma Board will not publicly propose to withdraw or modify the ARS Pharma Board Recommendation) in a manner adverse to Silverback, and no resolution by the ARS Pharma Board or any committee thereof to withdraw or modify the ARS Pharma Board Recommendation in a manner adverse to Silverback or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any Acquisition Proposal will be adopted or proposed (the actions set forth in the foregoing clause (ii), collectively, a "ARS Pharma Board Recommendation Change").

On the date of the Merger Agreement, ARS Pharma delivered the ARS Pharma Stockholder Written Consent which contained the Required ARS Pharma Stockholder Vote and was signed by certain officers, directors and stockholders of ARS Pharma which represent approximately 83% of the outstanding shares of ARS Capital Stock immediately prior to the date of the Merger Agreement. All of

such officers, directors and stockholders of ARS completed an investor questionnaire representing that they were "accredited investors" as defined in Regulation D promulgated under the Securities Act.

Appraisal Rights and Dissenters' Rights

Under the DGCL, Silverback stockholders are not entitled to appraisal rights in connection with the Merger.

ARS Pharma stockholders are entitled to statutory appraisal rights in connection with the Merger under Section 262 of the DGCL and under Chapter 13 of the California Corporations Code. One of the conditions to Silverback's obligation to consummate the Merger is that no stockholders of ARS Pharma shall have exercised statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of California Corporations Code with respect to their shares of ARS Pharma Capital Stock.

As of the date of the Merger Agreement, ARS Pharma stockholders representing approximately 83% of the outstanding shares of ARS Capital Stock immediately prior to the date of the Merger Agreement waived any statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of California Corporations Code with respect to their shares of ARS Pharma Capital Stock.

Covenants; Operation of Business Pending the Merger

During the period from the date of the Merger Agreement and continuing until the earlier of the termination of the Merger Agreement or the Effective Time, except (i) as set forth in Silverback's disclosure schedule, (ii) expressly permitted or required in accordance with the Merger Agreement, (iii) as required by applicable law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary (A) to protect the health and safety of Silverback's employees, (B) to respond to third party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable law, directive or guideline from any governmental body arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as may be consented to in writing by ARS Pharma (not be unreasonably withheld, delayed or conditioned), Silverback has agreed to conduct its business and operations in the ordinary course of business (which includes actions required to effect the Asset Dispositions or effect the winding down of Silverback's prior research and development activities) and in compliance in all material respects with all applicable laws and the requirements of all of its material contracts, and will not:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire, directly or indirectly, any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Silverback or in connection with the payment of the exercise price and/or withholding taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Silverback Equity Incentive Plans in accordance with the terms of such award in effect on the date of the Merger Agreement); *provided, however*, that to the extent that Silverback Net Cash is greater than $255 million, Silverback will be permitted to declare any such excess amount as a dividend;
- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Silverback (except for Silverback Common Stock issued upon the valid exercise of outstanding Silverback options or upon settlement of purchase rights under Silverback's 2020 Employee Stock Purchase Plan (the "Silverback ESPP") or Silverback restricted stock units); (B) any option, warrant or right to acquire any capital stock or any other security other than stock options or restricted stock unit awards granted to employees and service providers or offerings providing eligible employees with purchase rights under the Silverback ESPP, in either case, in the ordinary course of

business which are included in the calculation of the Silverback Outstanding Shares; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Silverback;

- except as required to give effect to anything in contemplation of the Closing, amend any of its organizational documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;
- (A) lend money to any person (except for the advancement of expenses to employees and directors in the ordinary course of business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of any Transaction Expenses, make any capital expenditure in excess of $50,000;
- forgive any loans to any person, including its employees, officers, directors or affiliates;
- other than as required by applicable law or the terms of any Silverback benefit plan as in effect on the date of the Merger Agreement: (A) adopt, terminate, establish or enter into any Silverback benefit plan; (B) cause or permit any Silverback benefit plan to be amended in any respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees other than increases in base salary and annual cash bonus opportunities and payments made in the ordinary course of business consistent with past practice; (D) increase the severance or change of control benefits offered to any current or new employees, directors or consultants or (E) hire any (x) officer or (y) employee whose annal base salary is or is expected to be more than $250,000 per year;
- recognize any labor union or labor organization, except as otherwise required by applicable law and after prior written consent of ARS Pharma (not be unreasonably withheld, conditioned or delayed);
- enter into any material transaction other than in the ordinary course of business;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its assets or properties, or grant any encumbrance with respect to such assets or properties, except in the ordinary course of business;
- either solely or in collaboration with any third party, directly or indirectly, commence, enter, join, revive, solicit, or otherwise get engaged in, any clinical trial other than the clinical trials existing on or prior to the date of the Merger Agreement and disclosed by Silverback;
- sell, assign, transfer, license, sublicense or otherwise dispose of any material Silverback intellectual property (other than pursuant to non-exclusive licenses in the ordinary course of business);
- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability or submit any voluntary disclosure application, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of business the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of business of not more than seven months), or adopt or change any material accounting method in respect of taxes;

- enter into, materially amend or terminate any Silverback material contract;
- other than as required by law or GAAP, take any action to change accounting policies or procedures;
- initiate or settle any legal proceeding;
- enter into or amend a contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions; or
- agree, resolve or commit to do any of the foregoing.

During the period from the date of the Merger Agreement and continuing until the earlier of the termination of the Merger Agreement or the Effective Time, except (i) as set forth in ARS Pharma's disclosure schedule, (ii) expressly permitted or required in accordance with the Merger Agreement, (iii) as required by applicable law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary (A) to protect the health and safety of ARS Pharma's employees, (B) to respond to third party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable law, directive or guideline from any governmental body arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as may be consented to in writing by Silverback (not be unreasonably withheld, delayed or conditioned), ARS Pharma has agreed to conduct its business and operations in the ordinary course of business and in compliance in all material respects with all applicable laws and the requirements of all of its material contracts, and will not, and will not cause or permit any of its subsidiaries to:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire, directly or indirectly, any shares of its capital stock or other securities (except in connection with the payment of the exercise price and/or withholding taxes incurred upon the exercise, settlement or vesting of any award granted under the ARS 2018 Plan in accordance with the terms of such award in effect on the date of the Merger Agreement);
- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of ARS Pharma or any of its subsidiaries (except for ARS Pharma Common Stock issued upon the valid exercise of outstanding ARS Pharma stock options); (B) any option, warrant or right to acquire any capital stock or any other security other than stock options or restricted stock unit awards granted to employees and service providers in the ordinary course of business which are included in the calculation of the ARS Pharma Outstanding Shares; or (C) any instrument convertible into or exchangeable for any capital stock or other security of ARS Pharma or any of its subsidiaries;
- except as required to give effect to anything in contemplation of the Closing, amend any of its or its subsidiaries' organizational documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, in connection with the Contemplated Transactions;
- form a subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;
- (A) lend money to any person (except for the advancement of expenses to employees and directors in the ordinary course of business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of any Transaction Expenses, make any capital expenditures in excess of the budgeted capital expenditure amounts set forth in ARS Pharma's operating budget delivered to Silverback on the date of the Merger Agreement (the "ARS Pharma Budget");

- other than as required by applicable law or the terms of any ARS Pharma benefit plan as in effect on the date of the Merger Agreement: (A) adopt, terminate, establish or enter into any ARS Pharma benefit plan; (B) cause or permit any ARS Pharma benefit plan to be amended in any respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees other than increases in base salary and annual cash bonus opportunities and payments made in the ordinary course of business consistent with past practice and which do not exceed, in the aggregate, the amounts specifically budgeted therefor in the ARS Pharma Budget; (D) increase the severance or change of control benefits offered to any current or new employees, directors or consultants (E) hire any (x) officer or (y) employee whose annual base salary is or is expected to be more than $250,000 per year or (F) terminate or give notice of termination to any officer other than for cause;
- recognize any labor union or labor organization, except as otherwise required by applicable law and after prior written consent of Silverback (not be unreasonably withheld, conditioned or delayed;
- enter into any material transaction other than in the ordinary course of business;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its assets or properties, or grant any encumbrance with respect to such assets or properties, except in the ordinary course of business;
- sell, assign, transfer, license, sublicense or otherwise dispose of any Company intellectual property (other than pursuant to non-exclusive licenses in the ordinary course of business);
- make, change or revoke any material tax election, fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return, settle or compromise any income or other material tax liability or submit any voluntary disclosure application, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the ordinary course of business the principal subject matter of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than pursuant to an extension of time to file any tax return granted in the ordinary course of business of not more than seven months), or adopt or change any material accounting method in respect of taxes;
- enter into, materially amend or terminate any ARS Pharma material contract;
- other than as required by law or GAAP, take any action to change accounting policies or procedures;
- initiate or settle any legal proceeding;
- enter into or amend a contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions; or
- agree, resolve or commit to do any of the foregoing.

Termination and Termination Fees

The Merger Agreement may be terminated prior to the Effective Time (whether before or after the required stockholder approvals to complete the Merger have been obtained, unless otherwise specified below):

(a) by mutual written consent of Silverback and ARS Pharma;

(b) by either Silverback or ARS Pharma if the Contemplated Transactions have not been consummated by January 21, 2023 (subject to possible extension as provided in this paragraph, the "End Date"); *provided*, *however*, that the right to terminate the Merger Agreement under this paragraph will not be available to a party if such party's action or failure to act has been a principal cause of the failure of the Contemplated Transactions to occur on or before the End Date and such action or failure to act constitutes a breach of the Merger Agreement; *provided*, *further*, *however*, that, in the event that a request for additional information has been made by any governmental body (including via a comment letter or other communication from the SEC) which request has not been satisfied by January 21, 2023, then either party will be entitled to extend the End Date for an additional 60 calendar days by written notice to the other party;

(c) by either Silverback or ARS Pharma if a court of competent jurisdiction or other governmental body has issued a final and non-appealable order, decree or ruling, or has taken any other action, having the effect of permanently restraining, enjoining or otherwise prohibiting the Contemplated Transactions;

(d) by Silverback if the ARS Pharma Stockholder Written Consent executed by certain officers, directors and stockholders of ARS Pharma which represent at least 75% of the voting securities of ARS Pharma has not been obtained within one business day of the date of the Merger Agreement; *provided, however,* that once the ARS Pharma Stockholder Written Consent has been obtained, Silverback may not terminate the Merger Agreement pursuant to this paragraph;

(e) by either Silverback or ARS Pharma if (i) the Silverback virtual special meeting (including any adjournments and postponements thereof) was held and completed and (ii) the Merger Proposal was not approved at such Silverback virtual special meeting by the Required Silverback Stockholder Vote;

(f) by ARS Pharma (at any time prior to the approval of the Merger Proposal by the Required Silverback Stockholder Vote) if a Silverback Triggering Event (as defined below) has occurred;

(g) by Silverback (at any time prior to the Required ARS Pharma Stockholder Vote being obtained) if an ARS Pharma Triggering Event (as defined below) has occurred;

(h) by ARS Pharma, upon a breach of any representation, warranty, covenant or agreement set forth in the Merger Agreement by Silverback or Merger Sub or if any representation or warranty of Silverback or Merger Sub has become inaccurate, in either case, such that certain closing conditions set forth in the Merger Agreement would not be satisfied as of the time of such breach or as of the time such representation or warranty has become inaccurate; provided that ARS Pharma is not then in material breach of any representation, warranty, covenant or agreement under the Merger Agreement; provided, further, that if such inaccuracy in Silverback's or Merger Sub's representations and warranties or breach by Silverback or Merger Sub is curable by the End Date by Silverback or Merger Sub, then the Merger Agreement will not terminate pursuant to this paragraph as a result of such particular breach or inaccuracy until the earlier of (i) End Date and (ii) the expiration of a 30 calendar day period commencing upon delivery of written notice from ARS Pharma to Silverback or Merger Sub of such breach or inaccuracy and its intention to terminate pursuant to this paragraph (it being understood that the Merger Agreement will not terminate pursuant to this paragraph as a result of such particular breach or inaccuracy if such breach by Silverback or Merger Sub is cured prior to such termination becoming effective);

(i) by Silverback, upon a breach of any representation, warranty, covenant or agreement set forth in the Merger Agreement by ARS Pharma or if any representation or warranty of ARS

Pharma has become inaccurate, in either case, such that certain closing conditions set forth in the Merger Agreement would not be satisfied as of the time of such breach or as of the time such representation or warranty has become inaccurate; provided that Silverback is not then in material breach of any representation, warranty, covenant or agreement under the Merger Agreement; provided, further, that if such inaccuracy in the ARS Pharma's representations and warranties or breach by ARS Pharma is curable by End Date by ARS Pharma then the Merger Agreement will not terminate pursuant to this paragraph as a result of such particular breach or inaccuracy until the earlier of (i) End Date and (ii) the expiration of a 30 calendar day period commencing upon delivery of written notice from Silverback to ARS Pharma of such breach or inaccuracy and its intention to terminate pursuant to this paragraph (it being understood that the Merger Agreement will not terminate pursuant to this paragraph as a result of such particular breach or inaccuracy if such breach by ARS Pharma is cured prior to such termination becoming effective); or

(j) by Silverback, at any time, if (i) Silverback has received a Superior Offer, (ii) Silverback has complied with its obligations under the Merger Agreement in order to accept such Superior Offer, (iii) Silverback concurrently terminates the Merger Agreement and enters into a definitive agreement with respect to such Superior Offer and (iv) within two business days of such termination, Silverback pays to ARS Pharma the applicable termination fee.

The party desiring to terminate the Merger Agreement will give the other party written notice of such termination, specifying the provisions of the Merger Agreement pursuant to which such termination is made and the basis therefor described in reasonable detail.

"ARS Pharma Triggering Event" will be deemed to have occurred if: (a) ARS Pharma has made an ARS Pharma Board Adverse Recommendation Change; (b) the ARS Pharma Board or any committee thereof has publicly approved, endorsed or recommended any Acquisition Proposal; or (c) ARS Pharma has entered into any letter of intent or similar document relating to any Acquisition Proposal in violation of the terms of the Merger Agreement.

"Silverback Triggering Event" will be deemed to have occurred if: (a) Silverback has failed to include in the proxy statement the Silverback Board Recommendation or has made a Silverback Board Adverse Recommendation Change; (b) the Silverback Board or any committee thereof has publicly approved, endorsed or recommended any Acquisition Proposal; or (c) Silverback has entered into any letter of intent or similar document relating to any Acquisition Proposal (other than a confidentiality agreement permitted pursuant to the Merger Agreement) in violation of the terms of the Merger Agreement.

Silverback must pay ARS Pharma a termination fee of $6 million if (i) (A) the Merger Agreement is terminated pursuant to clause (b), (e) or (h) above, (B) an Acquisition Proposal with respect to Silverback has been publicly announced or publicly disclosed to Silverback or the Silverback Board after the date of the Merger Agreement but prior to the termination of the Merger Agreement (which has not been withdrawn) and (C) within 12 months after the date of such termination, Silverback consummates a subsequent transaction in respect of such Acquisition Proposal and (ii) the Merger Agreement is terminated by ARS Pharma pursuant to clause (f) above (or at the time the Merger Agreement is terminated, ARS Pharma has the right to terminate the Merger Agreement pursuant to clause (f) above). Silverback must pay ARS Pharma a termination fee of $10 million if the Merger Agreement is terminated by Silverback pursuant to clause (j) above.

ARS Pharma must pay Silverback a termination fee of $6 million if (i) (A) the Merger Agreement is terminated pursuant to clause (b), (e) or (i) above, (B) an Acquisition Proposal with respect to ARS Pharma has been publicly announced or publicly disclosed to ARS Pharma or the ARS Pharma Board

after the date of the Merger Agreement but prior to the termination of the Merger Agreement (which has not been withdrawn) and (C) within 12 months after the date of such termination, ARS Pharma consummates a subsequent transaction in respect of such Acquisition Proposal and (ii) the Merger Agreement is terminated by Silverback pursuant to clause (g) above (or at the time the Merger Agreement is terminated, Silverback has the right to terminate the Merger Agreement pursuant to clause (g) above).

If the Merger Agreement is terminated by either ARS Pharma or Silverback pursuant to clause (e) above, Silverback will reimburse ARS Pharma for all reasonable out-of-pocket fees and expenses incurred by ARS Pharma in connection with the Merger Agreement and the Contemplated Transactions, up to a maximum of $1,500,000, by wire transfer of same-day funds within three business days following the date on which ARS Pharma submits to Silverback true and correct copies of reasonable documentation supporting such expenses.

Other Agreements

Director Indemnification and Insurance

The Merger Agreement provides that, subject to certain limitations as set forth in the Merger Agreement, from the Effective Time through the sixth anniversary of the date on which the Effective Time occurs, Silverback and the surviving company will fulfill Silverback and ARS Pharma's indemnity obligations, respectively, to each person who is, has been at any time prior to the date of the Merger Agreement, or who becomes prior to the Effective Time, a director, officer, fiduciary or agent of Silverback or ARS Pharma and their respective subsidiaries.

The Merger Agreement also provides that the provisions relating to the indemnification, advancement of expenses and exculpation of present and former directors and officers of Silverback set forth in Silverback's organizational documents will not be amended, modified or repealed for a period of six years from the Effective Time in any manner that would adversely affect the rights of individuals who, at or prior to the Effective Time, were officers or directors of Silverback. After the Closing, the organizational documents the surviving corporation will contain provisions at least as favorable as the provisions relating to the indemnification, advancement of expenses and exculpation of present and former directors and officers presently set forth in Silverback's organizational documents as of the date of the Merger Agreement. Silverback has agreed to secure and prepay a six year "tail policy" with an effective date as of the date of the Closing for the non-cancellable extension of Silverback's existing directors' and officers' liability insurance policy (the "D&O Tail Policy").

Listing

Silverback Common Stock currently is listed on The Nasdaq Global Market under the symbol "SBTX." Silverback has agreed to use commercially reasonable efforts (i) to maintain its existing listing on Nasdaq until the Effective Time and obtain approval of the listing of the combined company on Nasdaq, (ii) to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Silverback Common Stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance), and (iii) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial Nasdaq Listing Application for the Silverback Common Stock on Nasdaq and to cause such listing application to be conditionally approved prior to the Effective Time.

The parties will reasonably promptly inform the other of all verbal or written communications between Nasdaq and such party or its representatives, and will use commercially reasonable efforts to coordinate with respect to compliance with Nasdaq rules and regulations. ARS Pharma agrees to pay

all Nasdaq fees associated with the Nasdaq Listing Application. ARS Pharma will cooperate with Silverback as reasonably requested by Silverback with respect to the Nasdaq Listing Application and promptly furnish to Silverback all information concerning ARS Pharma and its stockholders that may be required or reasonably requested in connection with any action contemplated thereby.

Expenses

Pursuant to the Merger Agreement, all the Transaction Expenses will be paid by the party incurring such expense, whether or not the Merger is consummated, except (i) Silverback and ARS Pharma will each pay one-half of (a) the expenses in connection with the printing and filing of this proxy statement with the SEC, and any amendments and supplements hereto and paid to the a financial printer or the SEC, and (b) the filing fee under the HSR Act relating to the HSR filing required for the Merger, (ii) ARS Pharma will pay the Nasdaq fees associated with the Nasdaq Listing Application and (iii) in connection with a disagreement regarding Silverback Net Cash, the fees and expenses of the Accounting Firm will be allocated between ARS Pharma and Silverback in the proportion that the unsuccessfully disputed amount of Silverback Net Cash bears to the total disputed amount of Silverback Net Cash.

"Transaction Expenses" means, with respect to each party, all fees and expenses incurred by such party at or prior to the Effective Time in connection with the Contemplated Transactions and the Merger Agreement, including (a) any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of such party; (b) fees paid to the SEC in connection with filing this proxy statement, and any amendments and supplements hereto, with the SEC; (c) any fees and expenses in connection with the printing, mailing and distribution of this proxy statement and any amendments and supplements hereto; (d) any fees and expenses payable to Nasdaq; (e) only with respect to Silverback, any bonus, severance, change-in-control payments or similar payment obligations (including payments with "single-trigger" provisions triggered at and as of the Closing) that become due or payable to any director, officer, employee or consultant of Silverback in connection with the consummation of the Contemplated Transactions; and (f) only with respect to Silverback, the cost of the D&O Tail Policy.

Amendment of Merger Agreement

The Merger Agreement may be amended by the parties at any time with the written approval of the ARS Pharma, Merger Sub and Silverback, except that after the Merger Agreement has been adopted and approved by a party's stockholders, no amendment which by law requires further approval by the stockholders of that party will be made without such further stockholder approval.

AGREEMENTS RELATED TO THE MERGER

Support Agreements

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of Silverback entered into support agreements (the "Silverback Support Agreements") in favor of ARS Pharma relating to the Merger representing approximately 31% of Silverback's outstanding shares of Silverback Common Stock as of immediately prior to the date of the Merger Agreement. The Silverback Support Agreements provide, among other things, that such officers, directors and stockholders will vote all of their shares of Silverback Common Stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the Merger Proposal, and the other Contemplated Transactions, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any acquisition proposal involving a third party.

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of ARS Pharma entered into support agreements (the "ARS Pharma Support Agreements") in favor of Silverback relating to the Merger representing approximately 83% of the outstanding shares of ARS Pharma Capital Stock immediately prior to the date of the Merger Agreement. The ARS Pharma Support Agreements provide, among other things, that such executive officers, directors and stockholders vote all of their shares of ARS Pharma Capital Stock: (i) in favor of adopting the Merger Agreement and approving the Merger, the ARS Pharma Stockholder Matters, and the other Contemplated Transactions, (ii) against any proposal made in opposition to, or in competition with, the Merger Agreement or the Merger and (iii) against any acquisition proposal involving a third party.

Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, (i) certain executive officers, directors and stockholders of ARS Pharma representing approximately 84% of the outstanding shares of ARS Pharma Capital Stock immediately prior to the date of the Merger Agreement and (ii) certain stockholders of Silverback and each executive officer and director of Silverback expected to continue as an executive officer or director of the combined company representing approximately 31% of Silverback's outstanding shares of Silverback Common Stock as of immediately prior to the date of the Merger Agreement, entered into lock-up agreements (the "Lock-Up Agreements"), pursuant to which such executive officers, directors and stockholders accepted certain restrictions on transfers of the shares of Silverback common stock held by such executive officer, director or stockholder for the 180 day period following the Effective Time.

MATTERS BEING SUBMITTED TO A VOTE OF SILVERBACK'S STOCKHOLDERS

PROPOSAL NO. 1:

APPROVAL OF (I) THE ISSUANCE OF SHARES OF SILVERBACK COMMON STOCK OR OTHER SECURITIES OF SILVERBACK PURSUANT TO THE MERGER, WHICH WILL REPRESENT (OR ARE CONVERTIBLE INTO) MORE THAN 20% OF THE SHARES OF SILVERBACK COMMON STOCK OUTSTANDING IMMEDIATELY PRIOR TO THE MERGER AND (II) THE CHANGE OF CONTROL RESULTING FROM THE MERGER PURSUANT TO NASDAQ LISTING RULES 5635(A) AND 5635(B), RESPECTIVELY

At the Silverback virtual special meeting, Silverback's stockholders will be asked to approve (i) the issuance of shares of Silverback Common Stock or other securities of Silverback to the holders of ARS Capital Stock, stock options to purchase shares of ARS Common Stock and warrants to purchase ARS Capital Stock pursuant to the Merger, which shares of Silverback Common Stock or other securities of Silverback will represent (or are convertible into) more than 20% of the shares of Silverback Common Stock outstanding immediately prior to the Merger, and (ii) the change of control resulting from the Merger, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), respectively.

Immediately after the Merger, assuming Silverback holds $240 million of net cash at Closing, the pre-Merger equity holders of ARS Pharma are expected to hold approximately 63% of the outstanding shares of Silverback Common Stock and the pre-Merger equity holders of Silverback are expected to hold approximately 37% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method. Silverback will assume outstanding warrants to purchase shares of ARS Pharma Common Stock (after giving effect to the Preferred Stock Conversion) and unexercised options to purchase shares of ARS Pharma Common Stock, and such securities will be converted into warrants or options, as applicable, to purchase shares of Silverback Common Stock.

The terms of, reasons for and other aspects of the Merger Agreement, the Merger, the issuance of Silverback Common Stock pursuant to the Merger Agreement and the change of control resulting from the Merger are described in detail in the other sections in this proxy statement.

Required Vote

The affirmative vote of a majority of the votes cast virtually or by proxy at the Silverback virtual special meeting is required to approve Proposal No. 1. Abstentions and broker non-votes will have no effect on the outcome of this proposal. It is anticipated that Proposal No. 1 will be a non-discretionary proposal considered non-routine under the rules of the NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus may result in broker non-votes.

THE SILVERBACK BOARD RECOMMENDS THAT SILVERBACK'S STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 1 TO APPROVE (I) THE ISSUANCE OF SHARES OF SILVERBACK COMMON STOCK OR OTHER SECURITIES OF SILVERBACK PURSUANT TO THE MERGER, WHICH WILL REPRESENT (OR ARE CONVERTIBLE INTO) MORE THAN 20% OF THE SHARES OF SILVERBACK COMMON STOCK OUTSTANDING IMMEDIATELY PRIOR TO THE MERGER AND (II) THE CHANGE OF CONTROL RESULTING FROM THE MERGER PURSUANT TO NASDAQ LISTING RULES 5635(A) AND 5635(B), RESPECTIVELY. THE APPROVAL OF PROPOSAL NO. 1 IS REQUIRED TO CONSUMMATE THE MERGER.

PROPOSAL NO. 2:

APPROVAL OF POSSIBLE ADJOURNMENT OF THE SILVERBACK VIRTUAL SPECIAL MEETING

If Silverback fails to receive a sufficient number of votes to approve Proposal No. 1 Silverback may propose to postpone or adjourn the Silverback virtual special meeting, for a period of not more than 30 days, for the purpose of soliciting additional proxies to approve Proposal No. 1. Silverback currently does not intend to propose postponement or adjournment at the Silverback virtual special meeting if there are sufficient votes to approve Proposal No. 1.

The affirmative vote of a majority of the votes cast virtually or by proxy at the Silverback virtual special meeting is required to approve Proposal No. 2. Abstentions and broker non-votes will have no effect on the outcome of this Proposal. It is anticipated that Proposal No. 2 will be a discretionary proposal considered routine under the rules of the NYSE, which generally controls the ability of brokers to vote or not vote shares held in street name on certain matters, and thus will not result in broker non-votes.

THE SILVERBACK BOARD RECOMMENDS THAT SILVERBACK'S STOCKHOLDERS VOTE "FOR" PROPOSAL NO. 2 TO POSTPONE OR ADJOURN THE SILVERBACK VIRTUAL SPECIAL MEETING, IF NECESSARY, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF PROPOSAL NO. 1. THE APPROVAL OF PROPOSAL NO. 1 IS REQUIRED TO CONSUMMATE THE MERGER.

DESCRIPTION OF SILVERBACK'S BUSINESS

In addition to the information set forth below, please refer to the Silverback 10-K, Silverback 10-Q and the other documents filed with the SEC and incorporated by reference into this proxy statement for additional information regarding our business.

Overview

Silverback is a biopharmaceutical company focused on leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of cancer, chronic viral infections and other serious diseases. Silverback's platform enables them to strategically pair proprietary linker-payloads that modulate key disease-modifying pathways with monoclonal antibodies directed to specific disease sites.

In July 2020, Silverback initiated clinical development of its first ImmunoTAC product candidate, a TLR8 agonist conjugated to a HER2 antibody, SBT6050. Preclinical data suggested that Silverback would be able to demonstrate a therapeutic window and advance SBT6050 through clinical development as a monotherapy and in combination with standard-of-care agents that had a complementary mechanism-of-action. Silverback's Phase 1/1b program was designed to measure safety and tolerability, pharmacokinetic, pharmacodynamic and anti-tumor activity as monotherapy and in combination with pembrolizumab. On March 28, 2022, Silverback made the decision to discontinue its clinical development program for SBT6050 due to limited monotherapy activity and the adverse event profile when used in combination with pembrolizumab. SBT6290, comprised of the same linker payload conjugated to a Nectin4 antibody was expected to show a similar clinical profile and, therefore, Silverback also terminated this program prior to dosing patients. Following the decision on March 28, 2022, Silverback prioritized its resources to focus on the development of SBT8230 for the treatment of chronic Hepatitis B virus ("cHBV") and early-stage discovery programs.

SBT8230 is an ASGR1 antibody conjugated to a TLR8 agonist linker payload for the treatment of cHBV. ASGR1 is highly expressed in liver and is restricted in its expression to this organ. Other ASGR1-directed agents, such as those used in RNAi therapies, have shown robust liver localization. SBT8230 shows biodistribution profiles in non-human primates consistent with these agents, which is distinct from SBT6050 and SBT6290. The anti-viral immune response is achieved through activation of myeloid cells and subsequent activation of immune cells that drive an IFNg signal, which has been observed in the clinic with SBT6050. This has been shown by others to drive seroconversion, an important determinant of a functional cure. Silverback presented a preclinical update on SBT8230 in the fourth quarter of 2021. In the third quarter of 2022, Silverback completed Phase 1-enabling GLP toxicology studies and Phase 1-enabling CMC activities.

In addition, Silverback has internal discovery programs focused on evaluating and developing new antigen binding domains specific for targets of interest (including antibodies), next-generation linker technologies, and both agonist and antagonist small molecule payloads, that may be combined to create novel tissue-targeted antibody conjugates. Silverback's most advanced discovery program is a proprietary glucocorticoid receptor agonist linker-payload ("GC") conjugated to an antagonist monoclonal antibody targeting the CD40 receptor that is being developed for the treatment of autoimmune and inflammatory diseases. Silverback's approach is designed to leverage the combined anti-inflammatory and immunosuppressive effects of a cell surface receptor blockade of CD40 and the delivery of a glucocorticoid receptor agonist payload. Silverback's CD40-GC conjugate leverages next-generation linker technology developed internally, which is designed to improve the hydrophilic properties of our antibody drug conjugates. Silverback's CD40-GC program is currently six to 12 months away from development candidate selection.

In connection with the discontinuation of the SBT6050 and SBT6290 programs, Silverback announced a work force reduction of 27% to focus on the development of SBT8230 and early-stage discovery programs while evaluating strategic alternatives. Strategic alternatives were evaluated with a goal to identify the opportunity that would, in the opinion of the Silverback Board, create the most value for Silverback stockholders, including strategic mergers and acquisitions, asset acquisitions and sales, remaining a standalone company pursuing a limited pipeline focusing on SBT8230 and preclinical programs, and liquidation to distribute available cash. On July 21, 2022, Silverback announced that it entered into the Merger Agreement with ARS Pharma. In connection with the Merger, Silverback started to winddown its research and development activities and focus on exploring opportunities to divest its legacy programs, including SBT8230 for cHBV, next-generation linker technologies, and our preclinical GC conjugate program, and committed to reducing its workforce by approximately 75% by September 2, 2022 and the remaining 25% at Closing in order to preserve cash resources.

On August 10, 2022, the Silverback Board approved the termination of employment of Laura Shawver, Ph.D., the Chief Executive Officer of Silverback, effective as of September 2, 2022, to extend our cash runway and to allow Dr. Shawver to pursue other employment opportunities. Dr. Shawver has entered into a consulting agreement with Silverback effective as of the Transition Date pursuant to which she has agreed to provide, on an as-needed basis not to exceed 20 hours per week unless mutually agreed, transition services and to advise, consult and support Silverback's management team in connection with the closing of the Merger, winddown activities related thereto, the sale of Silverback's legacy assets and other services from the Transition Date until the earlier of (a) the Closing and (b) December 31, 2022. As consideration for her consulting services, Dr. Shawver will be paid an hourly rate of $300 and all outstanding equity awards held by Dr. Shawver as of the Transition Date will continue to vest and will remain exercisable during the consulting period. Dr. Shawver will also continue to serve as a member of the Silverback Board and is expected to serve on the combined company's board of directors following the Closing.

Effective as of the Transition Date, Jeffrey Pepe, Ph.D., J.D., has been appointed to serve as the Interim Chief Executive Officer, General Counsel and Corporate Secretary of Silverback.

DESCRIPTION OF ARS PHARMA'S BUSINESS

Unless otherwise indicated or the context otherwise requires, references in this Description of ARS Pharma's Business section to "ARS," the "Company" "we," "us," "our" and other similar terms refer to ARS Pharma and its consolidated subsidiary.

Overview

Company Summary

We are a biopharmaceutical company focused on the development of our novel, potentially first-in-class product candidate, *neffy*® (previously referred to as ARS-1) for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail®, which allows *neffy* to provide injection-like absorption of epinephrine at a low dose, in a small, easy-to-carry, easy-to-use, rapidly administered and reliable nasal spray.

Type I severe allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine injection, the only U.S. Food and Drug Administration ("FDA")-approved medication for these reactions. While epinephrine injection devices have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. Delay in treatment can allow the allergic reaction to progress in severity leading to symptoms that seriously impact patient quality of life, to potential need for emergency services and/or hospitalizations, and to life-threatening symptoms or events.

There are approximately 25 to 40 million people in the United States who experience Type I allergic reactions. Of this group, approximately 16 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only 3.3 million currently have an active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector. Even if patients or caregivers carry an autoinjector, more than half either delay or do not administer the device when needed in an emergency.

We believe *neffy*'s "no needle, no injection" delivery that eliminates needle-related apprehension and injury concerns, with its small pocket size, ease of use, and high reliability would, if approved, increase prescriptions for epinephrine and make it more likely for patients and caregivers to administer epinephrine sooner, achieve more rapid symptom relief and prevent the allergic reaction from progressing to a level of severity that could lead to hospitalization or even death. Data from our studies of *neffy* in more than 500 subjects demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products.

We submitted our New Drug Application ("NDA") to the FDA in the third quarter of 2022 and if our NDA is approved, we believe *neffy* will be the first "no needle, no injection" marketed epinephrine product for the emergency treatment of Type I allergic reactions. However, the timing for regulatory approvals is outside ARS Pharma's control, may be delayed and is uncertain.

Epinephrine and Allergic Reactions Background

Type I allergic reactions are potentially life-threatening hypersensitivity reactions that can occur within minutes of exposure to an allergen and need to be treated immediately to relieve symptoms and

prevent further progression. Initial symptoms significantly impact patient quality of life and include difficulty breathing, bronchospasms, hypotension, presyncope, itching, hives, swelling of eyes and lips, and abdominal pain and vomiting. If not treated immediately, more severe reactions known as anaphylaxis that involve constriction of the airways, swelling of the throat, rapid heart rate, severe hypotension and other respiratory and cardiac symptoms can develop and potentially present a medical and life-threatening emergency. Immediate administration of epinephrine is currently the only first-line treatment for Type I allergic reactions, including anaphylaxis. The only out-of-hospital delivery option today is an intra-muscular injectable product, typically offered as prefilled syringes or auto-injector devices, such as EpiPen®, which is marketed by Viatris Inc., and generic versions of EpiPen, marketed by Teva Pharmaceuticals, Inc. These intra-muscular auto-injection devices have several limitations that result in under-utilization by patients and may lead to serious complications and hospitalizations.

These limitations include:

- lack ease of portability with only 50% of patients filling prescriptions carrying the device;
- reluctance to use the device with approximately 25% to 50% of patients carrying the device refusing to administer;
- apprehension stemming from the use of a needle that leads to approximately 40% to 60% of patients delaying administration by up to 18 minutes even if they are carrying the device;
- a high rate of dosing errors, with meta-analyses reporting up to 35% of patients still failing to dose correctly even after training; and
- safety concerns including lacerations, caregiver self-injection and frequent potentially cardiotoxic blood vessel injections, which occurred in approximately 14% of EpiPen subjects in our patient self-administration studies.

As a result, many of the approximately 25 to 40 million patients at risk of severe Type I allergic reactions do not receive or fill prescriptions for intra-muscular injectables. Of 3.3 million patients that do fill their prescriptions, approximately half do not carry the intra-muscular injectable products with them on a regular basis, while many of the other half delay or hesitate treatment during a severe Type I allergic reaction. This may contribute to treatment postponement, prolonging troublesome symptoms, reducing quality of life and increasing the risk of complications or even death. In addition to the 3.3 million patients who currently fill their prescriptions for an epinephrine injectable device, we estimate that approximately 2.5 million patients received a prescription in the last 3 years, but either did not fill or renew it. We believe the advantages of *neffy* will be attractive to this group and lead to an increase in the number of patients filling their prescription as further described below. These patients are additive to the 3.3 million patients that do fill a prescription per year.

Notwithstanding their widespread lack of use, we estimate that net sales of intra-muscular injectable products approved for outpatient use in the United States was approximately $1 billion in 2021 among the approximately 3.3 million patients who filled a prescription.

Our Approach

neffy™ is an investigational drug currently in clinical trials for the emergency treatment of allergic reactions (type I) including anaphylaxis. neffy™ is not approved by the FDA, EMA or other health authorities.

neffy is designed to address the shortcomings of intra-muscular injectable devices. *neffy* is a convenient "no needle, no injection," solution designed to be easier to carry, more reliable and easier to administer, without the aversion, safety concerns and fear and pain of needles associated with intra-muscular injectables. Based on the factors set forth below, we believe that *neffy* can transform the paradigm of epinephrine delivery from cumbersome, unreliable, intra-muscular injectable devices to an intranasal delivery method that makes patients more likely to administer epinephrine sooner, thus achieving more rapid symptom relief and preventing symptoms from becoming serious or life-threatening.

- ***Comparable PK and PD to injection products***. In our clinical trials, we observed that *neffy* has comparable pharmacokinetics ("PK") and pharmacodynamics ("PD") compared to marketed epinephrine injectables.
- ***Needle-free, easy-to-use, pocket-sized and highly reliable nasal spray.*** *neffy* is easier to carry than approved intra-muscular injectables because it is pocket-sized, increasing the likelihood that the device is available for use in an emergency. Our registrational self-administration study (EPI-17) with 2.0 mg *neffy* demonstrated that adult patients had zero critical dosing errors, and 100% of trained adults and trained children were able to dose successfully in two human factors validation study with a total of 150 subjects.
- ***No risk of needle-related injuries***. *neffy* has no risk of needle-related injuries including injection into a blood vessel, lacerations, or caregiver self-injection since the sprayer device does not have a needle.
- ***Less hesitation to dose epinephrine.*** Early administration of epinephrine can reduce the severity, risk of hospitalization and mortality associated with severe Type I allergic reactions. In patient surveys we have conducted, patients indicated a relief from fear of injection and an expectation to utilize *neffy* without delay in a manner more consistent with recommended guidelines due to *neffy* being a nasal spray.
- ***Low potent dose of epinephrine.*** Delivery of higher exposures of epinephrine increases the risk of overexposure and potential adverse events. *neffy* has high bioavailability matching the approved doses of injection at a low dose of 2.0 or 1.0 mg intranasally. Even in the unlikely situation where epinephrine would be 100% bioavailable after administration of *neffy*, the resulting exposure is expected to be tolerable.

- ***Increased stability over existing treatment options***. *neffy* is expected to have a shelf-life at least comparable to the 18 month shelf-life of auto-injector products, but with improved stability and shelf-life at high-temperature than existing products in the market (up to 3 months at 50ºC or 122ºF) that allows *neffy* to retain potency even if accidentally left in a high temperature environment.
- ***Combination of previously validated product components***. *neffy* consists of a unique combination of three validated products, which we believe will significantly reduce *neffy's* clinical and commercial development risks: epinephrine, which has been approved by regulators and accepted by the physician community as the only effective option to treat Type I allergic reactions; the intranasal device, which has been commercially proven with millions of sprayers sold to date across four FDA-approved products, including NARCAN® for opioid overdose (marketed by Emergent BioSolutions); and Intravail, an innovative absorption enhancer that has been previously included in the formulations of FDA approved products, such as VALTOCO® and TOSYMRA® nasal spray. We believe the cost of goods for *neffy* will allow us to achieve gross profit margins similar to branded oral small molecule drugs assuming prices comparable to the marketed injectable products.
- ***Well positioned for regulatory submissions, and if approved, advance to commercialization.*** We submitted our NDA for *neffy* to the FDA in third quarter of 2022 and we believe that the completed trials are sufficient to serve as the basis for its approval in the United States. We and Recordati S.p.A. ("Recordati"), our commercialization partner in Europe, Russia/the Commonwealth of Independent States ("CIS"), the Middle East and French-speaking African countries, expect to submit a Market Authorization Application ("MAA") to the European Medicines Agency ("EMA") shortly after our NDA by the end of 2022.
- ***Potential for high demand and attractive product uptake conditions.*** We have conducted extensive market research with physicians, patients, parents and other caregivers that shows *neffy* has a clinical product profile that is highly desirable and addresses key unmet needs. We believe we can successfully commercialize *neffy* by targeting high-prescribing allergists, pediatricians and primary care physicians who we believe will prescribe *neffy* as it would be a very attractive treatment option within the patient community. In addition, our market research indicates that insurance plans (payors) perceive *neffy* as a differentiated product candidate, which we believe supports the potential for favorable market access for *neffy* at net prices comparable to, or at a premium to, the approved intra-muscular injectables. We currently own or license a robust global intellectual property portfolio including issued composition of matter and method patents relating to *neffy* that are not expected to expire until 2038 before consideration of any potential patent term extension.

Our Management Team, Financing History and Investors

We were created to innovate, develop and commercialize *neffy*, a novel, potentially first-in-class treatment that addresses Type I allergy patients' desire and need for a no needle, no injection, easy-to-use, portable and reliable solution for delivering epinephrine safely. To achieve this goal, we have assembled a management team with extensive experience in the development and commercialization of drugs, such as recently approved nasal sprays NARCAN (naloxone nasal spray) and VALTOCO (diazepam nasal spray).

Our company was founded by Richard Lowenthal, M.S., MSEL, Robert Bell, Ph.D. and Sarina Tanimoto, M.D., M.B.A. Pratik Shah, Ph.D. was our first external investor.

Mr. Lowenthal, our Co-Founder and Chief Executive Officer, has more than 25 years of biotechnology and pharmaceutical development experience including leading the regulatory approvals

of VALTOCO (diazepam nasal spray) and NARCAN (naloxone nasal spray). Dr. Bell, our Co-Founder and Chief Scientific Officer, has more than 25 years of product development experience including leading R&D at Barr Laboratories, Somerset Pharmaceuticals and UDL Laboratories. Dr. Tanimoto, our Co-Founder and Chief Medical Officer, has more than 20 years of pharmaceutical experience in clinical drug development including supporting the approval of multiple nasal spray products such as VALTOCO and NARCAN. Dr. Shah, our Chairman, has more than 30 years of experience founding and leading biopharmaceutical companies and healthcare investment decisions including his role as Executive Chairman of Design Therapeutics, former Chairman of Synthorx (now part of Sanofi) and former Chief Executive Officer of Auspex Pharmaceuticals (now part of Teva Pharmaceuticals).

Our commercial team is led by Eric Karas, Chief Commercial Officer, who has more than 25 years of sales, marketing, market access and strategic planning experience across multiple specialty products, including leading commercial initiatives for NARCAN® nasal spray at Emergent BioSolutions and Adapt Pharmaceutical (now part of Emergent BioSolutions). Harris Kaplan, Executive Vice President, Commercial Strategy has been involved in the development and launch of 125 new products totaling more than $300 billion in peak revenues, and Dan Relovsky, Senior Vice President of Marketing, has extensive and relevant launch experience across a number of therapeutic categories.

The other key members of the ARS team bring extensive finance, business development and commercial operations experience and include Kathleen Scott, Chief Financial Officer, Justin Chakma, Chief Business Officer, and Brian Dorsey, EVP of Operations and Project Management.

Since our inception, we have raised over $100.0 million in proceeds, including equity financing from a syndicate of leading life sciences investors that include, among others, RA Capital, SR One and Deerfield and from our licensing and collaboration agreements. We have entered into licensing and collaboration agreements for *neffy* with Recordati for development and commercialization rights in the European Union (“EU”), Iceland, Liechtenstein, Norway, Switzerland, the United Kingdom, Russia/CIS, Turkey, the Middle East and French-speaking African countries, Alfresa Pharma for Japanese rights, and Pediatrix Therapeutics (founded by F-Prime Capital, Eight Roads and Creacion Ventures) for Chinese rights.

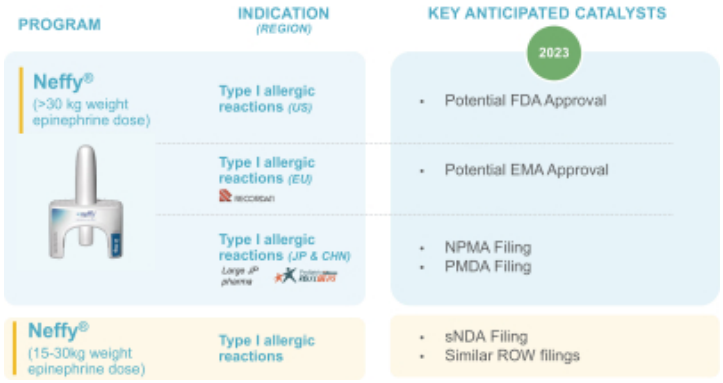
Our Pipeline: Suite of *neffy* Programs

We are focused on advancing *neffy* through regulatory approvals for the emergency treatment of Type I allergic reactions, including anaphylaxis, and commercialization. *neffy* is an intranasal composition of epinephrine that is designed to address the limitations of epinephrine intra-muscular injectable products that are available on the market today.

We submitted our NDA for the 2.0 mg *neffy* dose for adults and children greater than 30 kg in weight to the FDA in the third quarter of 2022. In regions outside of the U.S., we have entered partnerships for the development and commercialization of *neffy*. In the EU, together with our partner Recordati, we intend to submit our MAA for the 2.0 mg *neffy* dose for subjects greater than 30 kg in weight by the end of 2022. Additionally, we have partnered with Alfresa Pharma in Japan and Pediatrix Therapeutics in China to develop and commercialize *neffy* in those countries.

Furthermore, we also plan to pursue additional expansion in our pediatric labeling with *neffy* and are conducting a single-arm pharmacokinetic study in subjects 4 to 18 years of age. The interim pediatric data including subjects greater than 30 kg in weight is included in our initial NDA. We plan to submit a supplemental NDA (“sNDA”) for *neffy* for children weighing 15 to 30 kilograms to the FDA in 2023.

In addition, we believe *neffy* may be able to target other conditions in addition to Type I allergic reactions, and we have identified additional indications for further examination and potential future development.



Our Strategy

Our strategy is focused on developing and commercializing *neffy* as a potentially first-in-class approved intranasal treatment for the approximately 16 million patients in the United States who have been diagnosed and experienced severe Type I allergic reactions and are at risk of anaphylaxis, in geographic regions outside of the United States and for other allergy indications. Key elements of our strategy include:

- ***Obtain FDA approval of neffy***. We submitted our NDA to the FDA in the third quarter of 2022. If approved within our expected timeframe, *neffy* would be the first FDA-approved emergency treatment for Type I allergic reactions that is not an injection and that has no needle, which we believe would be an attractive treatment option for these patients. *neffy* has received Fast Track designation. However, the timing for regulatory approvals is outside ARS Pharma's control, may be delayed and is uncertain.
- ***Commercialize neffy in the United States***. If *neffy* is approved by the FDA, we plan to initially commercialize it in the United States by deploying a combination of direct promotion, virtual sales consultants, and non-personal promotion intended to reach, at a minimum, the healthcare professionals that account for 45% of the current epinephrine prescriptions. Our promotion will target high-prescribing allergists, pediatricians and primary care physicians through both traditional and non-traditional professional channels. Through these efforts, combined with direct-to-consumer omnichannel strategies to drive awareness and patients asking for *neffy*, we believe we can quickly and efficiently reach a majority of the approximately 3.3 million patients in the United States who filled a prescription for an epinephrine intra-muscular injectable device in 2021. In addition, we believe that the potential for *neffy* to address the limitations of auto-injectors will allow us to expand the market opportunity for *neffy* over time to include the broader population of approximately 2.5 million patients who have received a prescription, but either refused or discontinued treatment in the last three years, as well as the approximately 11 million patients who are diagnosed and under the care of physicians, but have not been prescribed an epinephrine intra-muscular injectable.
- ***Commercialize neffy outside of the United States with our partners***. We believe that there is significant commercial potential for *neffy* in markets outside of the United States. In 2020, we signed an exclusive licensing agreement with Recordati to commercialize *neffy* in Europe, Russia/CIS, the Middle East and French-speaking African countries and expect to submit our MAA by the end of 2022. We intend to submit regulatory filings equivalent to an NDA in Japan and China in collaboration with Alfresa Pharma and Pediatrix Therapeutics, respectively, to whom we have granted exclusive licenses in those regions for the development and commercialization of *neffy*.

- ***Conduct additional studies of neffy to address additional Type I allergic reactions***. There remains a significant unmet need for treatments for allergies that can produce Type I reactions. We are conducting clinical studies to support the expansion of labeling for *neffy* to outpatient epinephrine use in other Type I allergy conditions for which epinephrine intra-muscular injectables are not approved.

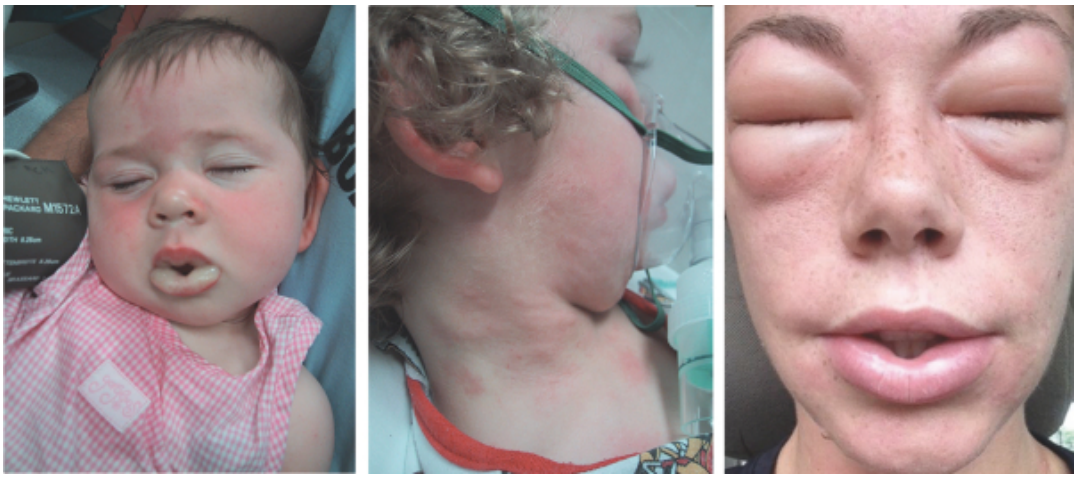
Overview of Type I Allergic Reactions and Current Challenges

Overview of Type I Allergic Reactions

The immune system plays an important role in monitoring and protecting the body against microbial threats. However, this system can lead to overstated immune and inflammatory responses that results in adverse outcomes known as hypersensitivity reactions. Type I allergic reactions are potentially life-threatening hypersensitivity reactions that can occur within minutes following exposure to an allergen and need to be treated immediately to relieve troublesome symptoms, mitigate severity and avoid a potentially fatal event. These severe reactions are caused by exposure to a specific allergen, typically foods (most commonly, nuts, eggs, shellfish), drugs and venoms and are mediated by immunoglobulin E IgE antibodies that bind to mast cells causing the release of histamines. The histamines induce smooth muscle contraction in the airways and a wheal and flare response in the skin producing swelling and inflammation. At the same time, widespread activation of mast cells leads to systemic effects of circulatory shock, hypotension or vascular collapse, and in the most severe cases respiratory arrest and death. The severity of a Type I allergic reaction is a function of the speed of onset and the number of organ systems affected by the reaction. As such, early intervention within minutes is critical in order to provide symptom relief and to prevent severe allergic reactions, known as anaphylaxis.

Table 1: Symptoms of Type I Allergic Reactions including Anaphylaxis

Body System	Common Symptoms of Type I Allergic Reactions
Respiratory	Chest tightness, wheezing, difficulty breathing Bronchospasm and repetitive coughing Upper airway or laryngeal angioedema including swelling of throat Respiratory failure
Cardiovascular	Hypotension, presyncope (feeling faint), loss of consciousness Cardiovascular arrest
Dermatological	Urticaria (hives) and pruritus (itching) Cutaneous angioedema (swelling of eyes and lips)
Gastrointestinal	Abdominal pain and vomiting



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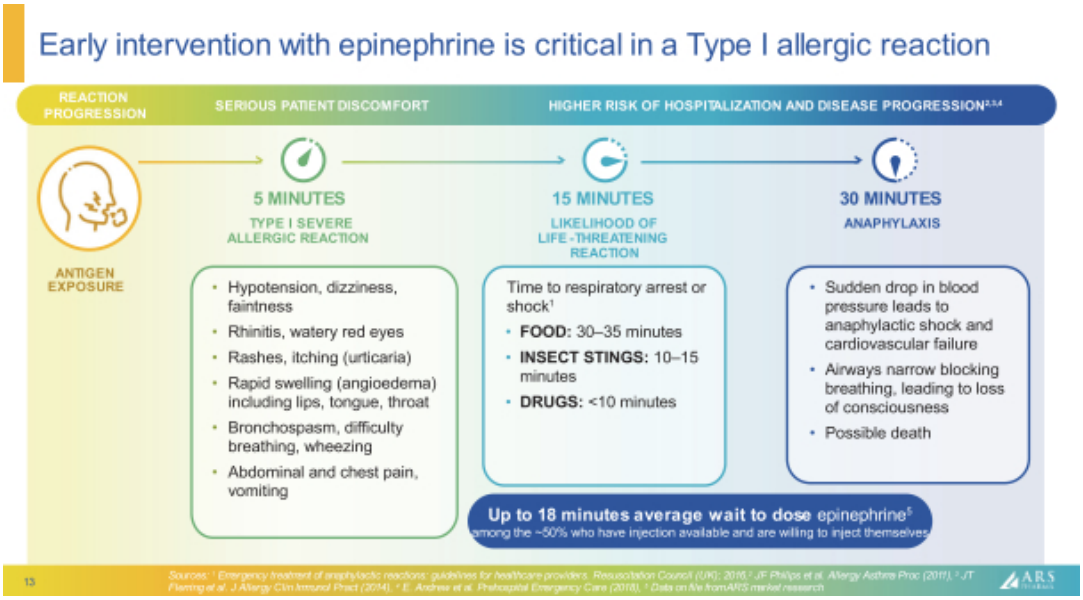
Role of Epinephrine in Treating Type I Allergic Reactions

Epinephrine intra-muscular injectables are the only current out-of-hospital treatment for severe Type I allergic reactions and are recommended to be prescribed to all patients who have experienced a severe Type I allergic reaction and have either experienced anaphylaxis or are at risk of anaphylaxis. When properly used, these devices can allow for the early administration of epinephrine to stop or reduce the intensity of the systemic allergic reaction before refractory anaphylaxis develops. Even a few minutes delay in the administration of epinephrine can lead to the need for emergency services and/or hospitalizations, comorbidities and life-threatening symptoms or events, while also prolonging the significant negative impact on patient quality of life by delaying symptom relief.

EpiPen epinephrine autoinjector was first approved by the FDA for the emergency treatment of Type I hypersensitivity reactions, including anaphylaxis, in December 1987. Other FDA-approved epinephrine intra-muscular injection products include Twinject® approved in May 2003, Adrenaclick® approved in November 2009, and Auvi-Q® approved in August 2012. In June 2017, the FDA approved Symjepi™ epinephrine injection, which is a pre-filled syringe for the same indication. These injection devices were approved by the FDA without pharmacokinetic data based on an assumption that injections and devices were all effectively the same as the reference listed drug of intra-muscular injection with a needle and syringe. Intra-muscular injection with a needle and syringe is considered the gold standard, and is almost exclusively used in non-community use clinical settings. Although there are no known differences in efficacy or time to observed effect in clinical practice between these devices, current data indicates that different devices deliver an intra-muscular dose of epinephrine with a range of PKs.

Epinephrine works due to its agonistic effects on the body's adrenergic receptors (alpha and beta receptors). By activating alpha-1 receptors, epinephrine prevents and relieves airway edema, hypotension and shock. By activating beta-1 receptors, epinephrine increases the rate and force of cardiac contractions. Lastly, epinephrine's effect on beta-2 receptors leads to bronchodilation and decreased allergy causing mediator release by mast cells.



Treatment guidelines recommend that epinephrine be administered immediately at the first sign of a severe allergic reaction. Epinephrine is the only medication that can reverse severe allergic reactions and reduce hospitalization and death. Early administration of epinephrine is associated with better outcomes and decreased likelihood of hospitalizations. The sooner epinephrine is administered following allergen exposure, the less severe the systemic allergic reaction may become, and the less likely it will develop into an anaphylaxis event. A short delay of even a few minutes in the recognition and treatment of anaphylaxis can lead to more serious symptoms, including potential hypoxia or death. Additionally, accompanying symptoms of even non-life-threatening allergic reactions can adversely impact health-related quality of life and can lead to loss of productivity, negatively impact social life, as well as lead to depression and anxiety and feelings of fear, frustration, worry and lack of control. A second dose of epinephrine is required for adequate treatment in about 10% of cases, irrespective of whether epinephrine was dosed using an auto-injector such as EpiPen or needle and syringe.

While antihistamines such as diphenhydramine, also known as Benadryl® (marketed by Johnson & Johnson), can sometimes relieve the dermatological symptoms and pruritus associated with severe Type I allergic reactions, treatment guidelines state that antihistamines should never be administered instead of epinephrine because they do not reverse the cardiovascular symptoms such as hypotension and shock, or respiratory distress. Instead, antihistamines can potentially mask symptoms and allow the disease to continue to progress silently.

In the United States, dosing recommendations for epinephrine use by intra-muscular injection remain at 0.1 mg, 0.3 mg or 0.5 mg with repeat dosing administered as needed to control a severe allergic reaction. Approximately 80% of epinephrine auto-injectors prescribed in the United States for outpatient use are the 0.3 mg dose level for persons greater than 30 kg in weight, approximately 15% contain doses of 0.15 mg for persons between 15 to 30 kg and less than 5% contain 0.1 mg doses for persons less than 15 kg. A low dose of epinephrine is important for safety as overexposure to epinephrine can lead to adverse events.

Limitations of Existing Epinephrine Products

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Epinephrine intra-muscular injectables have been proven to be highly effective if they are administered timely and effectively, and work as intended, but the limitations of these products include painful application, inconvenient size and a complicated mechanism of administration. These limitations discourage patients and caregivers from carrying these devices and administering epinephrine in a timely manner. Both uptake and use of intra-muscular injection devices has been limited among eligible patients with severe Type I allergic reactions at risk of anaphylaxis. Of the approximately 16 million people in the United States who have been diagnosed and experienced Type I severe allergic reactions, only 3.3 million currently have an active and filled epinephrine autoinjector prescription.

In studies published in peer-reviewed journals, only 23% to 48% of patients self-administered with an auto-injector during a severe Type I allergic reaction, likely due to less than half of patients actually carrying their prescribed injection device, and only half administering even if the device was available. Across our market research studies, approximately 40% to 60% of patients reported using an antihistamine first, which is not known to be effective, and if carrying an intra-muscular injectable, waited an average of 8 to 18 minutes to administer the device. The principal device-related reasons for delay were presence of a needle, concern about serious cardiac side effects, and potential pain. Patients, and particularly parents who administer to their child, perceive injection to be traumatic, which leads to a fear and avoidance of administering timely treatment. Further, the potentially life-threatening nature of a severe Type I allergic reaction is often accompanied with psychological stress and panic which can lead to delays or errors in proper intra-muscular injection, which can result in hospitalization or even death. In a meta-analysis of 32 studies evaluating epinephrine injectable administration techniques, 23% to 35% of participants failed to achieve the correct administration technique following training.

Further, there is variability in respect to whether auto-injector devices are able to reliably deliver a sufficient dose of epinephrine. The FDA has reported that EpiPen device failures lead to multiple deaths and dozens of hospitalizations annually.

The injection needle can be painful and dangerous not just due to the risk of skin lacerations and the possibility of the needle hitting a patient’s bone during administration, but also the risk of serious, sudden cardiovascular events resulting from accidental blood vessel injection. In our clinical studies, we observed instances of potential accidental blood vessel injection in approximately 14% of patients dosing themselves with EpiPen.

In comparison, *neffy* is perceived by patients and parents as a potentially “game changing” device that, if approved, could improve the management of severe Type I allergic reactions by addressing the current limitations of epinephrine intra-muscular injectable devices.

Clinical Development of *neffy*

neffy is designed to provide injection-like absorption of epinephrine at a 1.0 or 2.0 mg dose comparable to 0.3 mg injection, in a small, easy-to-carry, easy-to-use, rapidly administered and reliable nasal spray. Based on our development work to date, we believe *neffy*’s “no needle, no injection” clinical profile supports differentiation over intra-muscular injections for the emergency treatment of Type I allergic reactions, including anaphylaxis.

We submitted our NDA to the FDA in the third quarter of 2022 based on a rigorous clinical development program agreed upon during pre-NDA meeting discussion with the FDA in mid-2021. The FDA reference listed drug is intra-muscular needle-in-syringe injection products but there are several approved epinephrine intra-muscular injection products, including intra-muscular auto-injectors such as EpiPen, that establish a range of exposures that have indistinguishable efficacy, time to observed clinical effect and safety.

During our pre-NDA meeting in mid-2021, FDA agreed that bracketing based on the primary parameters of C_{max}, t_{max} and early partial AUCs from the range of PKs observed in listed epinephrine injection products was the best approach to ensure efficacy and safety, while bracketing by $AUC_{0\text{-}t}$ was considered an important parameter to ensure safety. PD measures of epinephrine activity such as systolic blood pressure and pulse rate were agreed to be supportive, and to be not meaningfully lower than injection. FDA also agreed that successfully demonstrating that *neffy* met these criteria in three primary studies described below would be sufficient to serve as a basis for our registration program for adults. Furthermore, FDA also agreed that a single study in pediatric subjects also described below would be sufficient to support our pediatric labeling.

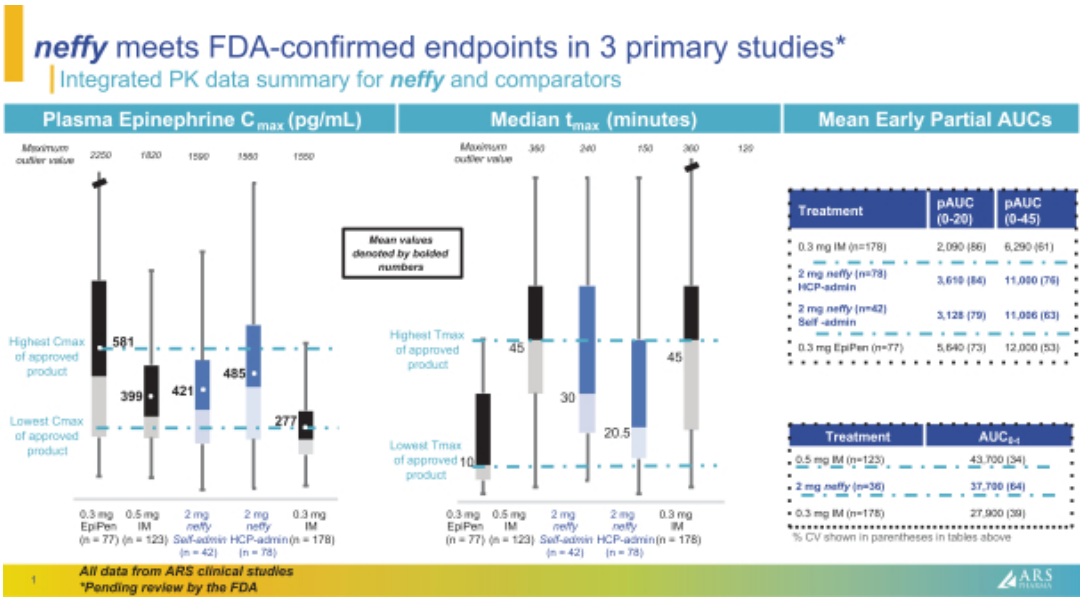
We have completed three registrational clinical trials in adults using our 2.0 *neffy* dose for which we filed our NDA to the FDA in the third quarter of 2022. The adult registrational program using the 2.0 mg *neffy* was intended to generate bioavailability, PDs and safety data in three primary studies: (i) during single and repeat dosing in healthy subjects (EPI-15), (ii) during self-administration by subjects with severe Type I allergies (EPI-17), and (iii) during rhinitis induced by a nasal challenge with an allergen (EPI-16). EPI-15 was conducted in the United States on behalf of ARS Pharma by WCCT

Global, Inc., a third-party contract research organization, and selected for 59 healthy male or female volunteers between the ages of 18 to 55 years. EPI-16 was conducted in the United States on behalf of ARS Pharma by Altasciences Clinical Los Angeles, Inc., a third-party contract research organization, and selected 36 male or female volunteers between the ages of 18 to 55 years with a positive history of seasonal allergic rhinitis related to tree or grass allergens as demonstrated by skin prick test and nasal allergen challenge at screening. EPI-17 was conducted in the United States on behalf of ARS Pharma by Novum Pharmaceutical Research Services, a third party contract research organization, and selected 45 male or female volunteers between the ages of 18 to 55 years who had an ongoing history of Type I allergies. To support our proposed pediatric labeling, we are also conducting a single-arm pharmacokinetic study in subjects 4 to 18 years of age with either 1.0 mg or 2.0 mg of *neffy* depending on the subject's weight (EPI-10). EPI-10 is being conducted in the United States by ARS Pharma and selected 42 male or female subjects between the ages of 4 and 18 years who have Type I allergies that required that the subject or caregiver been prescribed an epinephrine product. The interim results of this study from 57 subjects including 16 subjects dosed with 2.0 mg *neffy* were included in our initial NDA to the FDA that was submitted in the third quarter of 2022.

In addition, we have completed two proof of concept clinical studies that evaluated the bioavailability of our 2.0 mg *neffy* dose. These two earlier-stage studies were conducted in the United States on behalf of ARS Pharma by WCCT Global, Inc. and Altasciences Clinical Los Angeles, Inc, respectively, and selected a total of 26 healthy male or female volunteers between the ages of 18 to 55 years, and 42 male or female volunteers between the ages of 18 to 55 years who had an ongoing history of type I allergies.

2.0 mg *neffy* is intended to be the dose that is comparable to approved 0.3 mg epinephrine intra-muscular injection products for persons greater than 30 kg in weight, which represents approximately 80% of the prescriptions in the United States. 1.0 mg *neffy* is intended to be the dose for persons 15 to 30 kg in weight. We submitted our NDA to the FDA for the 2.0 mg dose of *neffy* for adults and children 30 kg and greater in weight in the third quarter of 2022. We plan to submit a supplemental NDA for the 1.0 mg dose of *neffy* in 2023 for subjects 15 to 30 kg in weight.

In our clinical studies in both adults and children, 2.0 mg *neffy* gave comparable epinephrine exposures that were within the range of approved intra-muscular injection products (needle-in-syringe products and EpiPen) on key pharmacokinetic parameters (C_{max}, t_{max}, early partial AUCs, $AUC_{0\text{-}t}$). The integrated data analysis summarizing the key outcomes for registration are shown below.



The hemodynamic response, measured by systolic blood pressure and heart rate, after administration of *neffy* was comparable to some injection products including EpiPen, and was greater than 0.3 mg intra-muscular needle-with-syringe. These hemodynamic responses were within normal physiologic ranges that are typically experienced during exercise or climbing stairs.

Across all the clinical trials, a total of more than 500 subjects have been exposed to *neffy*. All doses of *neffy* ranging from 0.5 mg to 2.0 mg single doses, as well as repeat doses up to 4 mg within 10 minutes, were well-tolerated by patients. There is no meaningful pain upon administration of *neffy* with average scores of 5 to 8 as assessed on a 100 mm visual analogue scale, across studies. There was no irritation observed based on formal scoring in all studies. There were no serious treatment-related adverse events, and adverse events reported have generally not resulted in side effects more severe than grade 1, and were comparable to injection products. Since *neffy* is given without needle, there was also no needle-related injuries or accidental blood vessel injections.

In contrast, for patients self-administering devices, which involved 132 subjects dosed for each of EpiPen and Symjepi, approximately 14% of subjects dosed with EpiPen (auto-injector) and 2% of subjects dosed with Symjepi (pre-filled needle-in-syringe) experienced a potential blood vessel injection leading to a rapid bolus dose of epinephrine, which could lead to serious side effects including cardiovascular events and cerebral hemorrhage according to the FDA EpiPen label. No subjects dosed with *neffy* experienced a blood vessel injection since it is not possible via the nasal route of administration.

Furthermore, our registrational self-administration study of 2.0 mg *neffy* by adults with severe Type I allergies (EPI-17) showed no critical dosing errors with *neffy* as evaluated by human factors professionals. Furthermore, *neffy* also showed zero dosing errors in two human factor validation studies involving 150 subjects when used by trained adults or trained children across multiple demographic groups, as well as when used by passers-byers with no prior experience or training with an epinephrine device.

Key features of *neffy* demonstrated in our clinical, human factors or stability studies include:

Clinical Feature	Supporting Clinical Data
Comparable PKs at a low dose of epinephrine	C_{max}, t_{max} and AUCs were within the range of approved intra-muscular injection products with a low intranasal dose of 2.0 mg n*effy* (people >30 kg in weight) and 1.0 mg n*effy* (people 15 – 30 kg weight).
Robust PDs within a range comparable to injection products with no risk of accidental blood vessel injections	PD responses including systolic blood pressure and heart rate were within normal physiologic changes and comparable to auto-injector products, with maximum changes less that of the EpiPen. *neffy* has no potential for the accidental blood vessel injections observed with injection products such as EpiPen, which can lead to rapid and high epinephrine exposures that cause rapid increases in systolic blood pressure and can lead to cerebral hemorrhage or other cardiovascular side effects.
No meaningful pain or irritation after administration	Visual analogue scale scores were an average of 5 to 8 on a 100 mm scale, and show no meaningful pain (or burning or stinging sensation) after administration, attributable to n*effy* being an aqueous formulation. There is also no irritation observed based on formal scoring. Needle containing intra-muscular injection products are known to be painful and cause reluctance to dose.
Easy to use	No critical dosing errors during self-administration with 2.0 mg n*effy* by type I allergy adult subjects (EPI-17). Zero percent error rate in two human factors studies with 150 persons, when used by trained adults or trained children and when used by untrained passers-byers.
Easy to carry	*neffy* is comparable in size to a wireless earbud case, and multiple *neffy* devices can fit in a patient or parent's pocket to satisfy guideline recommendations.
High reliability	*neffy*'s sprayer device is designed to deliver the effective dose more than 99.999% of the time, with no recalls or warnings among the millions of the same nasal sprayer devices sold to date.
No breathing or inhalation required	*neffy* is designed to be absorbed passively through the nasal mucosa without any inhalation, sniffing or breathing required, with its particles too large to enter the lungs.
Injection-like absorption even with nasal congestion	*neffy* reaches exposures comparable to approved injectable products even after induction of moderate to severe nasal rhinitis and/or edema (e.g. nasal congestion)
Shelf-life at least comparable to injection products, but also with high temperature stability	Drug stability studies show that n*effy* has a shelf-life at least comparable to the 18 month shelf-life of EpiPen, but with high temperature stability, based on stability data from the 2.0 mg dose of *neffy* for 12 months and the 1.0 mg dose of *neffy* for 24 months. *neffy* remains within specifications even when exposed to temperatures of 50°C (122°F) for at least three months, or temperatures of 40°C (104°F) for at least six months.

Planned Clinical Trials in Additional Indications

Epinephrine has been used empirically by physicians and included in treatment guidelines for multiple allergy conditions that do not fall under the emergency treatment of Type I allergic reactions indication that epinephrine auto-injectors are labelled for. The needle-free, portable, easy-to-use and potentially safer clinical profile of *neffy* supported by clinical efficacy data could enable the broader adoption of epinephrine in the outpatient setting for these other indications. We are conducting proof of concept studies evaluating *neffy* in additional allergy indications where *neffy* could potentially be used multiple times a year to treat acute episodes.

Development outside the United States

In partnership with Recordati, we intend to submit our MAA to the EMA for the 2.0 mg dose of *neffy* later in 2022 based on the same data package submitted in our NDA accepted for review by the FDA in the third quarter of 2022. In the Day 120 comments, we received during EMA's review of our prior 1.0 mg dose *neffy* MAA submission, EMA required a preclinical dog anaphylaxis study, which we completed with data showing no meaningful differences in epinephrine absorption of *neffy* in dogs in a normal state or an anaphylactic state. In April 2022, we voluntarily withdrew our 1.0 mg *neffy* MAA submission to re-submit a 2.0 mg *neffy* MAA submission and allow EMA to review both our 2.0 mg *neffy* and preclinical dog anaphylaxis study results.

We are also pursuing pediatric approval of *neffy* in Europe based on the same US pediatric study. We plan to submit a post-approval variation to EMA for the 1.0 mg *neffy* in 2023 following potential approval of the 2.0 mg *neffy* dose.

Our partners in Japan and China expect that they will file for regulatory approval in their respective regions in 2023 following our anticipated FDA approval of *neffy*.

Commercialization Opportunity and Commercialization Plan

Type I Allergy Market Overview

neffy is a needle-free, low-dose intranasal epinephrine nasal spray in clinical development for use as a rescue medication for people with Type I severe allergic reactions including anaphylaxis. *neffy* was designed to provide injection-like absorption of epinephrine, in a small, easy-to-carry, easy-to-use, rapidly administered, and reliable nasal spray device.

All systemic allergic reactions have the potential of progressing to anaphylaxis and becoming life-threatening. These reactions can be unpredictable and progress quickly to develop severe symptoms within a few minutes after exposure and can progress to a life-threatening event if not treated immediately. Patient and caregiver preparedness to act quickly and confidently during a severe allergic reaction is imperative. Hesitation can lead to worse clinical outcomes and can be fatal.

Epinephrine is the first-line treatment for the emergency treatment of Type I allergic reactions including anaphylaxis. Epinephrine needs to be given as soon as symptoms occur because it is the only medication proven to stop a potentially life-threatening allergic reaction.

Needle-free and easy-to-use *neffy* may allow for improved patient and caregiver preparedness to give epinephrine quickly, confidently, and without hesitation that is caused by fear of the needle. Intended for use at the first signs of an allergic response, *neffy* is designed to provide patients and their families with a new option to rapidly resolve symptoms and prevent progression to severe anaphylaxis.

If approved for use, we believe our first-in-class nasal spray may transform the way we think about and use life-saving epinephrine.

Existing US Market Opportunity

We estimate approximately 25 to 40 million people in the United States have experienced Type I allergic reactions. Of this group, approximately 16 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only about 3.3 million of them filled a prescription in 2021 for an epinephrine intra-muscular injectable device, including auto-injectors, equating to approximately 10 million devices.

Of those 3.3 million people, roughly half don't carry these devices due to many drawbacks that can result in patient and caregiver injury, hesitation, and delays in administration principally because of apprehension and pain of needles. In turn, the failure or delay of epinephrine delivery can allow the allergic reaction to progress in severity causing life-threatening symptoms or events that potentially require emergency services and/or hospitalization.

We believe *neffy* could address the needs of not only the approximately 3.3 million patients in the United States who currently fill intra-muscular injectable prescriptions, but also the more than 22 million eligible Type I allergy patients in the United States who are at risk of severe allergic reactions that are not prescribed or do not fill their epinephrine prescriptions, including approximately 2.5 million former injectable patients in the United States in the last three years that either refused to fill, or did not renew an intramuscular injectable device prescription.

Based on market access research and data from IQVIA, we estimate that 2021 U.S. net sales for intra-muscular injectable devices were approximately $1 billion. Approximately 80% of the epinephrine intra-muscular injectables sold in the United States in 2021 were for the 0.3 mg dose for adults and children greater than 30 kg in weight.

We have conducted multiple market research studies with caregivers, generally parents, and patients with severe Type I allergic reactions in the United States to evaluate potential market perceptions of *neffy* and currently available epinephrine delivery devices. Based on two independent quantitative market research studies including a total of 350 patients and 75 allergists, pediatricians and primary care physicians, approximately 80% of patients with a current epinephrine auto-injector prescription stated that they would prefer *neffy*. Furthermore, 100% of the physicians surveyed stated they would prescribe if their patient asked for *neffy*, indicating that *neffy* prescriptions would likely be highly driven by patient preference and awareness of *neffy*.

In our market research, parents and people with current or prior epinephrine auto-injector prescriptions were asked if and when they would adopt a new nasal spray device product such as *neffy*.

- A majority indicated they would adopt *neffy* within three months of it coming to market,
- 69% of patients indicated they would use *neffy* sooner than their current auto-injector device,
- 65 to 72% of patients indicated that they would use *neffy* first instead of an over the counter antihistamine
- 88% reported they would be more willing to use *neffy* in public.

These data suggest that *neffy* has the potential to be rapidly adopted by most of the approximately 3.3 million patients in the United States today who fill their epinephrine auto-injector prescription, if approved. These patients serve as our base estimate for the current epinephrine market for *neffy*.

Key potential growth levers for *neffy* within the existing epinephrine market for the emergency treatment of Type I allergic reactions, which currently consists of only intra-muscular injectable products include:

- **Consistent base market growth observed with the epinephrine intra-muscular injectable products.** From 2007 to 2021, the number of epinephrine intra-muscular injectable devices sold in the United States has increased by approximately 5% annually based on IQVIA unit sales data, primarily due to the increasing size of the overall population affected by severe Type I allergies, led by food-based allergies.
- **Potential promotional lift due to new marketing and education efforts by a branded product such as *neffy***. The existing market for epinephrine intra-muscular injectable products is characterized by being highly promotionally sensitive, particularly from a consumer perspective, and our market research has indicated that *neffy*'s user-friendly product profile has the potential to resonate significantly with consumers. We estimate that branded marketing of EpiPen prior to generic entry contributed a promotional lift of 31% over base epinephrine intra-muscular injectable market trends. We plan to reach and support patients directly through efficient direct-to-consumer advertising after educating professional physician practices and securing appropriate payer coverage for *neffy*.
- **Targeting the approximately 2.5 million former patients that either do not fill their epinephrine intra-muscular injectables prescriptions or whose prescriptions have recently lapsed**. The exodus of patients who have received prescriptions from the market has been attributed to a number of factors, including reduced promotional activities in recent years, limited adherence program effectiveness (lapsed prescriptions) and patient adversity to currently marketed products (i.e., fear of needles and concerns regarding poor reliability). In our market research of 100 former patients who refused to fill or renew a prescription, approximately 75% indicated a willingness to return to the market and request *neffy* if approved. We hope to engage with these patients through programs to encourage appropriate epinephrine use with *neffy* and increase consistency of epinephrine acquisition to help manage their condition.
- **Increased per patient device acquisition by patients and parents.** In our market research of 350 patients with an active intra-muscular injectable prescription, approximately 70% to 80% of patients reported an intention to acquire additional devices compared to their current injectable device if *neffy* is approved by the FDA. Currently, we estimate only between 20% to 30% of patients currently obtain more than one pack (containing two devices) per year today.

US Market Expansion Opportunity

While we believe the existing epinephrine intra-muscular injectables market is a large commercial opportunity for *neffy* with multiple independent opportunities for further growth, IQVIA claims data indicates that many diagnosed, identifiable eligible patients do not receive prescriptions for intra-muscular injectables. Outside of the five million patients who were recently prescribed an epinephrine injectable device, there are approximately 11 million patients who are under the care of physicians per IQVIA claims data, but have not been prescribed an epinephrine intra-muscular injectable device, as well as another approximately 9 million patients not currently under the care of physicians

- **Over time, targeting the approximately 11 million identified and diagnosed in-office patients in IQVIA claims data with Type I allergic reactions that are eligible but have not been prescribed epinephrine device.** In our market research, physicians indicated they would prescribe *neffy* to more than half of the patients who were eligible, but do not currently receive an intra-muscular injectable prescription.
- **Development in new allergy indications.** There are approximately 10 million patients with allergy conditions (e.g. urticaria flares and asthma exacerbations) where epinephrine has never

been formally developed as a prescription product, despite being used in-hospital to resolve such acute symptoms. Such patients in other conditions experience multiple episodes each year, and we believe they would likely use multiple *neffy* each year to resolve their symptoms.

Ex-US Market Opportunity

- Outside of the United States, we estimate that there are an additional 15 million patients in Europe, and over 30 million patients in Asia including China and Japan, that experience Type I allergic reactions that are clinically appropriate for being prescribed *neffy*.
- In 2021, epinephrine intra-muscular injectable sales outside the United States were approximately $250 million based on IQVIA data. In Europe and Japan, sales of epinephrine injectable devices are approximately $160 million. We believe education around Type I allergic reactions and marketing of intra-muscular injectables has been limited in these regions, and that promotion and the availability of *neffy* would significantly expand the market.
- Market research conducted in Europe with 120 patients who have an epinephrine auto-injector prescription indicated that 98% would prefer *neffy*, and that they would acquire approximately twice as many *neffy* devices compared to their current injectable device, if approved.
- To target these opportunities outside of the United States, we have entered into licensing and collaboration agreements with Recordati for the development and commercialization of *neffy* in the EU, Iceland, Liechtenstein, Norway, Switzerland, the United Kingdom, Russia/CIS, Turkey, the Middle East and French-speaking African countries, Alfresa Pharma for Japanese rights to *neffy* and Pediatrix Therapeutics (founded by F-Prime Capital, Eight Roads and Creacion Ventures) for Chinese rights to *neffy*.

Commercial Strategy

We believe that the epinephrine market is a highly consumer driven market. We expect this to be especially true for *neffy*, given that 100% of the physicians surveyed in our quantitative market research studies indicated that they would prescribe *neffy* if asked by a patient and approximately 70% of physicians would recommend *neffy*. As a result, we believe that driving consumer awareness, so that patients and parents ask their healthcare provider for *neffy*, while minimizing both access and educational barriers to acceptance is essential.

Our plan to execute on our go-to-market strategy for *neffy* includes the following:

We plan to create healthcare professional and consumer awareness and anticipation prior to launch. We plan to use the FDA's NDA review period to refine our go-to-market strategy and create

awareness about our company and our technology. We expect to expand medical affairs capabilities prior to commercial launch to establish additional relationships with key opinion leaders and gain insight into current practice patterns and burdens. The medical affairs team will also collaborate with the commercial team to help payers fully understand *neffy's* value proposition and the limitations associated with needle injectors. We also plan to begin to raise awareness and support meaningful education through partnership with patient advocacy groups and medical societies as well as a disease education campaign including through social media and digital.

Based on the unmet needs that we identified, our pre-launch activities may be focused on delivering disease awareness and education surrounding the appropriate epinephrine use to prevent anaphylaxis to allergists and pediatricians as well as parents and patients in partnership with allergy and professional advocacy groups. These disease education efforts will more specifically reinforce the importance of early administration of epinephrine at the first sign of a severe Type I allergic reaction, help stakeholders understand the factors that are associated with hesitation to fill and use epinephrine earlier in a reaction, and the importance of alternative epinephrine delivery options to support those affected by severe allergic reactions. In our market research, 42% of patients who had used an epinephrine injectable device during a recent episode reported that they delayed use by an average of approximately 9 minutes. If *neffy* were available, these patients reported that they would reduce their average wait time to use by 45%. Additionally, 47% of patients reported they were more likely to fill prescriptions and 86% of patients reported they would carry *neffy* with them. We believe a broad understanding of this evidence will help to establish and increase the urgency to treat patients with *neffy* and support our rapid launch uptake following FDA approval, if achieved.

We plan to initially commercialize *neffy* in the United States with a combination of direct promotion, virtual sales consultants, and non-personal promotion intended to reach, at a minimum, the healthcare professionals that account for 45% of the current epinephrine prescriptions. Our promotion will focus the launch on the highest potential practicing allergists, pediatricians, and primary care physicians. In our market research, approximately 80% of patients see their treating physicians at least every six months, and 98% at least once a year. We plan to optimize our field representatives based on planned research on current market dynamics, geo-targeting and assessment of current professional-industry interaction preferences initially to reach these professionals. We expect significant reach to be achieved based on expanded use of non-personal promotional tactics and virtual sales representatives to reach healthcare professionals and focus on the sequential activation of patient demand through direct-to-consumer tactics that will help also drive physician awareness due to overlapping exposure.

We intend to partner with patient advocacy organizations as well as influencers and leverage an omnichannel strategy including direct-to-patient and parent tactics, social and traditional media, digital presence, and additional public relations to drive awareness, for patients to ask for *neffy*, and communicate our value proposition. The pent-up patient demand that we believe is ready to be activated by *neffy* is reflected in our market research where 87% of patients indicated a high likelihood to proactively visit their physician in-person and ask about getting a new prescription for *neffy* (43% of patients indicating a 10 out of 10 likelihood, and 44% of patients indicating a 7-9 out of 10 likelihood). Our research also showed that physicians would recommend *neffy* to approximately 70% of their patients. In addition, the severe Type I allergy market has historically been highly promotionally sensitive, and in recent years, there has been limited investment in education or promotion, which we believe provides an opportunity for significant promotional lift from our planned marketing efforts.

We intend to establish *neffy* as the dominant and most recognized brand in the category. We believe *neffy*'s potential brand recognition and user-friendly profile can be an important driver of

growth and source of competitive differentiation, especially as the first “no needle, no injection” solution for severe Type I allergic reactions. We have designed *neffy* to offer healthcare professionals, patients and caregivers a simple, injection-free, portable, highly reliable and user-friendly alternative that facilitates early administration of epinephrine to provide rapid symptom relief and to stop the allergic reaction from progressing to more serious events. We believe the attractiveness and meaningful differentiation of *neffy* across both physicians and payers will stimulate a high patient and parent desire to switch to or return to managing their condition with *neffy*.

We intend to secure affordable market access for all consumers by optimizing contracting, co-pay support and distribution of *neffy*. To ensure access and affordability for *neffy*, we plan to engage with payors to convey the clinical rationale and value proposition of *neffy*. To date, we have conducted extensive market research with approximately 50 decision-makers at payors to help forecast the potential commercial opportunity for *neffy* in the United States. Health insurers surveyed have indicated that *neffy* is perceived as differentiated brand from epinephrine auto-injector products, with its needle-free route of administration and increased likelihood of being carried as the most important product attributes. Based on these analyses and our planned contracting strategy, we believe payers can support favorable and broad market access for *neffy*. Further, we will offer comprehensive patient support programs in the form of co-pay buydowns to help ensure access and affordability for all patients.

We intend to expand the market beyond the 3.3 million patients currently filling epinephrine injection device prescriptions. We believe that the severe Type I allergy market is currently significantly underpenetrated due to the lack of, and limitations in, current treatment options. We believe the availability of *neffy* could drive increased device uptake among the existing 3.3 million patients currently filling epinephrine injection device prescriptions, adoption by the approximately 2.5 million patient that receive, but do not fill their prescription, and the 11 million patients diagnosed and managed by physicians who do not currently have an epinephrine auto-injector, especially those incorrectly using antihistamines as a substitute. Other launches of intranasal products for emergency use into previously injection-only markets such as NARCAN (marketed by Emergent BioSolutions) and BAQSIMI (marketed by Eli Lilly) have rapidly captured a significant percentage of the existing market, and also expanded their respective markets. Both products use the same device that ARS has chosen for *neffy*. We believe that NARCAN’s widespread use clearly demonstrates market uptake in response to the advantages of an intranasal product via proven device over injection, considering in particular that NARCAN is used in life threatening rescue situations where reliable administration is required for confident administration, similar to severe Type I allergic reactions. Beyond just reliability, we believe that an intranasal product has unique advantages for treating a severe Type I allergic reaction due to patient and parent fear and avoidance of injection and because time is of the essence. This perspective is distinct from other diseases with chronic use of injection products, administration by a trained professional is required, or where the injection is more manageable and tolerated. In our market research, respondents have described *neffy* as “game-changing” and we believe *neffy*, if approved, can make a significant difference in patient lives and outcomes.

If approved, we plan to establish a distribution channel in the United States for the commercialization of *neffy*. We expect to sell *neffy* to wholesalers, who, in turn, will sell our *neffy* to retailors and other customers. We expect to use a third-party logistics provider for key services related to logistics, warehousing and inventory management, distribution, contract administration, order management and chargeback processing and accounts receivable management. We also plan to explore other non-traditional distribution channels including telemedicine.

To target markets outside of the United States, we have entered into strategic partnerships with several pharmaceutical companies to obtain regulatory approval and market *neffy*. These include Recordati for the EU, Iceland, Liechtenstein, Norway, Switzerland, the United Kingdom,

Russia/CIS, Turkey, the Middle East and French-speaking African countries, Alfresa Pharma for Japan and Pediatrix Therapeutics for China. We anticipate that in certain markets additional clinical trials of *neffy* may be required to obtain regulatory approval and/or ensure market access.

Competition

Our industry is highly competitive and subject to rapid technological changes. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Many of our potential competitors have substantially greater financial, technical, commercial and human resources than we do and significantly more experience in the discovery, development and regulatory approval of product candidates and the commercialization of those products. We believe that the key competitive factors that will affect the development and commercial success of *neffy* and the other product candidates that we may develop are their efficacy, safety and tolerability profile, convenience in dosing, product labeling, value and price, in addition to whether there are alternative therapies approved for other indications and prescribed for off-label use and the availability of reimbursement from the government and other third parties. Our commercial opportunity could be reduced if our competitors have products which are better in one or more of these categories.

We expect that, if approved, *neffy* would compete with a number of existing products and other product candidates that target Type I allergic reactions, including certain products that are or may become generic products. Additionally, the development of new treatment methods for the diseases we are targeting could render our current or future product candidates non-competitive or obsolete.

We anticipate that, if approved, *neffy* will compete primarily against epinephrine intra-muscular injectable products, for the emergency treatment of Type I allergic reactions including EpiPen and its generics, which are marketed by Viatris, Inc. and Teva Pharmaceuticals, Inc., respectively; Adrenaclick, which is marketed by Amneal Pharmaceuticals, Inc.; Auvi-Q, which is marketed by Kaleo, Inc.; Symjepi, which is marketed by Sandoz, Inc., a Novartis division.

We are not aware of any other company that has a “no needle, no injection” epinephrine product candidate in clinical development in the United States that has demonstrated PKs bracketed by the approved injection products for all pharmacokinetic parameters requested by the FDA. We are also not aware of any “no needle, no injection” epinephrine product candidate for the pediatric population that is in clinical development.

We are aware of several companies developing higher dose intranasal candidates including Bryn Pharma, Nasus Pharma, Orexo AB and Hikma Pharmaceuticals, Inc. (previously INSYS Therapeutics, Inc.). Amphastar Pharmaceuticals, Inc. is reported to be developing an intranasal candidate, but has not disclosed its dose. Aquestive Therapeutics is developing a sublingual candidate based on a prodrug of epinephrine.

Manufacturing and Supply

We do not own or operate manufacturing facilities for the production of *neffy*, nor do we have plans to develop our own manufacturing operations for clinical materials or commercial products in the foreseeable future. We currently depend on third-party contract manufacturing organizations (“CMOs”) for all of our required raw materials, drug substance and drug product for our preclinical research and clinical trials.

We currently rely on suppliers for raw materials including drug substance and multiple manufacturers for our product candidates and expect to rely on third-party suppliers and manufacturers

for the commercial supply of any approved products. We currently employ internal resources and third-party consultants as needed to manage our CMOs. These CMOs offer a comprehensive range of contract manufacturing and packaging services and have successfully handled the scale up of *neffy* in preparation for commercialization.

neffy is presented as a nasal spray in aqueous solution with epinephrine as the active pharmaceutical ingredient ("API") filled into glass vials and closed with a rubber stopper and assembled into the unit dose sprayer device. Over time, epinephrine is oxidized and loses potency resulting in a finite shelf-life, and the *neffy* solution inside the unit dose sprayer changes to an amber to brown color.

Epinephrine is the API used in *neffy*. We intend to use Cambrex Profarmco ("Cambrex") as one of our commercial sources for epinephrine API. Cambrex holds a U.S. drug master file for epinephrine produced at its facility in Italy, and its manufacturing process is fully validated. We have entered into a commercial supply agreement with Cambrex, and while we believe that Cambrex has sufficient capacity to satisfy our long-term requirements, there are several sources of API available, and we intend to launch with a second source of API and are in the process of qualifying this second API source.

Dodecyl maltoside or Intravail is purchased through our license agreement with Aegis Therapeutics, Inc. from two manufacturers, Dr. Reddy Laboratories and Inalco, which are based in India and Italy, respectively.

The unit dose sprayer device used to delivery drug product in *neffy* is produced by Aptar Pharma ("Aptar"). Aptar produces devices in France and we believe Aptar has sufficient capacity to satisfy our long-term requirements. The patent for the Aptar unit dose nasal spray device expired in early 2020, and we believe there will be generic supplies available soon after launch.

Manufacturing drug product for *neffy* is conducted by Renaissance Pharmaceuticals, Inc. ("Renaissance Pharma"), which has been actively involved in supporting the manufacture of *neffy* devices in our clinical development. We intend to use its facility in Lakewood, New Jersey as our primary source for drug product manufacturing and final packaging. We have entered into a commercial supply agreement with Renaissance Pharma, and believe they have sufficient capacity to satisfy our long-term requirements, although we are evaluating alternating sourcing options.

Ongoing stability studies demonstrate that *neffy* is stable at room temperature for at least 18 months, based on stability data from the 2.0 mg dose of *neffy* for 12 months and the 1.0 mg dose of *neffy* for 24 months, and we plan to continue to conduct ongoing registration stability studies that we anticipate will enable us to indicate on our label, if approved, that *neffy* is stable at room temperature for 18 months at 25^{o}C. We have also conducted studies indicating that *neffy* is also stable at temperature excursions including 40^{o}C for up to six months, and at 50^{o}C for up to three months.

Intellectual Property

We strive to protect our intranasal epinephrine product candidates by seeking, maintaining, and defending our patent rights in the United States and internationally. Our policy is to pursue, maintain and defend patent rights in strategic areas, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

We co-own or exclusively license the patents and patent applications relating to our intranasal epinephrine product candidates. As of June 2022, our patent portfolio consisted of issued patents and

pending patent applications that we co-own or exclusively license from Aegis Therapeutics LLC in the United States and other countries throughout the world. In total, as of that date, our patent portfolio consisted of four issued U.S. patents, one granted Australian patent, one granted Japanese patent, one granted patent in South Korea, two granted United Kingdom patents, two pending U.S. non-provisional patent applications, and over fifteen pending foreign patent applications directed to intranasal epinephrine formulations and methods of their use. These issued patents and pending patent applications are expected to expire in 2038, absent any patent term adjustments or patent term extensions for regulatory delay.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, and other proprietary information to develop and maintain our competitive position. We seek trademark protection in the United States and in certain other jurisdictions where available and when we deem appropriate. We currently have registrations for our “Neffy” mark in the United States as well as in foreign jurisdictions, including the International Bureau (WIPO), United Kingdom, European Union, and Japan.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates and processes. For this and more comprehensive risks related to our intellectual property, please see “*Risk Factors—Risks Related to ARS Pharma—Risks Related to ARS Pharma’s Intellectual Property.*”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see “*Risk Factors—Risks Related to ARS Pharma—Risks Related to ARS Pharma’s Intellectual Property.*”

We also seek to protect our intellectual property in part by entering into confidentiality agreements with companies with whom we share proprietary and confidential information in the course of business discussions, and by having confidentiality terms in our agreements with our employees, consultants,

scientific advisors, clinical investigators, and other collaborators and contractors and also by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see "*Risk Factors—Risks Related to ARS Pharma—Risks Related to ARS Pharma's Intellectual Property.*"

The patent positions of specialty pharmaceutical companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see "*Risk Factors—Risks Related to ARS Pharma—Risks Related to ARS Pharma's Intellectual Property.*"

Our Collaboration and Licensing Agreements

License Agreement with Aegis

In June 2018, we entered into a license agreement with Aegis Therapeutics, LLC ("Aegis"), which was amended in July 2020 and January 2021. Pursuant to the agreement, Aegis granted us an exclusive, worldwide, sublicensable license under patents and know-how relating to the INTRAVAIL drug delivery technology to research, develop, make (subject to Aegis supplying the INTRAVAIL drug delivery technology to us under a supply agreement), use, sell, offer for sale, import, and otherwise commercialize products incorporating epinephrine compounds ("Aegis Licensed Compounds"), including the *neffy* nasal spray. During the term of the agreement, we are required to use commercially reasonable efforts to obtain regulatory approval for products containing one or more Aegis Licensed Compounds and using the excipient (including INTRAVAIL) ("Aegis Licensed Products") and to thereafter maximize sales of the Aegis Licensed Products, and Aegis may not directly or indirectly exploit an Aegis Licensed Product or Aegis Licensed Compound or derivatives thereof without our consent.

Under the agreement, Aegis received an upfront license fee of $50,000 and is entitled to receive development milestone payments of up to $3.95 million in aggregate and commercialization milestone payments up to $16.0 million in the aggregate for each Aegis Licensed Product. We made a $0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019. We will be required to pay Aegis a milestone payment of $1.0 million contingent upon FDA's acceptance of a US NDA filing, which occurred in the third quarter of 2022, a milestone payment of $2.5 million contingent upon the FDA approval of the first Aegis Licensed Product and a milestone payment of $5.0 million contingent upon first commercial sale of the first Aegis Licensed Product. Additionally, Aegis is entitled to receive a low- to mid-single-digit percentage royalty, subject to reductions under certain conditions including due to generic competition or below threshold levels of profitability in specific countries around the world, on net sales of all Aegis Licensed Products during the applicable royalty term, which commences on the first commercial sale of a Aegis Licensed Product in a country and ends upon the later of the expiration of all licensed patents covering such Aegis Licensed Product in such country or 15 years after the date of the first commercial sale of the Aegis Licensed Product in such country ("Aegis Royalty Term").

The agreement will continue until the expiration of the last-to-expire Aegis Royalty Term, unless sooner terminated. We have the right to terminate the agreement at any time after a specified notice period to Aegis. Either party may terminate the agreement for uncured material breach of the other party, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period.

Collaboration and License Agreement with Alfresa

In April 2020, we entered into a collaboration and license agreement with Alfresa Pharma Corporation ("Alfresa"). Pursuant to the agreement, we granted Alfresa (i) an exclusive, sublicensable license under our patents relating to *neffy* to develop, use and import epinephrine compositions ("Alfresa Licensed Compositions") and related products ("Alfresa Licensed Products") in Japan (the "Alfresa Territory") and to promote, distribute, offer for sale and sell Alfresa Licensed Products in the Alfresa Territory, and (ii) a non-exclusive, sublicensable license to manufacture and commercialize Alfresa Licensed Products under the license described in clause (i), under our technology to make and have made Alfresa Licensed Compositions and Alfresa Licensed Products in and outside the Alfresa Territory solely for the purpose of exercising the license described in clause (i) in the Alfresa Territory. We expressly reserved all rights to practice and grant licenses under our technology outside the scope of the licenses granted to Alfresa, including the right to manufacture Alfresa Licensed Compositions and Alfresa Licensed Products in the Alfresa Territory. During the term of the agreement, (1) we and Alfresa are obligated to use commercially reasonable efforts to develop a Alfresa Licensed Product throughout the Alfresa Territory, and (2) Alfresa is obligated to use commercially reasonable efforts to (A) seek pricing and reimbursement approval, (B) seek and maintain regulatory approval for the Alfresa Licensed Products through the Alfresa Territory, and (C) market, promote and otherwise commercialize Alfresa Licensed Products in the field throughout the Alfresa Territory.

Under the agreement, we received a one-time upfront payment of $2.0 million and earned $5 million upon the achievement of a clinical milestone during 2021. We are eligible to receive regulatory milestones of up to $8.0 million in the aggregate. Further, we are eligible to receive a negotiable transfer price expected to be in the low double-digit percentage on net sales subject to the regulatory approval to commercialize *neffy* in Japan. We share the cost of any additional clinical studies required for approval of *neffy* in Japan. Additionally, Alfresa is obligated to either (i) enter into a commercial supply agreement with us pursuant to which we will supply drug product for commercial sale at an agreed upon transfer price, or (ii) if Alfresa elects to manufacture its own supply of drug product, pay us a royalty payment on the net sales of drug product in the Alfresa Territory in an amount equal to monetary value we would receive by supplying drug product to Alfresa at the transfer price.

The agreement will continue until the later of (i) expiration of the last-to-expire valid claim of our patents or joint patent with Alfresa covering the composition, method of manufacture or method of use in the field of any Alfresa Licensed Product in the Alfresa Territory, and (ii) 10 years after the first commercial sale of any Alfresa Licensed Product in the Alfresa Territory. Alfresa has the right to terminate the agreement (1) at any time after a specified notice period to us, or (2) upon notice to us if a binding decision is rendered invalidating any of our patents. Either party may terminate the agreement for uncured material breach of the other party, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period.

Collaboration and Distribution Agreement with Pediatrix

In March 2021, we entered into a collaboration and distribution agreement with Pediatrix Therapeutics ("Pediatrix"). Pursuant to the agreement, we granted Pediatrix (i) an exclusive, royalty-bearing, sublicensable license under our patents relating to *neffy* to develop, use, register and import epinephrine compositions ("Pediatrix Licensed Compositions") and related products ("Pediatrix

Licensed Products") in China, Macau, Hong Kong and Taiwan (the "Pediatrix Territory") and to promote, offer for sale and sell Pediatrix Licensed Products in the Pediatrix Territory; and (ii) an exclusive, royalty-bearing, sublicensable license to manufacture Pediatrix Licensed Compositions and Pediatrix Licensed Products solely for the purpose of exercising the license described in clause (i) in the Pediatrix Territory. We expressly reserved all rights to practice and grant licenses under our technology outside the scope of the licenses granted to Pediatrix. During the term of the agreement, Pediatrix is obligated to use commercially reasonable efforts to (1) develop the Pediatrix Licensed Products throughout the Pediatrix Territory, (2) prepare, obtain, maintain and renew all necessary regulatory approvals for the Pediatrix Licensed Products in the Pediatrix Territory, and (3) market, promote and otherwise commercialize the Pediatrix Licensed Products throughout the Pediatrix Territory.

Under the agreement, we received a one-time upfront payment of $3.0 million and are eligible to receive a regulatory milestone payment of $4.0 million and net sales milestone payments of up to $80.0 million in the aggregate. We will receive a per unit supply price for any sale of commercial supply to Pediatrix. Additionally, we are eligible to receive a tiered royalty on the net sales of all Pediatrix Licensed Products during the applicable royalty term, which is less than one percent below a minimum annual sales threshold, and increasing to low-to-mid double digit percentages above the minimum annual sales threshold, subject to reductions under certain conditions including due to generic competition. Pediatrix's obligation to pay us royalties continues on a Pediatrix Licensed Product-by-Pediatrix Licensed Product and region-by-region basis in the Pediatrix Territory, until the latest of (i) expiration of the last-to-expire valid claim of our patents covering such Licensed Product in such region; (ii) the expiration of all regulatory exclusivities that cover such Licensed Product in such region; or (iii) ten years after the first commercial sale of such Pediatrix Licensed Product in such region (the "Pediatrix Royalty Term").

The agreement will continue until the expiration of the last-to-expire Pediatrix Royalty Term. Pediatrix has the right to terminate the agreement at any time after a specified notice period to us. Either party may terminate the agreement for uncured material breach of the other party, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period.

License and Supply Agreement with Recordati Ireland

In September 2020, we entered into a license and supply agreement with Recordati Ireland, Ltd ("Recordati Ireland"). Pursuant to the agreement, we granted Recordati Ireland an exclusive, royalty-bearing, sublicensable license under our patents relating to *neffy* to (i) perform Recordati Ireland's development activities on the epinephrine compositions ("Recordati Ireland Licensed Compositions") and related products ("Recordati Ireland Licensed Products") for commercialization in the E.U., United Kingdom, and certain countries in the Middle East, Africa and Eurasia (the "Recordati Ireland Territory"), (ii) manufacture (or have manufactured) the Recordati Ireland Licensed Products for commercialization in the Recordati Ireland Territory, (iii) file and hold regulatory approvals for the Licensed Products in the Recordati Ireland Territory, and (iv) commercialize the Recordati Ireland Licensed Products in the Recordati Territory. We expressly reserved all rights to practice and grant licenses under the Recordati Ireland Licensed Compositions and Recordati Ireland Licensed Products outside the scope of the licenses granted to Recordati Ireland, including the right to develop and manufacture the Recordati Ireland Licensed Products in the Recordati Ireland Territory. Pursuant to the agreement, we undertook the obligation to perform certain studies, prepare and submit certain marketing authorization requests, and supply the Recordati Ireland Licensed Products to Recordati Ireland in accordance with the terms of the agreement. Recordati Ireland undertook to use commercially reasonable efforts to comply with regulatory activities that are required to a marketing authorization holder and to act to maximize the sale of the Recordati Ireland Licensed Products throughout the Recordati Ireland Territory.

Under the agreement, we received a one-time upfront payment of €10 million and are eligible to receive (i) regulatory milestone payments of up to €15.0 million in the aggregate, (ii) launch milestone payments of up to €5.0 million in the aggregate, and (iii) net sales milestone payments of up to €75.0 million in the aggregate. Additionally, we are eligible to receive a tiered royalty on the net sales of all Recordati Ireland Licensed Products during the applicable royalty term, ranging from mid-teens to mid twenty percentages, subject to caps and reductions under certain conditions including due to competition. To date, we have earned an upfront payment of €10.0 million and a regulatory milestone payment of €5.0 million

The agreement will continue in effect so long as Recordati Ireland, or its affiliates or sublicensees are commercializing the Recordati Ireland Licensed Products in the Recordati Ireland Territory, unless earlier terminated by one of the parties. Recordati Ireland has the right to terminate the agreement on a country-by-country basis after providing written notice to us if the applicable marketing authorization application is finally rejected and there is no reasonable basis for approval. Either party may terminate the agreement for uncured material breach of the other party, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period.

Manufacturing Agreement with Renaissance

In September 2020, we entered into a manufacturing agreement with Renaissance Lakewood, LLC ("Renaissance"). Pursuant to the agreement, Renaissance agreed to manufacture for, and provide to us, *neffy* nasal unit dose sprays ("Renaissance Products"). We are obligated to provide Renaissance with certain supplies to manufacture the Renaissance Products and to purchase from Renaissance a mid-double digit percentage of our annual aggregate Renaissance Product requirements in the E.U., and a high-double digit percentage of our annual aggregate Renaissance Product requirements in the U.S. The agreement contains conventional commercial pharmaceutical manufacturing provisions including certain minimum purchase amounts to be determined in the future based on forecast needs and minimum batch size projections. We may also request Renaissance perform certain services related to the Renaissance Product, for which we will pay reasonable compensation to Renaissance.

The initial term of the agreement commenced on the date it was entered into and continues (a) for Renaissance Product designated for commercial sale in the U.S. until the earlier of the fifth anniversary of the (i) target U.S. launch date and (ii) the initial U.S. launch date ("U.S. Initial Term"), and (b) for Renaissance Product designated for commercial sale in the E.U. and other countries, the earlier of the fifth anniversary of (i) the target E.U. launch date and (ii) the initial E.U. launch date ("E.U. Initial Term"), in each case unless earlier terminated by one of the parties. The U.S. Initial Term and E.U. Initial Term automatically renew for successive two-year terms ("Renewal Term"). Either party may elect not to renew the U.S. Renewal Term and/or the E.U. Renewal Term by providing the requisite prior notice to the other party. Either party may terminate the agreement (1) for uncured material breach of the other party, (2) upon notice for insolvency-related events of the other party that are not discharged within a defined time period, (3) on a product-by-product basis if the manufacture, distribution or sale would materially contravene any applicable law, (4) by providing the requisite notice if (a) we have not submitted a regulatory filing for any Renaissance Product in the U.S. on or before June 30, 2022, (b) the authorization and approval to distribute or sell Renaissance Product in the U.S. is not granted on or before the target U.S. launch date, (c) the authorization and approval representing more than a targeted number of units of Renaissance Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (d) we decided in our sole discretion to cease commercializing the Renaissance Product in the U.S., (5) in the case of a force majeure event that continues for six months or more, or (6) a violation by the other party of trade control or anti-corruption laws.

Legal Proceedings

From time to time, we may be involved in various legal proceedings and subject to claims that arise in the ordinary course of business. On August 12, 2021, Amphastar Pharmaceuticals, Inc. filed a Petition for *Inter Partes* Review ("IPR") with the United States Patent and Trademark Office ("USPTO"), seeking to invalidate claims 1-20 of United States Patent No. 10,682,414 (the "'414 patent"), and on February 14, 2022, the USPTO instituted review of those claims. Oral arguments are scheduled for November 16, 2022, and a decision in the proceeding is due by February 2023. The 414 patent, which was issued on June 16, 2020, is entitled "Intranasal Epinephrine Formulations and Methods for the Treatment of Disease". The claims of the 414 patent are directed to methods of treating a type-I hypersensitivity reaction, including anaphylaxis, using an aqueous nasal spray pharmaceutical formulation containing epinephrine or a salt thereof in a single dose. Although, the results of an IPR are inherently unpredictable and uncertain, and could result in the USPTO finding some or all of claims 1-20 of the 414 patent to be invalid or unenforceable, we do not believe that an adverse outcome will have a material adverse effect on our business, operating results, cash flows or financial condition. Regardless of the outcome, involvement in legal proceedings may have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors. See the section titled "*Risk Factors—Risks Related to ARS Pharma—Risks Related to ARS Pharma's Intellectual Property—ARS Pharma may become involved in lawsuits to protect or enforce its patents or other intellectual property, which could be expensive, time consuming and unsuccessful and could result in a court or administrative body finding its patents to be invalid or unenforceable.*"

Except as described above, we are currently not involved in any legal proceeding that we believe could have a materially adverse effect on our financial condition or results of operations. Except as described above, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or other body pending or, to the knowledge of our executive officers, threatened against or affecting us, our common stock, any of our subsidiaries or our subsidiaries' officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

Regulation of Packaging Components in the United States

ARS anticipates based on historical precedents of other nasal spray products that the sprayer component of *neffy* and any future product candidates ARS develops will be packaging. In the United States, packaging is reviewed in connection with the evaluation of the underlying drug marketing application. FDA reviewers would typically consult with their counterparts in the device center to ensure that the packaging meets applicable requirements regarding safety, effectiveness, durability and performance, but no separate marketing application for the sprayer components of such product candidates is required. In addition, under FDA regulations, packaging is subject to cGMP requirements. The FDA or comparable regulatory authorities may disagree with this characterization and require that ARS obtain a separate clearance or approval of the sprayer component as a medical device, which could further delay or prevent marketing approval of *neffy* or future product candidates. Any such delay or inability to obtain marketing approval of *neffy* or any future product candidate could substantially harm ARS's business.

Government Regulation and Product Approval

As a pharmaceutical company that operates in the United States, we are subject to extensive regulation. Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of

drug products such as those we are developing. Product candidates that we develop must be approved by the FDA, before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects.

Regulation of Combination Products in the United States

neffy is comprised of drug and delivery device components that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product.

A combination product with a primary mode of action attributable to the drug component, such as *neffy*, generally would be reviewed and approved pursuant to the drug approval processes set forth in the FDCA. In reviewing the NDA for such a product, however, FDA reviewers would consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products such as *neffy* are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulations applicable to medical devices.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the FDCA, and implementing regulations. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP") regulations and other applicable regulations;
- submission to the FDA of an investigational new drug ("IND"), which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA's good clinical practice ("GCP") regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA to assess compliance with GCP regulations;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Before testing any compounds with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP requirements. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The drug is administered to an expanded patient population to further evaluate dosage and clinical efficacy at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 trials. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected AEs or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well

as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act ("PREA") requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data need to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products

which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows the advisory committee's recommendations.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or (an) additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also determine that a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Fast Track Designation

The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria. For example, the FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is

acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

Fast track designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, such designations or shortened review periods may not provide a material commercial advantage.

Post-Approval Requirements

Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long term stability of the drug product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in

part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA

may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, the three year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Pediatric exclusivity is another type of non-patent market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other Healthcare Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback laws, false claims laws, data privacy and security laws, and other healthcare fraud and abuse laws, such as transparency laws regarding payments or other items of value provided to healthcare providers.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal healthcare program anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal healthcare program anti-kickback statute has been violated. Additionally, the intent standard under the federal anti-kickback statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the federal civil monetary penalties law, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and

marketing expenditures or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved.

Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we are subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price ("AMP"), and Best Price, Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face

competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. Furthermore, there can be no assurance that a product will be considered medically reasonable and necessary for a specific indication, that a product will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability to sell a product profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. For example, implementation of the ACA substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, administrative, executive, and Congressional legislative challenges to certain aspects of the ACA. For example, President Trump signed several executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been enacted. In 2017, the Tax Cuts and Jobs Act of 2017 included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011which went into effect on April 1, 2013, and due to subsequent legislative

amendments, will remain in effect until 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Congress is considering additional health reform measures.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Presidential executive orders, congressional inquiries, and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. However, several lawsuits have been brought against Health and Human Services ("HHS") challenging various aspects of the rules implemented during the Trump administration. As a result, the Biden administration and HHS have delayed the implementation or published rules rescinding some of these Trump-era policies. Additionally, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. In addition, the American Taxpayer Relief Act of 2021, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program ("MDRP"), which is currently capped at 100% of the AMP for a covered outpatient drug.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of

the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. HIPAA, as amended by HITECH, imposes obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act, the California Privacy Rights Act and the General Data Protection Regulation, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977 ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of an application for a clinical trial authorization ("CTA") much like the IND prior to the commencement of human clinical trials. In the EU, for example, a CTA must be submitted to each country's national health authority and an application made to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements and a favorable ethics committee opinion has been issued, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials are to a significant extent harmonized at the EU level, but could vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application either under the so-called centralized or national authorization procedures. The application used to file an NDA in the United States is similar to that required in the EU, but the exact requirements for authorization may vary.

Centralized Procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission following a favorable opinion by the EMA that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, other immune dysfunctions and viral diseases. The centralized procedure is optional for other products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health or which contain a new active substance for indications other than those specified to be compulsory.

National Authorization Procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorizations in more than one EU Member State of medicinal products that have not yet been authorized in any EU Member State and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

The EU also provides opportunities for market exclusivity. For example, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

The EMA grants orphan drug designation to promote the development of products for the treatment, prevention or diagnosis of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. In addition, orphan drug designation can be granted if the drug is intended for a life threatening or chronically debilitating condition in the EU and without incentives it is unlikely that sales of the drug in the EU would be sufficient to justify the investment required to develop the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free or reduced-fee protocol assistance, fee reductions for marketing authorization applications and other post-authorization activities and ten years of market exclusivity following drug approval, which can be extended to 12 years if trials are conducted in accordance with an agreed-upon pediatric investigational plan. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

In the EU, early access mechanisms for innovative medicines (such as compassionate use programs and named patient supplies), pricing and reimbursement, and promotion and advertising,

amongst other things, are subject to national regulations and oversight by national competent authorities and therefore significantly vary from country to country.

Sanctions for non-compliance with the aforementioned requirements, which may include administrative and criminal penalties, are generally determined and enforced at national level. However, under the EU financial penalties regime, the EMA can investigate and report on alleged breaches of the EU pharmaceutical rules by holders of a marketing authorization for centrally authorized medicinal products and the European Commission could adopt decisions imposing significant financial penalties on infringing marketing authorization holders.

The United Kingdom left the EU on January 31, 2020. Following the transition period which ended on December 31, 2020, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom in the coming years.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Facilities

We currently lease approximately 4,000 square feet of office space in San Diego, California, through December 2024. We believe that this facility will meet our current and near-term needs.

Employees and Human Capital Resources

As of December 31, 2021, we had nine full-time employees, one of whom has a Ph.D. or M.D. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

SILVERBACK MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

For Silverback's management's discussion and analysis of financial condition and results of operations, please refer to Item 7 in Part II set forth in Silverback's Form 10-K for the year ended December 31, 2021, filed with the SEC on March 31, 2022, and Item 2 in Part I set forth in Silverback's Form 10-Q for the quarterly period ended on June 30, 2022, filed with the SEC on August 11, 2022, which sections are incorporated by reference herein. The discussion and analysis of financial condition and results of operations should be read together with the audited and unaudited financial statements of Silverback and accompanying notes appearing in Silverback's Form 10-K for the year ended December 31, 2021, filed with the SEC on March 31, 2022, and Silverback's Form 10-Q for the quarterly period ended on June 30, 2022, filed with the SEC on August 11, 2022.

ARS PHARMA MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements of ARS Pharma and accompanying notes appearing elsewhere in this proxy statement. This discussion of the financial condition and results of operations of ARS Pharma contains certain statements that are not strictly historical and are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a high degree of risk and uncertainty. Actual results may differ materially from those projected in the forward-looking statements due to other risks and uncertainties that exist in ARS Pharma's operations, development efforts and business environment, including those set forth in the section entitled "Risk Factors—Risks Related to ARS Pharma," the other risks and uncertainties described in the section entitled "Risk Factors" and the other risks and uncertainties described elsewhere in this proxy statement. All forward-looking statements included in this proxy statement are based on information available to ARS Pharma as of the date hereof, and ARS Pharma assumes no obligation to update any such forward-looking statement.

Unless otherwise indicated or the context otherwise requires, references in this ARS Pharma Management's Discussion and Analysis of Financial Condition and Results of Operations section to "ARS," "we," "us," "our" and other similar terms refer to ARS Pharma and its consolidated subsidiary prior to the Merger and to Silverback and its consolidated subsidiaries after giving effect to the Merger.

Overview

We are a biopharmaceutical company focused on the development of our novel, potentially first-in-class product candidate, *neffy* (previously referred to as ARS-1) for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail®, which allows *neffy* to provide intranasal delivery of epinephrine. We believe *neffy*'s "no needle, no injection" approach will address a significant unmet need in the use of epinephrine, which is currently approved only in injectable formulations for the emergency treatment of Type I allergic reactions. There are approximately 25 to 40 million people in the United States who experience Type I allergic reactions. Of this group, approximately 16 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, but only 3.3 million currently have an active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector with them due to the many drawbacks of these devices. These drawbacks include the use of needles in the devices, which can result in patient and caregiver injury as well as hesitation and delays in administration due principally to apprehension and pain of needles, allowing the allergic reaction to progress in severity leading to symptoms that seriously impact patient quality of life, to potential need for emergency services and/or hospitalizations, and to life-threatening symptoms or events. Intra-muscular injections also are subject to dosing errors and risk of accidental blood vessel injections, which can cause a significant spike in the intravascular delivery of epinephrine potentially leading to serious cardiovascular complications or events. We believe *neffy*'s "no needle, no injection" delivery that eliminates apprehension, pain and safety concerns, small size allowing for ease of portability, ease of use, and high reliability provide it with a user-friendly profile that will increase prescriptions for epinephrine and make it more likely for patients and caregivers to administer epinephrine sooner, achieve more rapid symptom relief and prevent the allergic reaction from progressing to a level of severity that could lead to hospitalization or even death. Data from our studies of *neffy* demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products. We submitted our NDA to the FDA in the third quarter of 2022 and if our NDA is approved, we believe *neffy* will be the first "no needle, no injection" marketed epinephrine product for the emergency treatment of Type I allergic reactions. However, the timing for regulatory approvals is outside ARS Pharma's control, may be delayed and is uncertain.

Since our inception in 2015, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, performing research and development activities, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any product sales. We have funded our operations primarily through the private placement of convertible preferred stock, licensing, supply and distribution arrangements with our commercialization partners, and bank debt. From inception to June 30, 2022, we have raised net proceeds of approximately $76.3 million from the issuance of convertible preferred and common stock, $27.8 million from our collaboration, licensing, supply and distribution arrangements, and $10.0 million from bank debt. As of June 30, 2022, we had cash and cash equivalents of $44.6 million.

We have incurred net losses from operations since our inception. Our net loss was $20.2 million for the year ended December 31, 2021 and $13.7 million for the six months ended June 30, 2022. As of June 30, 2022, we had an accumulated deficit of $55.9 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, our expenditures on other development activities, the cost for regulatory filings, expenses for pre-commercial activities to establish sales, marketing and distribution capabilities for our product candidates, and our ability to earn potential regulatory and commercial milestones under our collaboration arrangements. We expect our expenses and operating losses will increase substantially as our product candidate, ARS-1 potentially is approved by the FDA and we commence commercialization efforts, any future product candidates advance through clinical trials, we expand our clinical, regulatory, quality, manufacturing and pre-commercial sales and marketing capabilities, and incur additional costs to operate as a public company following the completion of the Merger. If we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses for marketing, sales, manufacturing and distribution activities, and added expenditures to expand our operational, financial and management systems and increase personnel to support these operations.

We do not expect to generate any revenues from product sales unless and until we successfully obtain regulatory approval for one or more product candidates, if ever. Until such time, if ever, as we can generate substantial product revenue, we may finance our operations through equity offerings, debt financings, collaborations, strategic alliances, marketing, distribution or licensing arrangements or through other sources of financing. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. In addition, our current and future debt agreements may limit our ability to enter into certain debt financings without the consent of the lenders thereunder. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and may require us to delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We do not own or operate manufacturing facilities. We currently rely on third-party manufacturers and suppliers for *neffy*, and we expect to continue to do so to meet our nonclinical, clinical and any commercial activities. Our third-party manufacturers are required to manufacture our product candidates under cGMP requirements and other applicable laws and regulations.

We are closely monitoring the impact of the COVID-19 pandemic. The extent of the impact of the COVID-19 on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our CROs, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel.

Certain of our third-party service providers have experienced shutdowns or other business disruptions. We are continuing to assess the impact of the COVID-19 pandemic on our current and future business and operations, as well as on our industry and the healthcare system. Potential disruptions to our development efforts include, but are not limited to:

- delays or disruptions in clinical studies due to restrictions of on-site staff, limited or no access to facilities, and unforeseen circumstances at CROs and other vendors;
- delays in necessary interactions with regulators and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel.

The extent to which the pandemic may affect our preclinical studies, clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures, or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Additionally, we are unable to predict if a different pandemic could have similar or different impacts on our business, financial condition or stock price.

Recent Events

On July 21, 2022, we entered into an Agreement and Plan of Merger and Reorganization with Silverback and Merger Sub. The Merger is subject to the approval of the stockholders of Silverback and other customary closing conditions. Following the Closing, the combined company is expected to be publicly traded on the Nasdaq Global Market. On August 11, 2022, we entered into a First Amendment to the Agreement and Plan of Merger and Reorganization, pursuant to which we agreed to change the size of the combined company's board of directors to eleven directors comprised of eight ARS Pharma designees and three Silverback designees in order to satisfy the listing requirements of Nasdaq with respect to having a majority if independent directors on the combined company's board of directors.

At the Effective Time each share of ARS Pharma Capital Stock outstanding immediately prior to the Effective Time and after giving effect to the Preferred Stock Conversion (excluding shares held as treasury stock by ARS Pharma or held or owned by Silverback, Merger Sub or any subsidiary of Silverback or ARS Pharma and dissenting shares) will be automatically converted solely into the right to receive a number of validly issued, fully paid and nonassessable shares of Silverback Common Stock equal to the Exchange Ratio. Silverback will assume outstanding and unexercised options to purchase shares of ARS Pharma Common Stock, and in connection with the Merger they will be converted into options to purchase shares of Silverback Common Stock. Each warrant to purchase ARS Pharma Common Stock outstanding and unexercised immediately prior to the Effective Time (after giving effect to the Preferred Stock Conversion) will be assumed by Silverback and will become a warrant to purchase shares of Silverback Common Stock.

Immediately after the Merger, assuming Silverback Net Cash at Closing is $240 million, the pre-Merger equity holders of ARS Pharma are expected to hold approximately 63% of the outstanding shares of Silverback Common Stock and the pre-Merger equity holders of Silverback are expected to hold approximately 37% of the outstanding shares of Silverback Common Stock, in each case, on a fully diluted basis using the treasury stock method.

Financial Overview

Revenues

To date, we have not generated any revenues from the commercial sale of any products, and we may not generate revenues from the commercial sale of any products. We have signed collaboration and license agreements including supply and distribution for ARS-1 with Alfresa Pharma in Japan, Recordati for Europe, certain European Free Trade Associations, CIS, Middle East and African countries and Pediatrix in China. The terms of these agreements may include payment to us of one or more of the following: non-refundable, up-front license fees; clinical, regulatory, and/or commercial milestone payments; clinical development fees; and royalties or a transfer price on net sales of licensed products if ARS-1 receives marketing approval in these regions. We expect revenues to fluctuate in future periods based on our ability to meet various regulatory milestones, and contingent on successfully obtaining regulatory approval for ARS-1 in the US and the licensed regions, US product sales, commercial milestones, royalties or transfer price earned from our partner's net sales and the supply of commercial product as set forth in the agreements described earlier.

Research and Development Expenses

To date, our research and development expenses have related primarily to clinical development, process development and manufacturing costs of our product candidate. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, benefits and stock-based compensation charges for personnel engaged in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants and other third-party organizations to conduct our clinical studies and development activities;
- costs related to manufacturing our product candidates for clinical trials and process validation studies, including fees paid to third-party manufacturers;
- costs related to compliance with regulatory requirements and regulatory filings; and
- indirect expenses including insurance and facility-related expenses.

Our external research and development expenses for our clinical stage product candidate consists primarily of fees, materials and other costs paid to CROs, CMOs, consultant and contractors. Our clinical trials and manufacturing costs for the periods presented below reflect an allocation of expenses associated with personnel costs, equity-based compensation expense, and indirect costs incurred in support of overall research and development, such as facilities-related costs.

We expect that our research and development expenses will likely decrease slightly from current levels based on our planned clinical development and manufacturing activities, as we plan to transition to commercialization efforts with the potential launch of our first product in 2023. However, the timing for regulatory approvals is outside our control, may be delayed and is uncertain. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials and the manufacturing costs of our product candidates due to the inherently unpredictable nature of clinical development and manufacturing activities. Clinical development and manufacturing timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much

funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast to what degree our licensing, supply and distribution arrangements would affect our development plans and capital requirements.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the efficacy and safety profile of our product candidates, and
- the cost to seek regulatory approvals for any product candidates that successfully complete clinical trials
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- establishing or maintaining commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of the current COVID-19 pandemic environment; and
- the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. The process of conducting the necessary clinical research and manufacturing to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates or any future candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for our product candidates or any future candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product candidates' or any future candidates' development, which could increase our research and development expenses.

General and Administrative

General and administrative expenses consist primarily of salaries, benefits, equity-based compensation for personnel in executive, finance, business development, sales and marketing and

other corporate administrative functions. General and administrative expenses also include legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, facility costs, market research costs, and insurance costs.

We anticipate our general and administrative expenses will increase substantially in the future as we add sales and marketing personnel, infrastructure and programs to support pre-commercial activities, and if our product candidates receive marketing approval, commercialization activities. We also anticipate increased general and administrative personnel to support our operations, and higher patent and facility related costs. We also expect to incur added audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, board of director fees, and investor relations costs associated with operating as a public company following the Merger.

Total Other Income (Expense)

Total other income (expense) consists primarily of interest expense from bank debt, interest income from our cash and cash equivalents, and changes in the fair value of our warrant liability. We do not expect any further fair value adjustments for the warrant liability subsequent to this offering as the underlying securities will no longer be redeemable outside of our control.

Results of Operations

Comparison of the Six Months Ended June 30, 2022 and 2021:

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
Revenue:			
Revenue under collaboration agreements	$ 1,127	$ 4,224	$(3,097)
Total revenue			
Operating expenses:			
Research and development[1]	9,773	11,237	(1,464)
General and administrative[1]	4,797	1,864	2,933
Total operating expenses	14,570	13,101	1,469
Loss from operations	(13,443)	(8,877)	(4,566)
Other (expense) income, net	(227)	(416)	189
Net loss and comprehensive loss	$(13,670)	$ (9,293)	$(4,377)

(1) Includes stock-based compensation expense as follows (in thousands):

	Six Months Ended June 30,	
	2022	2021
Research and development	$ 109	$ 1,388
General and administrative	511	367
Total	$ 620	$ 1,755

Revenues. Revenue under collaboration agreements was $1.1 million for the six months ended June 30, 2022 compared to $4.2 million for the six months ended June 30, 2021. The 2022 revenues

include the recognition of deferred revenues for the portion of upfront and clinical and regulatory milestone payments under our collaborations with Alfresa Pharma and Recordati that have been allocated to research and development services provided for during the period. In contrast, the 2021 revenue includes recognition of $3.0 million from our collaboration agreement with Pediatrix signed in March 2021 for the issuance and delivery of a technology license and the recognition of deferred revenues for the portion of upfront and clinical and regulatory milestone payments under our collaborations with Alfresa and Recordati that have been allocated to research and development services provided for during the period. We expect these revenues to fluctuate in future periods based on our ability to meet various regulatory milestones, and contingent on successfully obtaining regulatory approval for ARS-1 in the licensed regions, the commercial milestones, royalties or transfer price earned from our partner's net sales and the supply of commercial product as set forth in these agreements.

Research and Development Expenses. Research and development expenses were $9.7 million and $11.2 million for the six months ended June 30, 2022 and 2021, respectively. The decrease of $1.5 million was due primarily to decreases in development expenses of $0.5 million related to receipt of development materials, which were received in the third quarter of 2022 compared to the first quarter of 2021, and a decrease in stock compensation expense of $1.3 million related to restricted stock which was fully recognized as of December 31, 2021, so there were no comparable costs in 2022. These decreases were partially offset by an increase in regulatory expenses of $0.3 million.

The following table summarizes our research and development expenses allocated by category for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2022	2021
Clinical trials	$ 4,260	$ 4,645
Manufacturing and non-clinical development	5,513	6,592
Total research and development expenses	$ 9,773	$ 11,237

General and Administrative Expenses. General and administrative expenses were $4.8 million and $1.9 million for the six months ended June 30, 2022 and 2021, respectively. The increase of $2.9 million was primarily due to an increase in expenses related to marketing and market research of $0.5 million, audit, legal, and outside services of $1.4 million, stock compensation expense of $0.4 million, facilities expense of $0.1 million, and compensation increases of $0.7 million due to increased compensation and the addition of three employees. These increases were offset by a decrease of $0.2 million related to restricted stock, which was fully recognized as of December 31, 2021.

Total Other Income (Expense). Total other expense was $0.2 million and $0.4 million for the six months ended June 30, 2022 and 2021, respectively. Other expense consisted primarily of interest expense related to our bank debt partially offset by interest income from our money market accounts. The change in the fair value of preferred stock warrants were de minimis for the six months ended June 30, 2022 and 2021.

Comparison of the Years Ended December 31, 2021 and 2020:

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Years Ended December 31,		Change
	2021	2020	
Revenue under collaboration agreements	$ 5,506	$17,835	$(12,329)
Operating expenses:			
Research and development[1]	20,273	14,070	6,203
General and administrative[1]	4,687	4,234	453
Total operating expenses	24,960	18,304	6,656
Loss from operations	(19,454)	(469)	(18,985)
Other expense, net	(789)	(596)	(193)
Net loss	$(20,243)	$ (1,065)	$(19,178)

(1) Includes stock-based compensation expense as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Research and development	2,114	2,783
General and administrative	715	761
Total	$ 2,829	$ 3,544

Revenues. Revenue under collaboration agreements was $5.5 million in 2021 compared to $17.8 million in 2020. The 2021 revenues include the recognition of deferred revenues for the portion of upfront and clinical and regulatory milestone payments under our collaborations with Alfresa and Recordati that have been allocated to research and development services provided for during the year and recognition of an upfront payment of $3.0 million under our collaboration and distribution agreement with Pediatrix signed in March 2021 relating to the issuance and delivery of a technology license. In contrast, the 2020 revenues include the portion of upfront and clinical and regulatory milestone payments under our collaborations with Alfresa and Recordati that have been allocated to research and development services provided for during the year. We expect these revenues to fluctuate in future periods based on our ability to meet various regulatory milestones, and contingent on successfully obtaining regulatory approval for ARS-1 in the licensed regions, the commercial milestones, royalties or transfer price earned from our partner's net sales and the supply of commercial product as set forth in these agreements.

Research and Development Expenses. Research and development expenses were $20.3 million and $14.1 million for 2021 and 2020 respectively. The increase of $6.2 million was due primarily to increases in clinical studies and the related pass through expenses for additional clinical trials that were conducted in 2021 for the NDA filing. Compensation also increased by $0.3 million due to pay raises and slightly higher bonuses.

General and Administrative Expenses. General and administrative expenses were $4.7 million and $4.2 million in 2021 and 2020, respectively. The increase of $0.5 million was primarily due to an increase in audit and outside services expense of $0.3 million. Compensation also increased by $0.2 million due to pay raises and slightly higher bonuses

Total Other Income (Expense). Total other expense was $0.8 million and $0.6 million for 2021 and 2020, respectively. Other expense consisted primarily of interest expense related to our bank debt

partially offset by interest income from our money market accounts. The change in the fair value of preferred stock warrants were de minis for 2021 and 2020.

Liquidity and Capital Resources

Sources of Liquidity and Capital

Since our inception, we have not generated any revenue from any product sale and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates until 2023 or after, if at all. We have funded our operations to date primarily with proceeds from the sale of preferred and common stock, revenue earned under collaboration, licensing, supply and distribution agreements and bank debt. From inception to June 30, 2022, we have raised net proceeds of approximately $76.3 million from the issuance of convertible preferred and common stock, $27.8 million from our collaboration, licensing, supply and distribution arrangements, and $10.0 million from bank debt. As of June 30, 2022, we had cash and cash equivalents of $44.6 million.

Cash flows

The following table summarizes our cash flows for each of the six month periods presented (in thousands):

	Six months ended June 30,	
	2022	2021
Net cash used in operating activities	$ (13,899)	$ (7,722)
Net cash used in investing activities	(43)	—
Net cash used in financing activities	(1,531)	—
Net decrease in cash and cash equivalents	$ (15,473)	$ (7,722)

Operating Activities

Net cash used in operating activities was $13.9 million for the six months ended June 30, 2022 compared to $7.7 million used in operating activities for the six months ended June 30, 2021. The $13.9 million net cash used in operating activities for the six months ended June 30, 2022 was primarily due to the net loss of $13.7 million and $0.9 million decrease in operating assets and liabilities, offset by $0.6 million in non-cash stock compensation and $0.1 million of non-cash interest expense.

The $7.7 million net cash used in operating activities for the six months ended June 30, 2021 was primarily due to the net loss of $9.3 million and $0.3 million decrease in operating assets and liabilities, offset by $1.8 million of non-cash stock-compensation and $0.1 million of non-cash interest expense.

Investing Activities

Net cash used in operating activities for the six months ended June 30, 2022 was less than $0.1 million due to the purchase of property and equipment. We had no cash flow from investing activities in for the six months ended June 30, 2021.

Financing Activities

Net cash used in financing activities of $1.5 million for the six months ended June 30, 2022 was primarily due to $1.8 million in payments on the notes outstanding offset by $0.3 million cash received

for stock option exercises. We had no cash flow from financing activities in for the six months ended June 30, 2021.

The following table summarizes our cash flows for each of the years presented (in thousands):

	Year ended December 31,	
	2021	2020
Net cash provided by (used in) operating activities	$(17,561)	$ 9,071
Net cash used in investing activities	(55)	—
Net cash provided by financing activities	53,158	5,099
Net increase in cash and cash equivalents	$ 35,542	$14,170

Operating Activities

Net cash used in operating activities was $17.6 million for 2021 compared to $9.1 million provided by operating activities for 2020. The $17.6 million net cash used in operating activities during 2021 was primarily due to the net loss of $20.2 million and a decrease in deferred revenue of $2.5 million, offset by $2.8 million of non-cash stock-compensation, $0.2 million of non-cash interest expense and a $2.1 million change in other operating assets and liabilities.

The $9.1 million net cash provided by operating activities during 2020 was primarily due to our net loss of $1.1 million and $0.4 million decrease in other operating assets and liabilities, offset by an increase in deferred revenue of $7.0 million due to upfront payments related to our collaboration agreements, $3.5 million of non-cash stock-compensation and $0.1M related to non-cash interest expense.

Investing Activities

Net cash used in operating activities in 2021 was $0.1 million due to the purchase of property and equipment. We had no cash flow from investing activities in 2020.

Financing Activities

Net cash provided by financing activities in 2021 was $53.2 million and included $54.8 million of proceeds from the issuance of Series D convertible preferred stock in August 2021 plus $0.2 million from common stock option exercises, offset by $1.8 million repayments on the bank note. Net cash provided from financing activities in 2020 was $5.1 million, consisting of $5.0 million of borrowing from bank debt and $0.1 million of proceeds from the exercise of common stock options.

Future Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the estimated amount of Silverback Net Cash at Closing, will be sufficient to meet the combined company's anticipated cash requirements through at least the next three years. In particular, we expect the Silverback Net Cash, together with our existing cash and cash equivalents will allow us to fund our expenses related to the FDA's review of our NDA submitted to the FDA for ARS-1 in the third quarter of 2022, fund proof of concept clinical trials of ARS-1 for additional indications fund pre-commercial manufacturing and sales and marketing activities, and if and when *neffy* is approved by the FDA, fund our commercial launch. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that

involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future funding requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the scope and costs of manufacturing our product candidates and commercial manufacturing activities;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the timing of any milestone and royalty payments under the Aegis License Agreement;
- the royalty payments due under the Aegis License Agreement;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our employee headcount and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company following the Merger.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through a combination of our existing cash, and following the Merger, the Silverback Net Cash, equity offerings, debt financings and other capital sources which may include strategic collaborations, licensing or other arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, our current or future debt agreements may limit our ability to incur additional debt. If we raise funds through additional collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, development programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock.

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the US and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Contractual Obligations and Commitments

Under our license agreement with the Aegis, we have payment obligations of up to $20.0 million contingent upon our achievement of certain regulatory and commercial milestones, and are required to make royalty payments in connection with the sale of products developed under that agreement. The Company will be required to pay Aegis a milestone payment of $1.0 million contingent upon FDA's acceptance of an US NDA filing, which occurred in the third quarter of 2022. We are unable to estimate the timing or likelihood of achieving additional milestones or royalty payments under this agreement. For additional information regarding the Aegis License Agreement, including our payment obligations thereunder, see the section of this proxy statement titled "*ARS Pharma Business—License Agreement with Aegis Therapeutics*" and the notes to our consolidated financial statements included elsewhere in this proxy statement.

Additionally, we have bank borrowings under our loan agreement with Silicon Valley Bank which require monthly principal payments of $0.3 million and interest at a floating annual rate of to the greater of (i) the prime rate used by lender plus 0.75% (prime rate of 4.75% at June 30, 2022), or (ii) 6.0%. The loan matures on March 1, 2024 and there is a $0.5 million final payment due at maturity. For additional information regarding the ARS Loan and Security Agreement, including our payment obligations thereunder, see the notes to our consolidated financial statements included elsewhere in this proxy statement.

In October 2021, we entered into a lease agreement to rent office space with a lease commencement date of December 2021. The lease has a term of 38 months. Annual rent expense will be $0.3 million and is subject to annual increases of 3%, plus our share of operating expenses and taxes.

We enter into contracts in the normal course of business with third-party contract organizations and vendors for clinical studies, manufacturing and other services and products. These contracts generally provide for termination after a notice period.

To date, we have not recognized any reserves related to uncertain tax positions. As of June 30, 2022, we had no accrued interest or penalties related to uncertain tax positions.

Critical Accounting Policies and Significant Judgements and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenues recognized under collaboration agreements, accruals for research and development expenses and valuation of equity awards. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of

assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies and estimates are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this proxy statement, we believe the following accounting policies and estimates to be most critical to the preparation of our consolidated financial statements.

Revenue

Our revenues generally consist of licenses and research services under license and collaboration agreements.

We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The upfront payments and fees received prior to satisfying the relevant revenue recognition criteria are recorded as deferred revenue in the balance sheet and recognized as revenue when the related revenue recognition criteria are met.

Collaboration agreements typically contain multiple elements, or performance obligations, including research and development services and technology licenses. Our assessment of what constitutes a separate performance obligation requires us to apply judgement. Specifically, we have to identify which goods and services we are required to provide under the contract are distinct. For our collaboration agreements, we have identified several performance obligations at the inception of the contract since the delivered elements are deemed capable of being distinct within the context of the contract. Accordingly, the initial transaction price is allocated to the various performance obligations where we recognized revenue related to the license, which was delivered upon contract inception, and the remaining performance obligation is recognized as the underlying services are provided under the cost-based input method over the research terms. Using the cost-based input method, we recognize revenue based on actual costs incurred as a percentage of total estimated costs as we complete our performance obligations. Any cumulative effect of revisions to estimated costs to complete our performance obligations is recorded in the period in which changes are identified and amounts can be reasonably estimated. This approach requires us to use significant judgement and make estimates of future expenditures. If our estimates or judgements change over the course of the collaboration, they may affect the timing and amount of revenue that it recognizes in the current and future periods.

The transaction price for a contract represents the amount to which we are entitled in exchange for providing goods and services to the customer. The transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment and certain milestones, all other fees we may earn under our collaborative agreements are subject to significant uncertainties of product development and commercial sales targets. The transaction price of an agreement is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied.

Accrued Research and Development

We have entered into various agreements with CROs, CMOs, and other service providers. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, our estimated accruals have not differed materially from actual costs incurred.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of equity awards recognized in the period using the Black-Scholes option pricing model. We recognize the expense for equity awards on a straight-line basis over the requisite service periods of the awards, which is usually the vesting period. Forfeitures are recognized as they occur. Estimating the fair value of equity awards pursuant to the Black-Scholes option pricing model requires us to make assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in these assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized.

The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally require significant judgment. We determine these assumptions in the following manner:

- ***Fair Value of Common Stock.*** See the subsection titled "—*Common Stock Valuations*" below.
- ***Expected Term.*** The expected term of stock options represents the period of time that the awards are expected to be outstanding. Because we do not have sufficient historical exercise behavior, we determine the expected term assumption using the simplified method for our employees and board members, which calculates the expected term as the average time-to-vesting and the contractual life of the award. The expected term for non-employees is generally the contractual term.
- ***Expected Volatility.*** As we are not yet a public company and do not have a trading history for our common stock, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.
- ***Risk-Free Interest Rate.*** The risk-free rate assumption is based on the U.S. Treasury yield in effect at the time of the grant with maturities consistent with the expected term of the awards.
- ***Expected Dividend Yield.*** The expected dividend yield assumption is based on our history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends and, therefore, used an expected dividend yield of zero.

See the notes to our consolidated financial statements included elsewhere in this proxy statement for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock awards. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

Common Stock Valuations

Since there has been no public market for our common stock, our board of directors, with input from management, determined the fair value of our common stock on each grant date by considering a number of objective and subjective factors, including the most recent independent third-party valuation of our common stock, sales of our convertible preferred stock to unrelated third-parties, our operating and financial performance, the lack of liquidity of our capital stock and general and industry-specific economic outlook, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and that may have changed from the date of the most recent valuation through the date of the grant. Historically, these independent third-party valuations of our equity instruments were generally performed contemporaneously with identified value inflection points.

These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. The Practice Aid identifies various available methods for allocating the enterprise value across classes and/or series of capital stock in determining the fair value of our common stock at each valuation date. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- our results of operations and financial position, including our levels of available capital resources;
- our stage of development and material risks related to our business;
- progress of our research and development activities;
- our business conditions and projections;
- the lack of marketability of our common stock and our preferred stock as a private company;
- the prices at which we sold shares of our convertible preferred stock to outside investors in arms-length transactions;
- the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry;
- the likelihood of achieving a liquidity event for our securityholders, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience of management;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Each valuation methodology was considered in our valuations.

The various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock in accordance with the Practice Aid include the following:

- ***Current Value Method.*** Under the current value method, once the fair value of the enterprise is established, the value is allocated to the various series of preferred and common stock based on their respective seniority, liquidation preferences or conversion values, whichever is greatest.
- ***Option Pricing Method ("OPM").*** Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options.
- ***Probability-Weighted Expected Return Method ("PWERM").*** The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.
- ***Hybrid Method.*** The Hybrid Method is a hybrid between the PWERM and OPM, estimating the probability-weighted value across multiple scenarios but using the OPM to estimate the allocation of value within one or more of those scenarios. The Hybrid Method can be useful alternative to explicitly modeling all PWERM scenarios in situations when the company has transparency into one or more near-term exits but is unsure about what will occur if the current plans fall through. Under these circumstances, it might be appropriate to use a hybrid of the PWERM and OPM.

For our valuation performed in August 2021, we estimated the fair value of our common stock using the precedent transaction method based on the Series D preferred stock financing completed in August 2021. For our valuation performed in January 2022, we used the Hybrid Method to estimate the fair value of our common stock.

Retrospective Reassessment of Fair Value of Common Stock for Financial Reporting Purposes

In consideration of the Merger, we reconsidered the value of options granted in 2022. We had performed a valuation in January 2022 using the Hybrid Method to estimate the value of our common stock, which was prior to any contemplation of the type of transaction anticipated from the Merger. The fair value of our common stock based upon that valuation was $1.77. In March and May 2022, we granted common stock options based on the valuation we performed in January 2022. Although we did not identify any specific material internal or external value-generating events between January 2022 and the dates of these option grant, on a retrospective basis and in light of our subsequent discussions regarding the proposed Merger with Silverback, management decided to reassess the fair market value of the common stock for financial reporting purposes. Thus, as part of the preparation of the financial statements necessary for inclusion in this proxy statement, we reassessed for financial reporting purposes, on a retrospective basis, the fair value of our common stock for each stock option granted in 2022. For purposes of this reassessment, we evaluated our original inputs and the methodologies used to determine our enterprise value, the methods we used to allocate enterprise value and the timing of the valuation. For such reassessment valuation performed in May 2022, we used the Hybrid Method to determine the fair value of our common stock, where the two scenarios considered included a reverse merger scenario and a stay private scenario. Under the reverse merger scenario, ARS Pharma was valued at the value stated in letter of interest, dated June 10, 2022, between ARS Pharma and Silverback, which was $435 million. Under the stay private scenario, the enterprise value was determined at the valuation date using the market approach, specifically a "roll-forward" of the backsolve to the Series D preferred stock financing in August 2021 to May 2022 using a

market adjustment factor that considered the changes in value of selected guideline public companies and certain market indices. The relative probabilities between the future exit scenarios were determined by management to be 50% for the reverse merger scenario and 50% for the stay private scenario. The probabilities of the two scenarios assigned as of May 31, 2022 were based upon expectations as to the timing and likely prospects of future event scenarios, including discussions subsequent to May 2022 regarding the Merger. Since discussions between ARS Pharma and Silverback were still preliminary in May, Silverback was in discussions with a number of potential counterparties, and a letter of interest or other agreement had not been signed between ARS Pharma and Silverback, management concluded these probabilities were reasonable. As a result, we concluded that the fair value per share of our common stock for financial reporting purposes was $4.49 per share as of May 31, 2022. We applied this reassessed value to grants awarded in May 2022 using the Black-Scholes option pricing model to determine the fair value of these grants.

For the grant in March 2022, we determined the fair market value of the common stock by utilizing the reassessment valuation completed as of May 31, 2022 and adjusting the probabilities of the two exit scenarios (reverse merger and stay private) since as of March 2022, no discussions regarding the reverse merger with Silverback or any other entity had commenced. The probabilities of the two scenarios assigned as of March 1, 2022 were estimated to be 10% for the reverse merger scenario and 90% for the stay private scenario. This resulted in a conclusion that the fair value per share of our common stock for financial reporting purposes was $2.37 per share as of March 1, 2022. We applied this reassessed value to the grants awarded in March 2022 using the Black-Scholes option pricing model to determine the fair value of these grants.

The following table summarizes by grant date the number of shares of common stock options granted from January 2022 to June 2022, the associated per share exercise price, and the reassessed per share fair value of our common stock for financial reporting purposes on the applicable grant date:

Grant Date	Number of Common Shares Underlying Options Granted	Exercise Price per Common Share	Reassessed Fair Value Per Common Share
March 1, 2022	700,000	$ 1.77	$ 2.37
May 24, 2022	546,000	$ 1.77	$ 4.49

We utilized the above reassessed fair values to determine the stock-based compensation expense, which is recorded in our consolidated financial statements. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different. Following the completion of the Merger, the fair value of the combined company's common stock will be based on the closing price as reported on the Nasdaq Global Market.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this proxy statement for information about recent accounting pronouncements, the timing of their adoption, and our assessment, if any, of their potential impact on our financial condition and results of operations.

Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our cash consists of cash in a readily available checking and money market accounts. As a result, the fair value of our portfolio is insensitive to interest rate changes.

Our outstanding long-term debt bears interest at a floating annual rate equal to the greater of (i) the prime interest rate used by the lender plus 0.75% (prime is 4.75% at June 30, 2022) or (ii) 6%. The impact of a 10% change in market interest rates would be less than $0.1 million annually and would not have a material impact on our financial condition and/or results of operations.

Foreign Currency

Our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies The collaboration revenues earned under our agreement with Recordati is payable in Euros. In addition, we incur expenses, including for clinical trials, non-clinical studies and certain development activities outside the United States based on contractual obligations denominated in currencies other than the U.S. dollar, including Euros, British Pounds and Australian dollars. At the end of each reporting period, these liabilities are converted to U.S. dollars at the then applicable foreign exchange rate. In January 2020, we formed a wholly-owned Irish subsidiary, ARS Pharmaceuticals IRL, Ltd., to facilitate the filing of regulatory approval for ARS-1 in European countries. The functional currency of our Irish entity is the United States dollar. Assets and liabilities of ARS Pharmaceuticals IRL that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets and capital accounts, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Expenses are generally remeasured at foreign currency exchange rates which approximate average rates in effect during each period. As of June 30, 2022, ARS Pharmaceuticals IRL, Ltd. had limited operations.

We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), net, in the consolidated statements of operations. We recorded and a de minimis amount of foreign currency gain and $0.2 million net realized foreign currency loss for the years ended December 31, 2021 and 2020, respectively.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe that inflation had a material effect on our results of operations during the periods presented.

MANAGEMENT FOLLOWING THE MERGER

The following table provides information regarding the expected directors and executive officers of the combined company following the closing of the Merger:

Name	Age	Position
Executive Officers		
Richard Lowenthal, M.S., MSEL	56	***President and Chief Executive Officer and Director***
Kathleen Scott	53	***Chief Financial Officer***
Sarina Tanimoto, M.D., M.B.A.	54	***Chief Medical Officer***
Eric Karas	50	***Chief Commercial Officer***
Justin Chakma	33	***Chief Business Officer***
Non-Employee Directors		
Pratik Shah, Ph.D.	52	***Director and Chair of the Board***
Peter Kolchinsky, Ph.D.	46	***Director***
Rajeev Dadoo, Ph.D.	52	***Director***
Brenton L. Saunders	52	***Director***
Phillip Schneider	66	***Director***
Michael Kelly	57	***Director***
Jonathan S. Leff	53	***Director***
Laura Shawver, Ph.D.	65	***Director***
Peter A. Thompson, M.D.	63	***Director***
Saqib Islam, J.D.	53	***Director***

Executive Officers

Richard Lowenthal, M.S., MSEL is a co-founder of ARS Pharma and has served as its President and a member of the ARS Pharma Board since ARS Pharma's inception in August 2015 and as ARS Pharma's Chief Executive Officer since September 2018. From August 2015 to November 2007, Mr. Lowenthal served as President of Pacific-Link Regulatory Consulting and Research, Inc., a medicinal product development consultancy founded by Mr. Lowenthal, where he provided leadership and mentoring on clinical development, regulatory affairs, quality assurance, licensing and investment opportunities, including supporting the clinical and regulatory development of Valtoco (diazepam nasal spray). Prior to Pacific-Link Regulatory Consulting and Research, Inc., Mr. Lowenthal held many leadership roles at several biopharmaceutical and pharmaceutical companies that included Chief Executive Officer and President of MTG Biotherapeutics Inc.; Vice President of Regulatory Affairs and quality assurance for Cadence Pharmaceuticals, Inc.; Head of Worldwide Regulatory Affairs, Quality Assurance and Drug Safety for Maxim Pharmaceuticals, Inc.; Vice President of Regulatory Affairs and Quality Assurance for AnGes, MG, Inc.; Global Project Leader and Global Director of Regulatory Affairs for Janssen Research Foundation; Director of Regulatory Affairs and Quality Assurance for Somerset Pharmaceuticals Inc.; and New Drug Review Chemist for the U.S. Food and Drug Administration in the Division of Neuropharmacologic Drug Products and the Division of Oncology and Pulmonary Drug Products. Mr. Lowenthal holds an M.Sc. in organic chemistry from Florida State University and a Master's in Business Science for Executive Leadership from the University of San Diego. He has served as past chair of the American Association of Pharmaceutical Scientists (San Diego region), as well as member of the USP Biotechnology Expert Committee, chair of the Virology Working group, member of the National Organization of Rare Disease Corporate Council and has worked with various PhRMA and ICH Working Groups. We believe Mr. Lowenthal is qualified to serve on the combined company's board of directors due to his over 28 years of biotechnology and pharmaceutical development experience, his experience as a founder, director and executive officer of biopharmaceutical companies and his educational background.

Kathleen Scott, has served as the Chief Financial Officer of ARS Pharma since February 2022. Ms. Scott previously served as the Chief Financial Officer of various life science companies, including Neurana Pharmaceuticals, Inc. (from January 2017 to March 2022), Recros Medica, Inc. (from August 2014 to April 2021), Adigica Health, Inc. (from February 2016 to March 2021), Clarify Medical, Inc. (from August 2014 to December 2016), Oncternal Therapeutics, Inc. (Nasdaq: ONCT) (from March 2016 to May 2016), MDRejuvena, Inc. (from August 2014 to August 2016) and BioSurplus, Inc. (from March 2010 to November 2014). Ms. Scott also previously served as a partner at RA Capital Advisors LLC, a San Diego private investment bank providing financial advisory services. She spent over 15 years with RA Capital Advisors, completing mergers, acquisitions, divestitures and restructurings for a broad range of corporate clients. Ms. Scott started her career as an auditor in Arthur Andersen's San Diego office, focusing on both public and private clients. Ms. Scott serves on the boards of directors of Dermata Therapeutics, Inc. (Nasdaq: DRMA), where she has served since August 2021, the YMCA of San Diego County and Corporate Directors Forum, and previously served as a member of the board of Conatus Pharmaceuticals Inc. from November 2019 to May 2020. Ms. Scott holds a bachelor's degree in economics/business from the University of California, Los Angeles and is a CPA and CFA charter holder.

Sarina Tanimoto, M.D., M.B.A., is a co-founder of ARS Pharma and has served as its Chief Medical Officer since September 2018. From August 2015 to September 2018, Dr. Tanimoto served as a member of the ARS Pharma Board. From August 2015 to November 2007, Dr. Tanimoto served as Chief Medical Officer of Pacific-Link Regulatory Consulting and Research, Inc., a medicinal product development consultancy, where she supported multiple programs from Phase 1 to Phase 3 clinical trials in various therapeutic areas, including several intranasal products. Prior to Pacific-Link Regulatory Consulting and Research, Inc., Dr. Tanimoto held roles in clinical and business development during her tenure at AnGes Inc., a biopharmaceutical company, and also served as a clinical scientist at Roche, a research healthcare company, where she was involved in global clinical development. Dr. Tanimoto earned an M.D. from University of Toyama, followed by internal medicine training at the National Center for Global Health and Medicine in Tokyo. She holds an M.B.A. from McGill University.

Eric Karas, has served as the Chief Commercial Officer of ARS Pharma since April 2022. From October 2018 to March 2022, Mr. Karas served as Vice President and General Manager of Commercial, North America at Emergent BioSolutions Inc. (NYSE: EBS). Prior to that, from December 2016 to October 2018, Mr. Karas led commercial initiatives for NARCAN® Nasal Spray at Adapt Pharma, Inc., which was acquired by Emergent BioSolutions in 2018. Prior to Adapt Pharma, Mr. Karas spent eight years at Auxilium Pharmaceuticals, Inc. overseeing all global commercial objectives related to its urology portfolio. He also led the launch readiness planning and go-to-market strategy for the launch of XIAFLEX® for Peyronie's disease. Auxilium Pharmaceuticals was acquired in 2015 by Endo International plc (Nasdaq: ENDP). Mr. Karas has also held cross-functional roles in government affairs, public relations, patient advocacy and sales leadership roles at Astellas Pharma Inc., Bristol-Myers Squibb Company (NYSE: BMY) and Merck & Co., Inc. (NYSE: MRK). Industry associations have recognized him for numerous disease awareness and branded campaigns targeting healthcare professionals and consumers. Mr. Karas received his M.B.A. in integrated management from Michigan State University, Broad School of Management, and a B.S. in accounting from Rutgers University.

Justin Chakma, has served as the Chief Business Officer of ARS Pharma since June 2019. From May 2018 to May 2019, Mr. Chakma served as VP, Head of Business Development and Strategy at Vedanta Biosciences, a biotechnology company developing medicines to modulate immune responses. Before that, from November 2015 to May 2018, he was a Senior Director of Business Development at Celgene Corporation (formerly Nasdaq: CELG) (acquired by Bristol-Myers Squibb Company). Prior to joining Celgene, Mr. Chakma held various roles in biotech and pharmaceutical

business development, financing and investments at Receptos, Inc. (formerly Nasdaq: RCPT) (acquired by Celgene), Auspex Pharmaceuticals, Inc. (formerly Nasdaq: ASPX) (acquired by Teva Pharmaceutical Industries Ltd.), and Thomas, McNerney & Partners, a venture capital firm. Mr. Chakma holds an M.B.A. from the Wharton School of the University of Pennsylvania, and bachelor degrees in neuroscience and economics from the University of Toronto.

Directors

Pratik Shah, Ph.D., has served as a member of the ARS Board since April 2016 and was appointed as the first Chair of the ARS Board in September 2018. Dr. Shah has also served as the Executive Chair and member of the board of directors for Design Therapeutics, Inc. (Nasdaq: DSGN), a biotechnology company, since December 2017, and as President of Marlinspike Group, LLC, since August 2018, and of Marlinspike Group Inc. from June 2015 to October 2020. Dr. Shah served as the Chair of the board of directors of Synthorx, Inc. (formerly Nasdaq: THOR), a clinical-stage biotechnology company, from October 2018 until its acquisition by Sanofi S.A. in January 2020. Dr. Shah also served as the President and Chief Executive Officer and Chair of the board of directors of Auspex Pharmaceuticals, Inc. (formerly Nasdaq: ASPX), biopharmaceutical company, from October 2013 until its acquisition by Teva Pharmaceutical Industries Ltd. in May 2015. From 2004 to 2014 he was a partner at Thomas, McNerney & Partners, a healthcare venture capital firm. Dr. Shah holds a B.S in Biological Sciences from the University of California at Irvine and a Ph.D. in Biochemistry and Molecular Biology and an M.B.A. in Finance, both from the University of Chicago. We believe Dr. Shah is qualified to serve on the combined company's board of directors due to his experience as a director and executive officer of biopharmaceutical companies, his extensive background as venture capitalist in the biopharmaceutical industry and his educational background.

Peter Kolchinsky, Ph.D., has served as a member of the ARS Board since August 2021. Dr. Kolchinsky is a founder and Managing Partner at RA Capital Management, L.P., a multi-stage investment manager dedicated to evidence-based investing in healthcare and life science companies that are developing drugs, medical devices, and diagnostics, where he has worked since 2001. Dr. Kolchinsky has also served as the Chairman and Chief Executive Officer of Research Alliance Corp. II (Nasdaq: RACB), a special purpose acquisition company, since July 2020, and as the Chief Executive Officer and board Chairman of Therapeutics Acquisition Corp. (formerly Nasdaq: RACA), a special purpose acquisition company, from April 2020 until the consummation of its busines combination in June 2021. Dr. Kolchinsky has served on the boards of directors of ICOSAVAX, Inc. (Nasdaq: ICVX), a vaccine development company, since March 2021 and currently serves on its nominating and corporate governance committee, WAVE Life Sciences, Ltd. (Nasdaq: WVE), a biotechnology company focused on delivering therapies for patients with serious, genetically-defined diseases, since January 2015 and currently serves on its compensation committee and the nominating and corporate governance committee, Forma Therapeutics Holdings, Inc. (Nasdaq: FMTX), a biopharmaceutical company focused on the development and commercialization of therapeutics for patients with hematologic diseases and cancers, since December 2019 and currently serves on its compensation committee, and Synthorx, Inc. (formerly Nasdaq: THOR), a clinical-stage biotechnology company, from May 2018 to January 2020, Dicerna Pharmaceuticals, Inc. (Nasdaq: DRNA), a biopharmaceutical company, from July 2013 to December 2019, and also serves on the boards of directors of a number of private companies. Dr. Kolchinksy also leads RA Capital's engagement and publishing efforts, which aim to make a positive social impact and spark collaboration among healthcare stakeholders, including patients, physicians, researchers, policymakers, and industry. He served on the Board of Global Science and Technology for the National Academy of Sciences from 2009 to 2012, is the author of "The Great American Drug Deal" and "The Entrepreneur's Guide to a Biotech Startup," and frequently writes and speaks on the future of biotechnology innovation. Dr. Kolchinsky holds a Ph.D. in virology from Harvard University and a B.S. degree in biology from Cornell University. We believe Dr. Kolchinsky is qualified to serve on the combined

company's board of directors due to his experience as an investor in the life sciences sector and as a director of a number of healthcare and life science companies.

Rajeev Dadoo, Ph.D., has served as a member of the ARS Board since August 2021. Since September 2020, Dr. Dadoo is managing partner of SR One Capital Management, L.P. Mr. Dadoo was previously a Partner at S.R. One, Limited, a wholly owned subsidiary of GlaxoSmithKline, which he joined in 2004. He is an alum of the Kauffman Fellows Program. His prior roles have included working in the Competitive Excellence group at GlaxoSmithKline, a global healthcare company which engages in the research, development, and manufacture of pharmaceutical medicines, vaccines, and consumer healthcare products, on various global projects and at Genentech, Inc., a biotechnology company, in technology and clinical development. He has also held product development and business development roles at Bio-Rad Laboratories, Inc. (NYSE: BIO), an American developer and manufacturer of specialized technological products for the life science research and clinical diagnostics markets, and Genome Therapeutics Corp., a biotechnology company, respectively. Dr. Dadoo holds a BA degree in Chemistry and Mathematics from Knox College, a PhD in Chemistry from Stanford University, and an M.B.A. from the Wharton School of the University of Pennsylvania. We believe Dr. Dadoo is qualified to serve on the combined company's board of directors due to his experience as a venture capitalist in the life science industry, his product development experience and his educational background.

Brenton L. Saunders, has served as a member of the ARS Board since May 2021. Mr. Saunders has served as the Executive Chairman of the board of directors of The Beauty Health Company (Nasdaq: SKIN) (formerly Vesper Healthcare Acquisition Corp.), a beauty health company, since July 2020. Mr. Saunders also served as the President and Chief Executive Officer of Vesper Healthcare Acquisition Corp., a special purpose acquisition company, from July 2020 to May 2021. Until its acquisition by AbbVie Inc. (NYSE: ABBV), Mr. Saunders served as Chairman (October 2016 to May 2020) and President and Chief Executive Officer (July 2014 to May 2020) of Allergan plc (formerly NYSE: AGN), a pharmaceutical company that focuses on medical aesthetics, eye care, central nervous system, and gastroenterology. Prior to that, Mr. Saunders served as Chief Executive Officer of Forest Laboratories Inc. (formerly NYSE:FRX), a pharmaceutical company focused on therapeutic areas of the central nervous and cardiovascular systems, a role he held until its merger with Actavis Plc (formerly NYSE: ACT), a global pharmaceutical company focused on acquiring, developing, manufacturing and marketing branded pharmaceuticals, generic and over-the-counter medicines, and biologic products, in 2014. Following the merger with Actavis, Mr. Saunders was named Chief Executive Officer of the combined business in 2015. From March 2010 until August 2013, Mr. Saunders served as Chief Executive Officer of Bausch + Lomb Incorporated, an eye health products company, until its acquisition by Valeant in 2013. Mr. Saunders currently serves as a director of Cisco Systems, Inc. (Nasdaq: CSCO), a global telecommunications company, and BridgeBio Pharma Inc. (Nasdaq: BBIO), a biopharmaceutical company. He is also a member of The Business Council. Mr. Saunders holds a Bachelor of Arts degree from the University of Pittsburgh, a Juris Doctor degree from the Temple University School of Law, and an M.B.A. from the Temple University School of Business. We believe Mr. Saunders is qualified to serve on the combined company's board of directors due to his over 25 years of experience in the healthcare industry, his experience as an executive and director of several prominent global pharmaceutical and healthcare companies.

Phillip M. Schneider, has served as a member of the ARS Board since May 2019. Mr. Schneider previously served as a director of Pfenex Inc., a clinical-stage biotechnology products company, from July 2014 to October 2020. Prior to that, Mr. Schneider held various positions with IDEC Pharmaceuticals Corporation, a biopharmaceutical company focused on therapies for the treatment of neurodegenerative, hematologic, and autoimmune diseases, from 1987 to 2003, including: Senior Vice President and Chief Financial Officer from 1997 to 2003; and Director of Finance and Administration from 1992 to 1997. Prior to that, Mr. Schneider held various management positions at

Syntex Pharmaceuticals Corporation, a pharmaceutical company, from 1985 to 1987, and KPMG LLP, an audit and tax advisory firm, from 1982 to 1984, where he attained his CPA license. Mr. Schneider previously served as a member of the board of directors at Arena Pharmaceuticals, Inc. (Nasdaq: ARNA), a clinical stage pharmaceutical company, from 2008 to 2018, Auspex Pharmaceuticals, Inc. (formerly Nasdaq: ASPX), biopharmaceutical company, from 2014 until its acquisition by Teva Pharmaceutical Industries Ltd. in 2015 and served as a member of the board of directors of Gen-Probe, Inc., a biotechnology company, from 2002 until its acquisition by Hologic Inc. in 2012. Mr. Schneider holds a B.S. in Biochemistry from the University of California, Davis and an M.B.A. from the University of Southern California. We believe Mr. Schneider is qualified to serve on the combined company's board of directors due to his experience in finance and accounting and knowledge of the biotechnology industry.

Michael Kelly, has served as a member of the ARS Board since May 2019. From March 2016 to June 2019, Mr. Kelly served as President of U.S. Operations for Adapt Pharma, Inc., which developed and commercialized NARCAN® (naloxone HCl) Nasal Spray. From December 2013 to March 2016, Mr. Kelly served as the Chief Executive Officer and a director of Covis Pharmaceuticals, Inc., a pharmaceutical company focused on therapeutic solutions for patients with life-threatening conditions and chronic illnesses. Mr. Kelly was also a member of the founding management team of Azur Pharma Limited, a specialty pharmaceutical company, and later, following a strategic merger, served as the Senior Vice President of Sales and Marketing for Jazz Pharmaceuticals plc (Nasdaq: JAZZ), biopharmaceutical company. Prior to his tenure at Azur Pharma, he served as Vice President of Commercial Operations at Guilford Pharmaceuticals Inc., a biopharmaceutical company, Vice President of Sales and Marketing at ViroPharma Incorporated, biotechnology company dedicated to the development and commercialization of products that address serious diseases, and held various commercial and medical roles at TAP Pharmaceuticals Inc., a pharmaceutical company. Mr. Kelly holds a Bachelor of Science in business administration from The College of New Jersey and a Master of Business Administration from Rider University. We believe Mr. Kelly is qualified to serve on the combined company's board of directors due to his over 25 years of experience in the pharmaceutical industry, including as an executive, director and senior manager at several pharmaceutical companies.

Jonathan S. Leff, has served as a member of the ARS Board since September 2018. Mr. Leff has also served as a member of the board of directors of Larimar Therapeutics, Inc. (Nasdaq: LRMR), clinical-stage biotechnology company focused on developing treatments for complex rare diseases, since May 2020, and its predecessor, Chondrial Therapeutics, Inc., from December 2016 until May 2020. Mr. Leff is a partner at Deerfield Management Company, L.P. and Chairman of the Deerfield Institute. He joined Deerfield in 2013 and focuses on venture capital and structured investments in biotechnology and pharmaceuticals. Prior to Deerfield, Mr. Leff served as Managing Director at Warburg Pincus LLC, a private equity company, from 2000 to 2012, where he led the firm's investment efforts in biotechnology and pharmaceuticals. Mr. Leff also previously served as a member of the Executive Committee of the Board of the National Venture Capital Association ("NVCA") and led NVCA's life sciences industry efforts as Chair of NVCA's Medical Innovation and Competitiveness Coalition. He also served on the Emerging Companies Section Board of the Biotechnology Industry Organization. Mr. Leff is a board member of several not-for-profit organizations, including the Spinal Muscular Atrophy Foundation, Reagan-Udall Foundation and the Columbia University Medical Center Board of Advisors. He also previously served on the boards of several other publicly-traded biotechnology and pharmaceutical companies, including Proteon Therapeutics, Inc. (formerly Nasdaq: PRTO), a biopharmaceutical company developing pharmaceuticals for patients with renal and vascular diseases, from 2017 to 2019, AveXis, Inc. (formerly Nasdaq: AVXS), a biotechnology company that develops treatments for rare neurological genetic disorders, from 2014 to 2017 and Nivalis Therapeutics, Inc. (Nasdaq: NVLS), a clinical-stage pharmaceutical company developing a class of disease modifying therapies, from 2014 to 2016. Mr. Leff currently also serves on the boards of several private biopharmaceutical companies and has previously served on the boards of other privately held

biopharmaceutical companies. Mr. Leff received an A.B. from Harvard University, a M.B.A. from the Stanford University Graduate School of Business and a M.S. from John Hopkins University. We believe Mr. Leff is qualified to serve on the combined company's board of directors due to his experience as a venture capitalist in the biotechnology and pharmaceuticals industry, his experience as a director of biopharmaceutical companies and his educational background.

Laura Shawver, Ph.D., has served as the Chief Executive Officer of Silverback and member of the Silverback Board since April 2020. Dr. Shawver has also served as a member of the board of directors for Relay Therapeutics, Inc. since March 2017 and Nkarta, Inc. since March 2020. Previously, Dr. Shawver served as the President and Chief Executive Officer and as a member of the board of directors of Synthorx, Inc. from November 2017 until its acquisition by Sanofi in January 2020. From September 2011 through April 2018, she served as Chief Executive Officer of Cleave Biosciences, and since September 2011 she has served as a member of the board of directors. Previously, Dr. Shawver was an Entrepreneur in Residence for 5AM Ventures and at Phenomix Corp., SUGEN, Inc. and Berlex Biosciences (formerly Triton Biosciences). Dr. Shawver holds a B.S in microbiology and a Ph.D. in pharmacology, both from the University of Iowa. We believe Dr. Shawver is qualified to serve on the combined company's board of directors due to her extensive experience and expertise as both a director and member of the executive leadership teams of biopharmaceutical companies, her background as a scientist and drug developer, and her educational background.

Peter Thompson, M.D., is one of the co-founders of Silverback and has served as the Chair of the Silverback Board April 2016. Dr. Thompson previously served as our Chief Executive Officer from April 2016 until April 2020. Dr. Thompson is a Partner at OrbiMed Advisors LLC, an investment firm. Dr. Thompson has also served on the board of directors of Prevail Therapeutics, Inc. since August 2017, Alpine Immune Sciences, Inc. since July 2017, Corvus Pharmaceuticals, Inc. since December 2014, and PMV Pharmaceuticals, Inc. since November 2014, as well as several private companies. Previously, Dr. Thompson served on the board of Synthorx, Inc. until its acquisition by Sanofi in January 2020, Adaptimmune Therapeutics plc until June 2018, Principia Biopharma Inc. until September 2018, and Sierra Oncology, Inc. until December 2015. Dr. Thompson also previously served in executive leadership roles at Trubion Pharmaceuticals, Inc., Chiron Corporation, and Becton, Dickinson and Company. Dr. Thompson is an Affiliate Professor of Neurosurgery at the University of Washington. In addition, Dr. Thompson holds numerous patents and was a board-certified internist and oncologist. Dr. Thompson holds a Sc.B. and B.A in mathematics and molecular biology from Brown University and an M.D. from Brown University Medical School. We believe Dr. Thompson is qualified to serve on the combined company's board of directors due to his experience in management and venture capital in the biopharmaceutical industry.

Saqib Islam, J.D., has served as a member of the Silverback Board since July 2017. Mr. Islam has also served as the Chief Executive Officer and a member of the board of directors of Springworks Therapeutics, Inc. since August 2018. In addition, Mr. Islam has also served on the board of directors of Passage Bio, Inc. since March 2019. From February 2016 to August 2017, Mr. Islam served as Chief Business Officer at Moderna Therapeutics, Inc. From February 2013 to February 2016, Mr. Islam was Executive Vice President, Chief Strategy and Portfolio Officer at Alexion Pharmaceuticals, Inc. Prior to joining Alexion, Mr. Islam served in various Managing Director positions at Morgan Stanley and Credit Suisse. Mr. Islam holds a B.A. from McGill University and a J.D. from Columbia Law School. We believe Mr. Saqib is qualified to serve on the combined company's board of directors based on his experience and expertise in operations management and executive leadership at various biopharmaceutical companies.

Family Relationships

Except for Mr. Lowenthal and Dr. Tanimoto, who are married to one another, there are no family relationships among our directors and executive officers.

Composition of the Board of Directors Following the Merger

The Silverback Board is currently divided into three staggered classes, with each class serving a three-year term. The staggered structure of the Silverback Board will remain in place for the combined company's board of directors following the completion of the Merger. The terms of the combined company's Class I, Class II and Class III directors will expire upon the election and qualification of successor directors at the annual meetings of stockholders to be held in 2024, 2025, and 2023, respectively. Following the closing of the Merger, the combined company's directors will be divided among the three classes as follows:

- The Class I directors will be: Dr. Shah, Dr. Dadoo and Mr. Kelly.
- The Class II directors will be: Mr. Lowenthal, Mr. Saunders, Dr. Kolchinsky and Dr. Thompson.
- The Class III directors will be: Dr. Shawver, Mr. Islam, Mr. Schneider and Mr. Leff.

Independence of the Board of Directors

Under the Nasdaq listing standards, a majority of the members of the combined company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the combined company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including: (1) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the combined company to such director and (2) whether such director is affiliated with the combined company, a subsidiary of the combined company or an affiliate of a subsidiary of the combined company.

The board of directors undertook a review of the proposed composition of the board of directors of the combined company following the Merger, the composition of the proposed committees and the independence of the proposed directors and considered whether any director has a material relationship with the combined company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, the board of directors has determined that Dr. Kolchinsky, Dr. Dadoo, Mr. Schneider, Mr. Kelly, Mr. Leff and Mr. Islam do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq.

In making these determinations, the board of directors considered the current and prior relationships that each non-employee director has with the combined company and all other facts and circumstances the combined company's board of directors deemed relevant in determining their independence, including the beneficial ownership of the combined company's capital stock by each non-employee director, and the transactions involving them described in the section titled "*Related Party Transactions of the Combined Company*."

Board Leadership Structure

The combined company's board of directors will be responsible for the control and direction of the combined company. The Chair of the combined company's board of directors will be selected by the combined company's board of directors and is initially expected to be Dr. Shah. As a general policy, the board of directors believes that separation of the positions of Chair of the board of directors and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Lowenthal is expected to serve as President and Chief Executive Officer while Dr. Shah is expected to serve as the Chair of the board of directors but not as an officer. Silverback and ARS Pharma currently expect and intend the positions of Chair of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

Role of Board in Risk Oversight

The combined company's board of directors will have an active role, as a whole and also at the committee level, in overseeing the management of risk, including general oversight of risks and regular review of information regarding risks facing the combined company, including credit risks, liquidity risks and operational risks. The compensation committee will be responsible for overseeing the management of risks relating to executive compensation plans and arrangements. The audit committee will be responsible for overseeing the management of risks relating to accounting matters and financial reporting. The corporate governance and nominating committee will be responsible for overseeing the management of risks associated with the independence of the board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors will be expected to be regularly informed through discussions from committee members about such risks.

Committees of the Combined Company's Board of Directors

The combined company's board of directors will have an audit committee, a compensation committee and a corporate governance and nominating committee, each of which will have the composition and the responsibilities described below.

Audit Committee

The Audit Committee of the board of directors was established by the Silverback Board in accordance with Section 3(a)(58)(A) of the Exchange Act to oversee our corporate accounting and financial reporting processes and audits of our financial statements. For this purpose, the Audit Committee performs several functions which include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;

- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing, with our independent auditors and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management are implemented;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the Audit Committee and the Audit Committee charter.

The members of the Audit Committee are expected to be Mr. Schneider, Mr. Kelly, and Dr. Dadoo, with Mr. Schneider serving as the chair. Our board of directors has determined that each member of the Audit Committee is an independent director under Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards and under Rule 10A-3 under the Exchange Act. Each member of our Audit Committee can read and understand fundamental financial statements in accordance with Nasdaq audit committee requirements. In arriving at this determination, the board of directors has examined each Audit Committee member's scope of experience and the nature of their employment in the corporate finance sector.

Our board of directors has determined that Mr. Schneider qualifies as an Audit Committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board of directors has considered Mr. Schneider's formal education and the nature and scope of his experience with public companies. Both our independent registered public accounting firm and management will periodically meet privately with our Audit Committee.

Compensation Committee

The members of the Compensation Committee are expected to be Dr. Dadoo and Mr. Islam, with Dr. Dadoo serving as the chair. Our board of directors has determined that each of the members of our

Compensation Committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act and satisfies the Nasdaq independence requirements. The functions of the Compensation Committee will include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and making recommendations to the full board of directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full Board of Directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the Compensation Committee and the Compensation Committee charter.

Nominating and Corporate Governance Committee

The members of the Nominating and Corporate Governance Committee are expected to be Dr. Kolchinsky and Mr. Leff, with Dr. Kolchinsky serving as the chair. Our board of directors has

determined that each of the members of this committee satisfies the Nasdaq independence requirements. The functions of this committee will include, among other things:

- identifying, reviewing and evaluating candidates to serve on our Board of Directors consistent with criteria approved by our Board of Directors;
- determining the minimum qualifications for service on our Board of Directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our Board of Directors;
- evaluating nominations by stockholders of candidates for election to our Board of Directors;
- considering and assessing the independence of members of our Board of Directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our Board of Directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and assessing on an annual basis the performance of the Nominating and Corporate Governance Committee and the Nominating and Corporate Governance Committee charter.

Director Liability and Indemnification

At or prior to the closing of the Merger, the combined company will have in effect directors' and officers' liability insurance and will enter into indemnification arrangements with each of its directors and executive officers. The indemnification agreements and the combined company's certificate of incorporation and bylaws will require it to indemnify the directors and officers to the fullest extent permitted by Delaware law.

Corporate Governance Guidelines

The combined company's board of directors will maintain corporate governance guidelines that set forth expectations for directors, director independence standards, board committee structure and functions and other policies for the governance of the combined company in accordance with Nasdaq's listing standards. The corporate governance guidelines will be made available on the combined company's website.

Code of Business Conduct and Ethics

The combined company's board of directors will maintain a Code of Business Conduct and Ethics that applies to all board members, officers and employees. The Code of Business Conduct and Ethics, and any applicable waivers or amendments, will be made available on the combined company's website.

RELATED PARTY TRANSACTIONS OF THE COMBINED COMPANY

Described below are any transactions occurring since January 1, 2020 and any currently proposed transactions to which either Silverback or ARS Pharma was a party and in which

- the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of Silverback or ARS Pharma's total assets, as applicable, at year-end for the last two completed fiscal years; and
- a director, executive officer, holder of more than 5% of the outstanding capital stock of Silverback or ARS Pharma, or any member of such person's immediate family had or will have a direct or indirect material interest.

In addition to the transactions described below, please see the compensation agreements and other arrangements described under the sections titled "*The Merger—Interests of the Silverback Directors and Executive Officers in the Merger.*"

Silverback Transactions

For information regarding Silverback's related party transactions, refer to the information under Item 13 of Part III of the Silverback 10-K, which is incorporated by reference into this proxy statement.

Change in Control and Severance Benefits Arrangements

See "*The Merger—Interests of the Silverback Directors and Executive Officers in the Merger*" for a description of the terms of the change in control and severance benefits arrangements.

Director and Executive Officer Compensation

For information regarding the Silverback's executive and director compensation, refer to the information under Items 11 and 12 of Part III of the Silverback 10-K, which is incorporated by reference into this proxy statement.

ARS Pharma Transactions

Series D Convertible Preferred Stock Financing

In August 2021, ARS Pharma entered into a Series D preferred stock purchase agreement with various investors, pursuant to which ARS Pharma issued and sold an aggregate of 9,337,066 shares of its Series D convertible preferred stock at a price per share of approximately $5.89 for gross proceeds of approximately $55 million.

The table below sets forth the number of shares of ARS Pharma Series D convertible preferred stock purchased by its executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members.

Name	Series D Convertible Preferred Stock (#)	Aggregate Purchase Price ($)
Greater than 5% stockholders:		
Entities or Persons affiliated with Deerfield Management[1]	1,680,672	9,899,998.42
Entities or Persons affiliated with SR One Capital[2]	3,395,297	19,999,996.98
Entities or Persons affiliated with RA Capital Management.[3]	2,546,473	14,999,999.22

(1) Consists of shares of ARS Pharma Series D convertible preferred stock held by Deerfield Private Design Fund III, L.P. and Deerfield Private Design Fund IV, L.P.

(2) Consists of shares of ARS Pharma Series D convertible preferred stock held by SR One Capital Fund II Aggregator, L.P. and SR One Co-Invest VI, LLC.
(3) Consists of shares of ARS Pharma Series D convertible preferred stock held by RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund II, L.P.

Investor Rights, Management, Voting and Co-Sale Agreements

In connection with the ARS Pharma Series D preferred stock financing, ARS Pharma entered into amended and restated investor rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, rights of first offer, voting rights and rights of first refusal, among other things, with certain holders of ARS Pharma capital stock. All of the holders of more than 5% of ARS Pharma capital stock are parties to these agreements. ARS Pharma's executive officers and directors who are parties to these agreements or who are related to parties to these agreements are Mr. Lowenthal, Dr. Tanimoto, Dr. Shah and Dr. Kolchinsky. Pursuant to the terms of the Merger Agreement, these agreements will terminate immediately prior to the Closing.

Consulting Arrangements

In April 2021, we entered into a consulting agreement, as amended on April 25, 2022 (as amended, the "Saunders Consulting Agreement"), with Mr. Saunders, a member of the ARS Pharma Board, pursuant to which Mr. Saunders provided general advice and assistance to ARS Pharma with respect to the development of its current and future product candidates. In June 2021, ARS Pharma issued an option to purchase 500,000 shares of ARS Pharma common stock at a per share exercise price of $1.19 to Mr. Saunders as compensation for his services under the Saunders Consulting Agreement. The option vests over four years from April 26, 2021, with ¼ vesting on the first anniversary of the vesting commencement date, and the remainder vesting in 36 equal monthly installments, subject to continued service through each such vesting date. The option is subject to accelerated vesting in the event of a Change of Control during the optionholder's Continuous Service (each as defined in the ARS 2018 Plan). Only service as a consultant pursuant to the Saunders Consulting Agreement will qualify as Continuous Service under the ARS 2018 Plan for purposes of the continued vesting of Mr. Saunders' option. The Saunders Consulting Agreement automatically renews on an annual basis unless earlier terminated by either party upon 60 days' prior written notice.

In September 2018, ARS Pharma entered into a consulting agreement with Marlinspike Group, LLC ("Marlinspike"). Dr. Shah, the Chair of the ARS Board, is the President of Marlinspike, which provides management and business consulting services as well as business development support to us for a monthly fee of $20,000. Mr. Chakma, the Chief Business Officer of ARS Pharma is a consultant of Marlinspike. The consulting agreement had an initial term of one year from the effective date and automatically renews for one-month terms. The consulting agreement may be terminated by either party upon 14 days' prior written notice. ARS Pharma incurred aggregate fees of $240,000 to Marlinspike for each of the years ended December 31, 2021 and 2020. As of July 31, 2022, ARS Pharma incurred aggregate fees of $140,000 to Marlinspike to date during 2022 pursuant to the consulting agreement.

In September 2015, ARS Pharma entered into a consulting agreement with Pacific-Link Consulting LLC ("PLC"). Mr. Lowenthal, the President and Chief Executive Officer of ARS Pharma and member of the ARS Pharma Board, and Dr. Tanimoto, the Chief Medical Officer of ARS Pharma, are the owners of PLC, which provides general advice and assistance to ARS Pharma with respect to the development of current and future drug products. ARS Pharma incurred aggregate fees of approximately $1.1 million and approximately $1.3 million, to PLC for the years ended December 31, 2021 and 2020, respectively. On July 1, 2022, ARS Pharma entered into a revised consulting agreement with PLC that superseded the initial consulting agreement. The revised consulting agreement has an initial term through July 1, 2023 and automatically renews for one-year terms,

unless either party provides notice to the other party that the agreement will be discontinued. The revised consulting agreement may be terminated by either party upon 60 days' prior written notice. As of July 31, 2022, ARS Pharma incurred aggregate fees of $1.3 million to PLC to date during 2022 pursuant to the initial consulting agreement and the revised consulting agreement.

Indemnification Agreements

ARS Pharma has entered into indemnification agreements with its directors and executive officers, and in connection with the Merger, the combined company intends to enter into new indemnification agreements with each director and executive officer of ARS Pharma continuing as a director or executive officer of the combined company.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

On July 21, 2022, Silverback entered into the Merger Agreement with ARS Pharma and Merger Sub. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into ARS Pharma, with ARS Pharma surviving the Merger as a wholly owned subsidiary of Silverback. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

At the Effective Time: (i) ARS Pharma Common Stock outstanding immediately prior to the Effective Time and after giving effect to the Preferred Stock Conversion, excluding any shares held by ARS Pharma or Silverback or any of their respective subsidiaries and any dissenting shares, will be automatically converted solely into the right to receive a number of Silverback Common Stock equal to the Exchange Ratio, with any fractional shares rounded up to the nearest whole share of Silverback Common Stock; (ii) each option to purchase shares of ARS Pharma Capital Stock (each, an "ARS Pharma Option") that is outstanding and unexercised immediately prior to the Effective Time under ARS's 2018 Equity Incentive Plan (the "ARS 2018 Plan"), whether or not vested, will be converted into and become an option to purchase Silverback Common Stock, and Silverback will assume the ARS 2018 Plan and each such ARS Pharma Option in accordance with the terms of the ARS 2018 Plan and the terms of the stock option agreement by which such ARS Pharma Option is evidenced; and (iii) each warrant to purchase shares of ARS Pharma Capital Stock (each, an "ARS Pharma Warrant") that is outstanding and unexercised immediately prior to the Effective Time and after giving effect to the Preferred Stock Conversion, will be converted into and become a warrant to purchase Silverback Common Stock, and Silverback will assume each ARS Pharma Warrant in accordance with its terms.

The equity holders of Silverback immediately prior to the Effective Time are expected to own approximately 37% of the aggregate number of outstanding shares of Silverback Common Stock immediately after the Effective Time, and the equity holders of ARS Pharma immediately prior to the Effective Time are expected to own approximately 63% of the aggregate number of outstanding shares of Silverback Common Stock immediately after the Effective Time on a fully-diluted basis using the treasury stock method, subject to certain assumptions, including, but not limited to, Silverback's net cash at the Closing being $240.0 million.

The following unaudited pro forma condensed combined financial information gives effect to the Merger, which has been accounted for as a reverse recapitalization under U.S. generally accepted accounting principles ("GAAP"). ARS Pharma is considered the accounting acquirer for financial reporting purposes. This determination is based on the expectations that, immediately following the Merger: (i) ARS Pharma stockholders will own a substantial majority of the voting rights of the combined organization; (ii) ARS Pharma will designate a majority (eight of eleven) of the initial members of the board of directors of the combined organization; and (iii) ARS Pharma's senior management will hold all key positions in senior management of the combined organization. The transaction is expected to be accounted for as a reverse recapitalization of Silverback by ARS Pharma because on the effective date of the Merger, the pre-combination assets of Silverback are expected to be primarily cash and other non-operating assets. ARS Pharma concluded that any in process research and development assets potentially still remaining as of the combination would be de-minimis when compared to the cash and investments obtained through the transaction.

As a result of ARS Pharma being treated as the accounting acquirer, ARS Pharma's assets and liabilities will be recorded at their pre-combination carrying amounts. Silverback's assets and liabilities will be measured and recognized at their fair values as of the effective date of the Merger, and combined with the assets, liabilities, and results of operations of ARS Pharma after the consummation of the Merger. As a result, upon consummation of the Merger, the historical financial statements of ARS Pharma will become the historical consolidated financial statements of the combined company.

The unaudited pro forma condensed combined balance sheet data assumes that the Merger took place on June 30, 2022, and combines the historical balance sheets of Silverback and ARS Pharma as of such date. The unaudited pro forma condensed combined statements of operations and comprehensive loss for the six-month period ended June 30, 2022 and for the year ended December 31, 2021 assumes that the Merger took place as of January 1, 2021 and combines the historical results of Silverback and ARS Pharma for the period then ended. The unaudited pro forma condensed combined financial information was pursuant to the rules and regulations of Article 11 of SEC Regulation S-X.

The unaudited pro forma condensed combined financial information is provided for illustrative purposes only, does not necessarily reflect what the actual consolidated results of operations would have been had the acquisition occurred on the dates assumed and may not be useful in predicting the future consolidated results of operations or financial position.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the closing of the Merger, will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined company's future results of operations and financial position. Differences between the preliminary estimates and final amounts will likely occur as a result of the amount of cash used for Silverback's operations, changes in the fair value of Silverback Common Stock, and other changes in Silverback's assets and liabilities.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this pro forma financial information.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Silverback and ARS Pharma, and their respective management's discussion and analysis of financial condition and results of operations included elsewhere in, or incorporated by reference to, this proxy statement.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. The accounting policies of Silverback may materially vary from those of ARS Pharma. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the Merger, management will conduct a final review of Silverback's accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Silverback's results of operations or reclassification of assets or liabilities to conform to ARS Pharma's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

Unaudited Condensed Combined Pro Forma Balance Sheets
As of June 30, 2022
(In thousands)

	Silverback Therapeutics Inc.	ARS Pharmaceuticals Inc.	Transaction Accounting Adjustments	Notes	Pro Forma Combined
Assets					
Current assets:					
Cash and cash equivalents	$ 218,690	$ 44,590	$ —		$263,280
Short-term investments	39,285	—	—		39,285
Prepaid expenses and other current assets	5,154	798	—		5,952
Total current assets	263,129	45,388	—		308,517
Long-term investments	24,218	—	—		24,218
Other non-current assets	6,652	661	—		7,313
Total assets	$ 293,999	$ 46,049	$ —		$340,048
Liabilities and stockholders' equity					
Current liabilities:					
Deferred revenue	$ —	$ 344	$ —		$ 344
Note payable	—	3,505	—		3,505
Other current liabilities	11,143	3,612	25,950	A,B,C	40,705
Total current liabilities	11,143	7,461	25,950		44,554
Deferred revenue, net of current portion	—	2,982	—		2,982
Note payable, net of current portion	—	3,170	—		3,170
Other non-current liabilities	4,065	429	—		4,494
Total liabilities	15,208	14,042	25,950		55,200
Convertible preferred stock and stockholders' deficit:					
Convertible preferred stock	—	76,039	(76,039)	D	—
Stockholders equity (deficit):					
Common stock	4	260	(254)	D,F	10
Additional paid-in capital	510,607	11,634	(166,143)	G	356,098
Accumulated other comprehensive loss	(1,548)	—	1,548	F	—
Accumulated deficit	(230,272)	(55,926)	214,938	H	(71,260)
Total stockholders' equity (deficit)	278,791	(44,032)	(25,950)		284,848
Total liabilities, and stockholders' equity (deficit)	$ 293,999	$ 46,049	$ —		$340,048

Unaudited Pro Forma Condensed Combined Statement of Operations and Comprehensive Loss
For the Six Month Period Ended June 30, 2022
(In thousands, except share and per share information)

	Silverback Therapeutics Inc.	ARS Pharmaceuticals Inc.	Transaction Accounting Adjustments	Notes	Pro Forma Combined
Revenue from collaboration agreements	$ —	$ 1,127	$ —		$ 1,127
Operating expenses:					
Research and development	29,142	9,773	—		38,915
General and administrative	15,354	4,797	—		20,151
Total operating expenses	44,496	14,570	—		59,066
Loss from operations	(44,496)	(13,443)	—		(57,939)
Interest income (expense)	436	(227)	—		209
Net loss	(44,060)	(13,670)	—		(57,730)
Unrealized loss on available for-sale securities	(1,222)	—	—		(1,222)
Comprehensive loss	$ (45,282)	$ (13,670)	$ —		$ (58,952)
Net loss per share, basic and diluted	$ (1.25)	$ (0.53)			$ (0.61)
Weighted-average shares used in computing net loss per share, basic and diluted	35,120,282	25,796,385	34,213,478	l	95,130,145

Unaudited Pro Forma Condensed Combined Statement of Operations and Comprehensive Loss
For the Year Ended December 31, 2021
(In thousands, except share and per share information)

	Silverback Therapeutics Inc.	ARS Pharmaceuticals Inc.	Transaction Accounting Adjustments	Notes	Pro Forma Combined
Revenue from collaboration agreements	$ —	$ 5,506	$ —		$ 5,506
Operating expenses:					
Research and development	$ 61,501	$ 20,273	$ 8,077	C,E	$ 89,851
General and administrative	28,083	4,687	7,257	C,E	40,027
Total operating expenses	89,584	24,960	15,334		129,878
Loss from operations	(89,584)	(19,454)	(15,334)		(124,372)
Interest income, net	106	(789)	—		(683)
Net loss	(89,478)	(20,243)	(15,334)		(125,055)
Unrealized loss on available for-sale securities	(326)	—	—		(326)
Comprehensive loss	$ (89,804)	$ (20,243)	$ (15,334)		$ (125,381)
Net loss per share, basic and diluted	$ (2.56)	$ (0.83)			$ (1.34)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	34,926,403	24,428,673	34,073,498	I	93,428,574

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Transaction

ARS Pharma, Silverback, and Merger Sub have entered into the Merger Agreement, pursuant to which Merger Sub, a wholly owned subsidiary of Silverback, will merge with and into ARS Pharma, with ARS Pharma surviving as the surviving company. As a result of the Merger, ARS Pharma will be a wholly owned subsidiary of Silverback. Upon the Effective Time, all shares of ARS Common Stock outstanding immediately prior to the Effective Time, after giving effect to the Preferred Stock Conversion, will be converted into the right to receive approximately 60,240,812 shares of Silverback's Common Stock in the aggregate, based on an assumed Exchange Ratio of 1.2441, which is subject to certain adjustments, including based on the Silverback Net Cash at Closing. This Exchange Ratio is an estimate only and the final Exchange Ratio will be determined pursuant to a formula described in more detail in the Merger Agreement. Silverback will assume outstanding and unexercised options to purchase shares of ARS Capital Stock, and in connection with the Merger they will be converted into options to purchase shares of Silverback Common Stock based on the agreed upon Exchange Ratio.

As a result of the Merger, current holders of ARS Pharma Capital Stock, warrants and options to purchase ARS Pharma Capital Stock are expected to own, or hold rights to acquire, in the aggregate approximately 63% of the fully-diluted common stock of Silverback and Silverback's current stockholders, option holders and warrant holders are expected to own, or hold rights to acquire, in the aggregate approximately 37% of the fully-diluted common stock of Silverback following the Effective Time, in each case, using the treasury stock method. These estimates are subject to adjustment prior to the closing of the Merger, including an adjustment to the extent that the Silverback Net Cash at Closing is more or less than $240.0 million. Substantially concurrent with the completion of the Merger, Silverback will change its corporate ticker symbol as described in the Merger Agreement.

ARS Pharma estimates that the aggregate value of the consideration to be paid in the Merger will be approximately $206.2 million. The fair value of consideration transferred is based on the number of common shares Silverback stockholders will own upon consummation of the Merger, multiplied by the closing price of fair value of Silverback Common Stock on August 4, 2022. The number and value of the shares of Silverback Common Stock to be issued pursuant to the Merger will not be determined until the completion of the Merger and therefore, the final aggregate value of the consideration paid in the Merger, may be more or less than $206.2 million. The fair value of consideration transferred is not indicative of the combined entities enterprise value upon consummation of the Merger.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the Silverback stockholders.

2. Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information has been prepared in accordance with SEC Regulation S-X Article 11 ("Article 11"). The unaudited pro forma condensed combined statements of operations and comprehensive loss for the six-month period ended June 30, 2022 and for the year ended December 31, 2021, give effect to the Merger as if it had been consummated on January 1, 2021.

The unaudited pro forma condensed combined balance sheet as of June 30, 2022 gives effect to the Merger and combines the historical balance sheets of Silverback and ARS Pharma as of such date. Based on ARS Pharma's preliminary review of ARS Pharma's and Silverback's summary of significant accounting policies and preliminary discussions between management teams of ARS Pharma and Silverback, the nature and amount of any adjustments to the historical financial

statements of Silverback to conform its accounting policies to those of ARS Pharma are not expected to be material. Upon completion of the Merger, further review of Silverback's accounting policies may result in additional revisions to Silverback's accounting policies and classifications to conform to those of ARS Pharma.

For accounting purposes, ARS Pharma is considered to be the acquiring company and the Merger is expected to be accounted for as a reverse recapitalization of Silverback by ARS Pharma because on the Merger date, the pre-combination assets of Silverback are expected to be primarily cash and other non-operating assets.

For purposes of these pro forma financial statements, this estimated purchase price consideration consists of the following:

The total estimated purchase price and allocated purchase price is summarized as follows:

	Amount
Estimated number of shares of the combined company to be owned by Silverback's stockholders[(i)]	38,216,915
Multiplied by the estimated fair value per share of Silverback's common stock[(ii)]	5.03
Total (in thousands)	$ 192,231
Estimated fair value of assumed Silverback equity awards based on pre-combination service (in thousands)[(iii)]	13,943
Total estimated purchase price (in thousands)	$ 206,174

(i) Reflects the number of shares of common stock of the combined company that Silverback equity holders would own as of the Closing pursuant to the Merger Agreement. This amount is calculated, for purposes of this unaudited pro forma condensed combined financial information, based on shares of Silverback Common Stock outstanding as of July 18, 2022, and contemplation of options to be net exercised using the treasury stock method, and reflects the acceleration and forfeiture of equity awards as a result of Closing and as a result of terminations prior to and at Closing.

(ii) Reflects the price per share of Silverback Common Stock, which is the closing trading price of Silverback Common Stock outstanding as of July 18, 2022, and contemplation of options to be net exercised using the treasury stock method on August 4, 2022. The actual purchase price will fluctuate until the Effective Time of the Merger. The final purchase price arising from the number of shares of Silverback Common Stock outstanding as of July 18, 2022, and contemplation of options to be net exercised using the treasury stock method and the fair market value of Silverback Common Stock outstanding, as well as the fair value of the Silverback equity awards, immediately prior to the closing of the Merger could result in a total purchase price different from that assumed in this unaudited pro forma condensed combined financial information, and that difference may be material. Therefore, the estimated purchase price expected to be transferred reflected in this unaudited pro forma condensed combined financial information does not purport to represent what the actual purchase price will be when the Merger is completed.

(iii) Reflects the estimated acquisition-date fair value of the assumed Silverback's equity awards attributable to pre-combination service (which amount is determined based on the closing trading price of Silverback Common Stock on August 4, 2022, the number of Silverback equity awards expected to be outstanding as of the Effective Time, and the estimated period of service provided by the holders of the awards prior to the Effective Time).

The actual purchase consideration for the net assets of Silverback will vary based on the net cash calculation prior to Closing, the Exchange Ratio, and Silverback share price at Closing as described above and that difference could be material. As such, the estimated purchase consideration reflected in these unaudited pro forma condensed combined financial information does not purport to represent what the actual purchase consideration will be when the Merger is completed. The actual purchase price will fluctuate until the Effective Time of the Merger, and the final valuation of the purchase consideration could differ significantly from the current estimate.

Under reverse recapitalization accounting, the assets and liabilities of Silverback will be recorded, as of the completion of the Merger, at their fair value. Any difference between the consideration

transferred and the fair value of the net assets of Silverback following determination of the actual purchase consideration for Silverback will be reflected as an adjustment to additional paid-in capital. Consequently, under reverse recapitalization accounting, the subsequent financial statements of ARS Pharma will reflect the operations of the acquirer for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of the legal acquirer and a recapitalization of the equity of the accounting acquirer. The accompanying unaudited proforma condensed combined financial information is derived from the historical financial statements of Silverback and ARS Pharma, and include adjustments to give pro forma effect to reflect the accounting for the transaction in accordance with U.S. GAAP. The historical financial statements of ARS Pharma shall become the historical financial statements of the combined company.

ARS Pharma and Silverback may incur significant costs associated with integrating the operations of ARS Pharma and Silverback after the Merger is completed. The unaudited pro forma condensed combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies expected to result from the Merger.

The unaudited pro forma condensed combined financial information may differ from the final purchase accounting for a number of reasons, including the fact that the estimates of the fair values of Silverback net cash is preliminary and subject to change up to the closing date. The differences that may occur between the preliminary estimates and the final purchase accounting could have a material impact on the accompanying unaudited pro forma condensed combined financial information.

3. Shares of Silverback Common Stock Issued to ARS Stockholders upon Closing of the Merger

Prior to the Merger, all outstanding shares of ARS Pharma Preferred Stock are expected to be converted into ARS Pharma Common Stock, which will be exchanged for shares of Silverback Common Stock based on the Exchange Ratio determined in accordance with the Merger Agreement. The estimated Exchange Ratio for purposes of the unaudited pro forma condensed combined financial information was derived on a fully-diluted basis as of July 18, 2022 using a stipulated value of ARS Pharma of approximately $435.0 million and of Silverback of approximately $255.0 million. The estimated number of shares of common stock that Silverback expects to issue to ARS Pharma's stockholders (ignoring rounding of fractional shares and assuming no exercise of outstanding ARS Pharma warrants or options) is determined as follows:

Shares of ARS Pharma Common Stock	26,021,763
Shares of ARS Pharma Preferred Stock	22,399,435
Total	48,421,198
Exchange Ratio	1.2441
Estimated shares of Silverback common stock expected to be issued to ARS Pharma stockholders upon Closing	60,240,812

The stipulated value of Silverback of $255.0 million included in the calculations above assumes Silverback Net Cash at closing of $240.0 million. The Exchange Ratio and the post-Merger equity ownership may change if Silverback Net Cash at Closing is between $210.0 million and $255.0 million. The Exchange Ratio formula is derived based upon an ARS Pharma fixed valuation of $435.0 million and the stipulated value of Silverback of $255.0 million. Holding all other inputs constant, if Silverback Net Cash at Closing is $210.0 million, the Exchange Ratio is estimated to be 1.4015 and the number of shares of Silverback Common Stock to be issued to ARS Pharma stockholders (ignoring rounding of

fractional shares and assuming no exercise of outstanding ARS Pharma warrants or options) is estimated to be 67,862,309. If Silverback Net Cash at closing is $255.0 million, the exchange ratio is estimated to be 1.1788 and the number of shares of Silverback common stock to be issued to ARS Pharma stockholders (ignoring rounding of fractional shares and assuming no exercise of outstanding ARS Pharma warrants or options) is estimated to be 57,078,908.

4. Adjustments to Unaudited Pro Forma Condensed Combined Financial Statements

Adjustments included in the column under the heading “Transaction Accounting Adjustments” are primarily based on information contained within the Merger agreement. Further analysis will be performed after the completion of the Merger to confirm these estimates or make adjustments in the final purchase price allocation, as necessary.

Given ARS Pharma’s history of net losses and valuation allowance, management assumed a statutory tax rate of 0%. Therefore, the pro forma adjustments to the condensed combined statements of operations and comprehensive loss resulted in no additional income tax adjustment to the pro forma financials.

The unaudited pro forma adjustments included in the unaudited pro forma condensed combined financial information are as follows:

A. To reflect preliminary estimated transaction costs that are expected to be incurred by ARS Pharma of $1.2 million in connection with the Merger, such as legal fees, accounting expenses and consulting fees, as an increase in accrued liabilities and a reduction to additional paid-in capital in the unaudited pro forma condensed combined balance sheet. As the Merger will be accounted for as a reverse recapitalization equivalent to the issuance of equity for the net assets, primarily cash and investments, of Silverback, these direct and incremental costs are treated as a reduction of the net proceeds received within additional paid-in capital.

B. To reflect preliminary estimated transaction costs that are expected to be incurred by Silverback of $11.8 million in connection with the Merger, such as adviser fees, legal, and directors and officers liability insurance expenses, as an increase in accrued liabilities and accumulated deficit in the unaudited pro forma condensed combined balance sheet.

C. Compensation expense of $13.0 million related to severance, retention and transaction bonuses resulting from employment agreements entered into by Silverback in contemplation of the Merger is reflected as an increase to accumulated deficit and accrued liabilities in the unaudited pro forma condensed combined balance sheet. In the unaudited pro forma condensed combined statement of operations and comprehensive loss for the year ended December 31, 2021, $6.5 million and $6.5 million is reflected as research and development and general and administrative expense, respectively.

D. Reclassification of $76,289, representing $76,039 of preferred stock and $250 of par relating to common stock, to reflect the conversion of 22,399,435 shares of ARS Pharma Preferred Stock into shares of ARS Pharma Common Stock immediately prior to the Merger and the exchange of outstanding ARS Pharma Common Stock, including converted preferred stock, into 60,240,812 shares of Silverback Common Stock based on the assumed Exchange Ratio for purposes of these pro forma condensed combined financial information. The par value of ARS Pharma Common Stock is $0.01 while the par value of Silverback Common Stock is $0.0001, leading to an adjustment to decrease common stock par value and increase additional paid-in capital of $0.5 million.

E. To reflect (1) $13.9 million of consideration transferred related to the pre-combination service of replacement awards and (2) the post-combination stock-based compensation

expense of $2.4 million as an increase in additional paid-in capital and accumulated deficit related to the acceleration of vesting upon the change of control and termination of employment for certain awards and the modification of certain awards extending the exercise period from 3 months to 12 months. In the unaudited pro forma condensed combined statement of operations and comprehensive loss for the year ended December 31, 2021, $1.6 million and $0.8 million is reflected as research and development and general and administrative expense, respectively.

F. To reflect the elimination of Silverback's historical net equity, which represents the net assets acquired in the reverse recapitalization (in thousands):

	Amount
Pre-combination Silverback additional paid-in capital:	
Pre-combination stock-based compensation expense (Note E)	(13,943)
Historical Silverback additional paid-in capital	(510,607)
Total pre-combination Silverback additional paid-in capital	(524,550)
Pre-combination Silverback accumulated deficit:	
Silverback transaction costs (Note B)	11,774
Historical Silverback accumulated deficit	230,272
Total pre-combination Silverback accumulated deficit	242,046
Silverback common stock	(4)
Silverback accumulated other comprehensive loss	1,548
Total adjustment to historical equity (net assets of Silverback)	$(280,960)

G. The pro forma adjustments recorded to additional paid-in capital as noted above, include (in thousands):

	Amount
Elimination of pre-combination Silverback additional paid-in capital (Note F)	(524,550)
Record purchase of Silverback historical net assets (Note F)	280,960
Expected transaction costs of ARS Pharma (Note A)	(1,226)
Conversion of ARS Pharma Preferred Stock into ARS Pharma Common Stock (Note D)	76,289
Recognition of accelerated post-combination stock compensation (Note E)	2,384
Total adjustment to additional paid-in capital	$ (166,143)

H. The pro forma adjustments recorded to accumulated deficit as noted above, include (in thousands):

	Amount
Elimination of historical Silverback accumulated deficit (Note F)	230,272
Severance costs of Silverback employees (Note C)	(12,950)
Recognition of accelerated stock compensation (Note E)	(2,384)
Total adjustment to accumulated deficit	$214,938

I. The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net income for the year ended December 31, 2021 and the six months ended June 30, 2022. In addition, the number of shares used in calculating the pro forma combined basic and diluted net loss per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company for the respective

periods. For the year ended December 31, 2021 and the six months ended June 30, 2022, the pro forma weighted average shares outstanding has been calculated as follows:

	June 30, 2022	December 31, 2021
ARS Pharma weighted-average shares of common stock outstanding	25,796,385	24,428,673
Impact of ARS Pharma Preferred Stock assuming conversion as of January 1, 2021	22,399,435	22,399,435
Total	48,195,820	46,828,108
Application of exchange ratio to historical ARS Pharma weighted-average shares outstanding	1.2441	1.2441
Adjusted ARS Pharma weighted-average shares outstanding	59,960,420	58,258,849
Historical Silverback shares of common stock outstanding	35,169,725	35,169,725
Total pro forma weighted average shares outstanding	95,130,145	93,428,574

The stipulated value of Silverback of $255.0 million assumes Silverback Net Cash at Closing of $240.0 million. The Exchange Ratio, post-Merger equity ownership, and related Adjustments to Unaudited Pro Forma Condensed Combined Financial Statements may change if Silverback Net Cash is between $210.0 million and $255.0 million at Closing. Holding all other inputs constant, if Silverback Net Cash at Closing is $210.0 million, the pro forma weighted average shares used in computing net loss per share, basic and diluted and resulting net loss per share, basic and diluted, for the year ended December 31, 2021 would be 100,799,319 shares and ($1.24), respectively, and for the six month period ended June 30, 2022 of 102,716,167 shares and ($0.56), respectively. If Silverback Net Cash at Closing is $255.0 million, the pro forma weighted average shares used in computing net loss per share, basic and diluted and resulting net loss per share, basic and diluted, for the year ended December 31, 2021 would be 90,370,699 shares and ($1.38), respectively, and for the six month period ended June 30, 2022 of 91,982,958 shares and ($0.63), respectively. Further impacts to the Unaudited Pro Forma Condensed Combined Financial Statements due to changes in Silverback Net Cash at Closing are immaterial.

PRINCIPAL STOCKHOLDERS OF SILVERBACK

The following table sets forth certain information regarding the ownership of Silverback Common Stock as of June 30, 2022 by: (i) each person or group of affiliated persons known by Silverback to be the beneficial owner of more than 5% of the Silverback Common Stock; (ii) each director; (iii) each of Silverback's named executive officers; (iv) and all executive officers and directors of Silverback as a group.

The following table is based upon information supplied by officers, directors and principal stockholders and Schedules 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, Silverback believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 35,187,344 shares outstanding on June 30, 2022, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address for the following stockholders is c/o Silverback Therapeutics, Inc., 500 Fairview Ave. N, Suite 600, Seattle, Washington 98109.

	Beneficial Ownership	
Beneficial Owner	Number of Shares (#)	Percent of Total (%)
Greater than 5% Stockholders		
Entities affiliated with OrbiMed Advisors LLC(1)	8,740,887	24.8%
FMR LLC(2)	3,753,737	10.7
Wasatch Advisors, Inc.(3)	2,974,228	8.5
The K2 Principal Fund, L.P.(4)	1,906,618	5.4
Nextech Invest AG(5)	1,910,029	5.4
Named Executive Officers and Directors		
Laura Shawver, Ph.D. (6)	1,143,006	3.2
Valerie Odegard, Ph.D.(7)	373,275	1.0
Jonathan Piazza(8)	347,476	1.0
Vickie L. Capps(9)	97,912	*
Robert Hershberg, M.D., Ph.D.(10)	128,569	*
Saqib Islam, J.D.(11)	119,685	*
Maria Koehler, M.D., Ph.D.(12)	11,805	*
Andrew Powell, J.D.(13)	78,724	*
Jonathan Root, M.D.(14)	131,499	*
Peter Thompson, M.D.(15)	8,777,148	24.9
All current executive officers and directors as a group (10 persons)(16)	11,209,099	30.0

* Represents beneficial ownership of less than 1%.

Beneficial ownership is determined in accordance with SEC rules and includes any shares as to which the stockholder has sole or shared voting power or investment power as well as any shares that the stockholder has the right to acquire within 60 days of June 30, 2022, whether through the exercise, settlement or conversion of any stock option, restricted stock units, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(1) Consists of 269,323 shares of common stock held by OPI VI—HoldCo LLC, 7,519,187 shares of common stock held by OrbiMed Private Investments VI, LP, and 952,377 shares of common stock held by OrbiMed Partners Master Fund Limited (collectively, "OrbiMed VI"). OrbiMed Capital GP VI LLC ("GP VI)" is the general partner of OrbiMed VI. OrbiMed Advisors LLC ("Advisors") is the managing member of GP VI. By virtue of such relationships, GP VI and Advisors may be deemed to have voting and investment power with respect to the shares held by OrbiMed VI and as a result may be deemed to have beneficial ownership of such shares. Peter Thompson, M.D. is an employee of Advisors and is the Chairman of our Board of Directors. Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein. Each of GP VI and Advisors disclaims beneficial ownership of the shares held by OrbiMed VI, except to the extent of its or his pecuniary interest therein if any. The address for each of these entities is 601 Lexington Avenue, 54th Floor, New York, New York 10022.

(2) FMR LLC has sole voting and investment control over 1,607,856 shares of common stock it holds, and sole investment control over the remaining 2,145,881 shares of common stock it holds. Abigail P. Johnson is a director, the chairman and the chief executive officer of FMR LLC and may be deemed to have sole investment control and beneficial ownership over all FMR LLC shares. The address of FMR LLC is 245 Summer Street, Boston, Massachusetts 02210. This information is based on a Schedule 13G/A filed with the SEC on February 9, 2022, reporting holdings as of December 31, 2021.

(3) Wasatch Advisors, Inc. has sole voting and investment control over 2,513,138 shares of common stock it holds, and sole investment control over the remaining 461,090 shares of common stock it holds. JB Taylor is the chief executive officer of Wasatch Advisors, Inc. and may be deemed to have sole investment control and beneficial ownership over all Wasatch Advisors, Inc. shares. The address of Wasatch Advisors, Inc. is 505 Wakara Way, Salt Lake City, UT 84108. This information is based on a Schedule 13F filed with the SEC on May 13, 2022, reporting holdings as of March 31, 2022.

(4) K2 Genpar 2017 Inc. (Genpar 2017) is the general partner to The K2 Principal Fund, L.P. (the Fund). K2 & Associates Investment Management Inc. (K2 & Associates) is a direct 66.5% owned subsidiary of Shawn Kimel Investments, Inc. (SKI) and is the investment manager of the Fund. Daniel Gosselin is Vice President of SKI, secretary of Genpar 2017 and President of K2 & Associates, and may be deemed to have voting and investment powers and beneficial ownership over the shares held by the Fund. The business address of each of SKI, the Fund, Genpar 2017, and K2 & Associates is 2 Bloor St West, Suite 801, Toronto, Ontario, M4W 3E2.This information is based on a Schedule 13G filed with the SEC on July 18, 2022.

(5) Nextech VI GP S.a r.l. (Nextech GP) is the general partner of Nextech VI Oncology SCSp (Nextech VI). Rocco Sgobbo, Dalia Bleyer and Ian Charoub are members of the board of managers of Nextech GP and share voting and dispositive power over the shares held by Nextech VI, and may be deemed to own beneficially the shares held by Nextech VI. Nextech Invest AG is the investment advisor of Nextech VI. Nextech Invest AG has delegated voting and investment control to Lemanik Asset Management S.A. (Lemanik). Alexandre Dumont and Florian Sebe of Lemanik share voting and investment power with respect to the shares held by Nextech VI. The address of Nextech Invest AG is Bahnhofstrasse 18, Zurich, V8 CH-8001. This information is based on a Schedule 13F filed with the SEC on May 16, 2022, reporting holdings as of March 31, 2022.

(6) Consists of (a) 79,895 shares of common stock held by Dr. Shawver and (b) 1,063,111 shares of common stock that Dr. Shawver has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options, 350,410 shares of which will be unvested but exercisable as of August 29, 2022.

(7) Consists of 373,275 shares of common stock that Dr. Odegard has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options.

(8) Consists of (a) 17,320 shares of common stock held by Mr. Piazza, and (b) 330,156 shares of common stock that Mr. Piazza has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options, 163,460 shares of which will be unvested but exercisable as of August 29, 2022.

(9) Consists of (a) 61,576 shares of common stock held by Ms. Capps, 17,619 shares of which are subject to a right of repurchase by us as of June 30, 2022, and (b) 36,336 shares of common stock that Ms. Capps has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options.

(10) Consists of 128,569 shares of common stock that Dr. Hershberg has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options, 10,704 shares of which will be unvested but exercisable as of August 29, 2022.

(11) Consists of (a) 15,239 shares of common stock held by Mr. Islam and (b) 104,446 shares of common stock that Mr. Islam has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options, 13,410 shares of which will be unvested but exercisable as of August 29, 2022.

(12) Consists of 11,805 shares of common stock that Dr. Koehler has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options.

(13) Consists of 78,724 shares of common stock that Mr. Powell has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of stock options, 20,263 shares of which will be unvested but exercisable as of August 29, 2022.

(14) Consists of (a) 95,238 shares of common stock held by Dr. Root, and (b) 36,261 shares of common stock that Dr. Root has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of options.

(15) Consists of the shares listed in footnote (1) above and 36,261 shares of common stock that Dr. Thompson has the right to acquire from us within 60 days of June 30, 2022 pursuant to the exercise of options. Dr. Thompson shares voting and dispositive power with respect to the shares held by OrbiMed VI.

(16) Includes the shares described in note (6) through note (15) above.

HOUSEHOLDING OF PROXY MATERIALS

The SEC has adopted rules that permit companies and intermediaries (*e.g.*, brokers) to satisfy the delivery requirements for proxy statements and annual reports with respect to two or more stockholders sharing the same address by delivering a single proxy statement addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

A number of brokers with account holders who are Silverback stockholders will be householding Silverback's proxy materials. A single proxy statement will be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once a stockholder has received notice from its broker that they will be householding communications to such stockholder's address, householding will continue until such stockholder is notified otherwise or until it revokes its consent. If, at any time, a stockholder no longer wishes to participate in householding and would prefer to receive a separate proxy statement and annual disclosure documents, it may notify its broker, and direct its written request to Silverback Therapeutics, Inc. at Silverback's principal executive offices at 500 Fairview Ave N, Suite 600, Seattle, Washington 98109, Attention: Investor Relations. Stockholders who currently receive multiple copies of the proxy statement and annual disclosure documents at their address and would like to request householding of their communications should contact their broker.

FUTURE STOCKHOLDER PROPOSALS

Silverback's stockholders may submit proposals on matters appropriate for stockholder action at meetings of Silverback's stockholders in accordance with Rule 14a-8 promulgated under the Exchange Act. For such proposals to be included in Silverback's proxy materials relating to Silverback's 2023 annual meeting of stockholders, all applicable requirements of Rule 14a-8 must be satisfied and such proposals must be received by Silverback no later than December 29, 2022. However, if Silverback's 2023 annual meeting of stockholders is not held between May 11, 2023 and July 10, 2023, then the deadline will be a reasonable time prior to the time Silverback begins to print and mail its proxy materials.

If a Silverback stockholder wishes to submit a proposal (including a director nomination) at the 2023 annual meeting of stockholders that is not to be included in Silverback's proxy materials, such written request must be received by Silverback's Corporate Secretary between February 10, 2023 and March 12, 2023, provided that, if the 2023 annual meeting of stockholders is earlier than May 11, 2023 or later than July 10, 2023, such written request must be received by our Corporate Secretary not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. Silverback stockholders are also advised to review Silverback's amended and restated bylaws which contain additional requirements about advance notice of stockholder proposals and director nominations. In addition to satisfying the foregoing requirements and any additional requirements under Silverback's amended and restated bylaws, to comply with the universal proxy rules, stockholders who intend to solicit proxies in support of director nominees other than Silverback's nominees must provide notice that sets forth the information required by Rule 14a-19 under the Exchange Act no later than April 11, 2023.

Such proposals should be submitted to Silverback's Corporate Secretary at Silverback Therapeutics, Inc., 500 Fairview Ave. N, Suite 600, Seattle, Washington 98109 or, if sent following the closing of the Merger, to the combined company's corporate secretary at ARS Pharmaceuticals, Inc., 11682 El Camino Real, Suite 120, San Diego, CA 92130.

The chair of the 2023 annual meeting of stockholders may determine, if the facts warrant, that a matter has not been properly brought before the meeting and, therefore, may not be considered at the meeting. In addition, if stockholders do not also comply with the requirements of Regulation 14A under the Exchange Act, Silverback's management will have discretionary authority to vote all shares for which it has proxies in opposition to any such stockholder proposal or director nomination.

STOCKHOLDER COMMUNICATION WITH SILVERBACK BOARD

Silverback's stockholders may communicate with the Board by writing to its Corporate Secretary at Silverback Therapeutics, Inc., 500 Fairview Ave. N, Suite 600, Seattle, Washington 98109. Each communication must set forth: the name and address of the stockholder on whose behalf the communication is sent and the number of our shares that are owned beneficially by such stockholder as of the date of the communication. Silverback's Corporate Secretary will review these communications and will determine whether they should be presented to the Silverback Board. The purpose of this screening is to allow the Silverback Board to avoid having to consider irrelevant or inappropriate communications. All communications directed to the Audit Committee in accordance with Silverback's Open Door Policy for Reporting Complaints Regarding Accounting and Auditing Matters that relate to questionable accounting or auditing matters involving Silverback will be promptly and directly forwarded to Silverback's compliance officer.

WHERE YOU CAN FIND MORE INFORMATION

Silverback files annual, quarterly and special reports, proxy statements and other information with the SEC. Silverback SEC filings are also available to the public from commercial document retrieval services and on the website maintained by the SEC at http://www.sec.gov.

In addition, the SEC allows Silverback to disclose important information to you by referring you to other documents filed separately with the SEC. This information is considered to be a part of this proxy statement, except for any information that is superseded by information included directly in this proxy statement or incorporated by reference subsequent to the date of this proxy statement as described below.

INFORMATION INCORPORATED BY REFERENCE

This proxy statement incorporates by reference the documents listed below that Silverback has previously filed with the SEC (other than, in each case, documents or information deemed to have been furnished and not filed in accordance with SEC rules). They contain important information about Silverback and its financial condition.

- Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022, including the information specifically incorporated by reference in the Annual Report on Form 10-K from Silverback's definitive proxy statement on Schedule 14A filed with the SEC on April 28, 2022;
- Quarterly Reports on Form 10-Q for the for the quarterly periods ended March 31, 2022 and June 30, 2022, filed with the SEC on May 12, 2022 and August 11, 2022, respectively;
- Current Reports on Form 8-K filed with the SEC on March 17, 2022, May 6, 2022, June 13, 2022, July 21, 2022, September 2, 2022 and September 30, 2022; and

- the description of Silverback's common stock contained in its registration statement on Form 8-A, filed with the SEC on December 1, 2020, including all amendments and reports filed for the purpose of updating such description.

To the extent that any information contained in any report on Form 8-K, or any exhibit thereto, was furnished to, rather than filed with, the SEC by Silverback, such information or exhibit is specifically not incorporated by reference.

In addition, Silverback incorporates by reference any future filings it may make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this proxy statement and before the date of the Silverback virtual special meeting (excluding any current reports on Form 8-K to the extent disclosure is furnished and not filed). Those documents are considered to be a part of this proxy statement, effective as of the date they are filed. In the event of conflicting information in these documents, the information in the latest filed document should be considered correct.

Silverback has supplied all information contained in this proxy statement relating to Silverback, and ARS Pharma has supplied all information contained in this proxy statement relating to ARS Pharma.

If you would like to request documents from Silverback or ARS Pharma, please send a request in writing or by telephone to either Silverback or ARS Pharma at the following addresses:

Silverback Therapeutics, Inc.
500 Fairview Ave N, Suite 600
Seattle, Washington 98109
Attn: General Counsel
Telephone: (206) 456-2900
Email: legal@silverbacktx.com

ARS Pharmaceuticals, Inc.
11682 El Camino Real, Suite 120
San Diego, CA 92130
Attn: General Counsel
Telephone: (858) 771-9307
Email: info@ars-pharma.com

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Audited Consolidated Financial Statements:

Unaudited Condensed Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of ARS Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ARS Pharmaceuticals, Inc. (the Company) as of December 31, 2021 and December 31, 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and December 31, 2020, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

San Diego, California
August 11, 2022

ARS Pharmaceuticals, Inc.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share amounts)

	December 31, 2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 60,063	$ 24,521
Prepaid expense and other current assets	667	1,861
Total current assets	60,730	26,382
Right-of-use asset	621	—
Fixed assets, net	72	23
Other assets	23	2
Total assets	$ 61,446	$ 26,407
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $159 in 2021 and $146 in 2020)	$ 3,107	$ 2,134
Lease liability, current portion	144	—
Deferred revenue, current	1,457	3,518
Note payable, current	3,479	2,558
Total current liabilities	8,187	8,210
Lease liability, net of current portion	480	—
Deferred revenue	2,996	3,442
Note payable, less current portion	4,930	7,460
Unvested common stock liability	—	27
Preferred stock warrant liability	83	87
Total liabilities	16,676	19,226
Commitments and contingencies		
Convertible preferred stock and stockholders' deficit:		
Series A convertible preferred stock, $0.01 par value, 4,764,000 shares authorized, issued and outstanding at December 31, 2021 and 2020. Liquidation preference of $397	365	365
Series B convertible preferred stock, $0.01 par value, 606,060 shares authorized, issued and outstanding at December 31, 2021 and 2020. Liquidation preference of $1,000	1,000	1,000
Series C convertible preferred stock, $0.01 par value, 7,749,999 and 7,730,769 shares authorized at December 31, 2021 and 2020, respectively, and shares 7,692,309 issued and outstanding at December 31, 2021 and 2020, respectively. Liquidation preference of $20,000	19,868	19,868
Series D convertible preferred stock, $0.01 par value, 9,337,066 and no shares authorized, issued and outstanding at December 31, 2021 and 2020, respectively. Liquidation preference of $55,000	54,806	—
Stockholders' deficit		
Common stock, $0.01 par value, 56,000,000 and 42,821,433 shares authorized, 25,695,416 and 22,346,875 shares issued and outstanding at December 31, 2021 and 2020, respectively; excluding no and 3,178,125 shares subject to repurchase at December 31, 2021 and 2020, respectively	257	223
Additional paid-in capital	10,730	7,738
Accumulated deficit	(42,256)	(22,013)
Total stockholders' deficit	(31,269)	(14,052)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 61,446	$ 26,407

See accompanying notes.

ARS Pharmaceuticals, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share information)

	Year Ended December 31, 2021	2020
Revenue:		
Revenue under collaboration agreements	$ 5,506	$ 17,835
Total revenue	5,506	17,835
Operating expenses:		
Research and development (including related party amounts of $1,072 in 2021 and $1,266 in 2020)	20,273	14,070
General and administrative (including related party amounts of $410 in 2021 and $240 in 2020)	4,687	4,234
Total operating expenses	24,960	18,304
Loss from operations	(19,454)	(469)
Other (expense) income, net	(789)	(596)
Net loss and comprehensive loss	$ (20,243)	$ (1,065)
Net loss per common share, basic and diluted	$ (0.83)	$ (0.05)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	24,428,673	20,217,469

See accompanying notes.

ARS Pharmaceuticals, Inc.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	4,764,000	$ 365	606,060	$ 1000	7,692,309	$19,868	—	$ —	18,009,375	$ 180	$ 4,101	$ (20,948)	$ (16,667)
Vesting of restricted common stock	—	—	—	—	—	—	—	—	4,237,500	42	(5)	—	37
Exercise of stock options	—	—	—	—	—	—	—	—	100,000	1	98	—	99
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	3,544	—	3,544
Net loss and comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	(1,065)	(1,065)
Balance at December 31, 2020	4,764,000	365	606,060	1000	7,692,309	19,868	—	—	22,346,875	223	7,738	(22,013)	(14,052)
Issuance of Series D convertible preferred stock for cash, net of issuance costs of $194	—	—	—	—	—	—	9,337,066	54,806	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	—	—	—	3,178,125	32	(4)	—	28
Exercise of stock options	—	—	—	—	—	—	—	—	170,416	2	167	—	169
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	2,829	—	2,829
Net loss and comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	(20,243)	(20,243)
Balance at December 31, 2021	4,764,000	$ 365	606,060	$ 1000	7,692,309	$19,868	9,337,066	$54,806	25,695,416	$ 257	$ 10,730	$ (42,256)	$ (31,269)

See accompanying notes.

ARS Pharmaceuticals, Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2021	2020
Operating activities:		
Net loss	$(20,243)	$ (1,065)
Non-cash adjustments to reconcile net loss to net cash provided by (used) in operating activities:		
Stock-based compensation expense	2,829	3,544
Debt discount	—	2
Non-cash interest expense	207	119
Change in fair value of warrant liability	(4)	1
Depreciation	6	6
Changes in operating assets and liabilities:		
Prepaid and other current assets	1,194	(1,683)
Other assets	(21)	(2)
Accounts payable and accrued liabilities (including related party amounts of $13 in 2021 and $101 in 2020)	974	1,189
Operating right-of-use assets and lease liabilities, net	4	—
Deferred revenue	(2,507)	6,960
Net cash provided by (used) for operating activities	(17,561)	9,071
Investing activities:		
Purchase of property and equipment	(55)	—
Net cash used in investing activities	(55)	—
Financing activities:		
Proceeds from bank note payable	—	5,000
Repayment of bank note payable	(1,817)	
Proceeds from issuance of preferred stock, net	54,806	—
Proceeds from exercise of common stock options	169	99
Net cash provided by financing activities	53,158	5,099
Net increase (decrease) in cash and cash equivalents	35,542	14,170
Cash and cash equivalents at beginning of year	24,521	10,351
Cash and cash equivalents at end of year	$ 60,063	$24,521
Supplemental disclosures:		
Interest paid	$ 576	$ 325

See accompanying notes.

ARS Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

ARS Pharmaceuticals, Inc. (the "Company"), is a privately-held company incorporated in Delaware in August 2015. In January 2020, the Company formed a wholly-owned subsidiary in Ireland, ARS Pharmaceuticals IRL, Limited, to facilitate the filing of regulatory approval for ARS-1 in European countries. The Company is focused on the development and commercialization of ARS-1 (brand name Neffy®), a proprietary product candidate for the needle-free intranasal delivery of epinephrine for the emergency treatment of type I allergic reactions including anaphylaxis.

Liquidity and Capital Resources

From August 5, 2015 (inception) through December 31, 2021, the Company has devoted substantially all of its efforts to acquiring its asset, developing intellectual property and conducting product development and clinical trials, raising capital, and building infrastructure. Since inception, the Company has funded its operations primarily with net proceeds from the issuance of convertible preferred stock, payments earned under collaboration agreements and bank debt. The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. The Company has experienced net losses and negative cash flows from operating activities and had an accumulated deficit of $42.3 million as of December 31, 2021.

The Company expects to continue to incur net losses into the foreseeable future and will need to obtain additional financing in order to initiate and complete clinical trials, complete process development and commercialize any product candidates for which it receives regulatory approval. The Company plans to continue to fund its losses from operations and capital funding needs through future public or private equity or debt financing or through collaborations or partnerships with other companies. The novel coronavirus-2019 ("COVID-19") pandemic and ongoing geopolitical events continue to rapidly evolve and have already resulted in a significant disruption of global financial markets. The Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and further disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the pandemic or geopolitical actions. If such further disruption occurs, the Company could experience an inability to access additional capital. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC"), and Accounting Standards Update ("ASU"), of the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of the Company and ARS Pharmaceuticals IRL, Limited for the year ended December 31, 2021. All intercompany accounts and transactions have been eliminated in consolidation. The Company's functional and reporting currency is the U.S. dollar. Assets and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets,

which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense) in the consolidated statements of operations. All adjustments considered necessary for a fair presentation have been included. These adjustments consist of normal and recurring accruals, as well as non-recurring charges.

Use of Estimates

The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to revenue recognized for its collaboration agreements, accruals for research and development expenses and valuation of equity awards. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

The full extent to which the COVID-19 pandemic and ongoing geopolitical events will directly or indirectly impact the Company's business, results of operations and financial condition, including research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and ongoing geopolitical events and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. The Company has considered potential impacts arising from the COVID-19 pandemic and ongoing geopolitical events and is not presently aware of any events or circumstances that would require the Company to update its estimates, judgments or revise the carrying value of its assets or liabilities.

Cash and Cash Equivalents

Cash and cash equivalents include cash readily available in checking, money market and sweep accounts. The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and limits its exposure to cash risk by placing its cash with high credit quality financial institutions.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally five years. Repairs and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows which the asset or asset group are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds its fair value. The Company has not recognized any impairment losses from inception through December 31, 2021.

Leases

Effective January 1, 2021, the Company early adopted ASC No. 2016-02, Leases (Topic 842) ("ASC 842"), which supersedes the current accounting for leases, using the modified retrospective transition method. The Company has elected to apply the practical expedients allowed by the standard for existing leases. The new standard, while retaining two distinct types of leases, finance and operating, (i) requires lessees to record a right-of-use ("ROU") asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and recognize lease expense in a manner similar to current accounting, (ii) eliminates current real estate specific lease provisions, (iii) modifies the lease classification criteria and (iv) aligns many of the underlying lessor model principles with those in the new revenue standard. The Company determines the initial classification and measurement of its ROU asset and lease liabilities at the lease commencement date and thereafter, if modified. The Company recognizes a ROU asset for its operating leases with lease terms greater than 12 months. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. The lease liability is calculated by using the present value of all lease payments, with the present value determined by using the incremental borrowing rate for operating leases determined by using the incremental borrowing rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment as well as a review of peer companies. Variable charges for common area maintenance and other variable costs are recognized as expense as incurred. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in research and development and general and administrative expenses in the consolidated statements of operations.

Warrant Liability

The Company has issued freestanding warrants to purchase shares of its Series C convertible preferred stock. The Series C convertible preferred stock warrant is classified as a liability in the accompanying consolidated balance sheets. The Company adjusts the carrying value of such Series C convertible preferred stock warrant to its estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded within other income (expense) in the consolidated statements of operations. The warrant liability will continue to be adjusted to fair value until such time as the Series C convertible preferred stock warrant is no longer outstanding or the underlying securities are no longer redeemable outside the control of the Company.

Revenue Recognition

Our revenues generally consist of licenses and research services under license and collaboration agreements. We recognize revenue when we transfer promised goods or services to customers in an

amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Research and Development Costs

Research and development are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation expense, external research and development costs incurred under agreements with contract research organizations, investigative sites and consultants to conduct our clinical studies, costs related to compliance with regulatory requirements, costs related to manufacturing the Company's product candidates for clinical trials and other allocated expenses.

Payments for research and development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying consolidated balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. The Company uses judgments and estimates to determine the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses in the statements of operations and expensed as incurred since recoverability of such expenditures is uncertain.

License Fees

Costs incurred to acquire technology licenses and milestone payments made on existing agreements are charged to research and development expense or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company recognizes expense for awards subject to performance-based milestones over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based

milestone is probable based on the expected satisfaction of the performance conditions at each reporting date. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and recognizes forfeitures as they occur.

The Company's equity incentive plan allows for the issuance of restricted stock awards that may be subject to vesting. The unvested shares of any restricted stock awards are held in escrow as the stock award vests or until the holder's termination of services, whichever occurs first. In the event the holder's services terminate, the Company has the right of repurchase, at its option, the portion of unvested stock awards. For all early exercised unvested stock awards, a liability is established related to the cash received for the unvested portion of the stock award, which represents the Company's repurchase rights if the award holders were to be terminated and their stock repurchased.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

Segment Reporting

Operating segments are components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker for purposes of making decisions regarding resource allocation and assessing performance. The Company views its operations and managed its business as one operating segment.

Fair Value Measurements

The Company categorizes its assets and liabilities measured at fair value in accordance with the authoritative accounting guidance that establishes a consistent framework for measuring fair value, and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1—Quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2—Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and
- Level 3—Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The carrying values of the Company's current financial assets and current financial liabilities approximate their fair values due to the short-term nature of these instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, management believe the fair value of the note payable approximates its carrying value.

Assets measured at fair value on a recurring basis as of December 31, 2021 were as follows (in thousands):

		Fair Value Measurements Using		
	Balance as of December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 59,401	$ 59,401	$ —	$ —

Assets measured at fair value on a recurring basis as of December 31, 2020 were as follows (in thousands):

		Fair Value Measurements Using		
	Balance as of December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 23,691	$ 23,691	$ —	$ —

Financial liabilities measured at fair value on a recurring basis include the preferred stock warrant liability described below. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

Liabilities measured at fair value on a recurring basis as of December 31, 2021 were as follows (in thousands):

		Fair Value Measurements Using		
	Balance as of December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Preferred stock warrant liability	$ 83	$ —	$ —	$ 83

Liabilities measured at fair value on a recurring basis as of December 31, 2020 were as follows (in thousands):

		Fair Value Measurements Using		
	Balance as of December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Preferred stock warrant liability	$ 87	$ —	$ —	$ 87

The estimated fair value of the preferred stock warrant liability at issuance was determined using the Black-Scholes valuation model that considered the fair value of the underlying Series C convertible preferred stock, the exercise price of the warrant, the assumed volatility of the Company utilizing a group of peers, an expected term equal to the contractual life of the instrument and a risk-free rate consistent with the term.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs:

	Preferred Stock Warrant Liability
Balance at December 31, 2020	$ 87
Fair value of preferred stock warrant issued	—
Change in fair value of preferred stock warrant liability	(4)
Balance at December 31, 2021	$ 83

During 2020, the Company issued 19,230 of Series C preferred stock warrants in connection with the second draw under its debt agreement.

Net Loss Per Common Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net loss per

share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company. For purposes of this calculation, convertible preferred stock, stock options, and preferred stock warrants are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive.

	December 31, 2021	December 31, 2020
Convertible preferred stock	22,399,435	13,062,369
Warrants to purchase convertible preferred stock	38,460	38,460
Restricted common stock	—	3,178,125
Common stock options granted and outstanding	4,085,517	2,193,933
Total	26,523,412	18,472,887

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016 02, Leases (Topic 842) ("ASU 2016 02" or "ASC 842"). The new standard, while retaining two distinct types of leases, finance and operating, (i) requires lessees to record a right of use ("ROU") asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and recognize lease expense based on straight line rent, (ii) eliminates current real estate specific lease provisions, (iii) modifies the lease classification criteria and (iv) aligns many of the underlying lessor model principles with those in the new revenue standard. ASU 2016-02 is effective for the Company's annual periods beginning after December 15, 2021 and early adoption is permitted. The Company elected to early adopt ASU 2016 02 effective as of January 1, 2021 by applying the modified retrospective transition approach. The Company has elected to adopt the package of transition practical expedients, including combining lease and non-lease components into a single lease component and excluding leases with terms of 12 months or less from the recognition requirement. As of the date of adoption, the Company had no leases which required the Company to record a ROU asset and obligation as the company's only lease was a month to month lease, which qualified as a short-term lease. The adoption did not result in the recognition of any initial lease liabilities or right-of-use assets, and the Company was not required to adjust its comparative period financial information or make the new required lease disclosures for periods before the date of adoption. The Company applied the guidance to all new leases entered into during the year ended December 31, 2021, including its new facility lease.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes.* The standard simplifies the accounting for income taxes, eliminates certain exceptions within ASC 740, *Income Taxes*, and clarifies certain aspects of the current guidance to promote consistency among reporting entities. The new guidance will be effective for the Company as of January 1, 2022. Most amendments within the standard are required to be applied on a prospective basis, while certain amendments must be applied on a retrospective or modified retrospective basis. The Company adopted this guidance in 2021; there was no material impact on the financial statements as a result of the adoption.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial

instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. This update is effective for the Company beginning January 1, 2023. The Company is currently evaluating the impact that the adoption of this guidance will have on its financial statements and related disclosures

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity.* The guidance, among other items, provides guidance on how to account for contracts on an entity's own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity's own equity (i) permits settlement in unregistered shares, (ii) whether counterparty rights rank higher than shareholder's rights, and (iii) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity's own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective or modified retrospective basis. The amendments in this ASU are effective for the Company on January 1, 2024. The Company is currently evaluating the impact that the adoption of this guidance will have on its financial statements and related disclosures.

3. Balance Sheet Details

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2021	2020
Prepaid expenses	$ 666	$ 1,477
Accounts receivable	—	380
Other receivable	1	4
Total	$ 667	$ 1,861

Property and equipment consisted of the following (in thousands):

	December 31, 2021	2020
Equipment	$ 86	$ 31
Less: accumulated depreciation	(14)	(8)
Total	$ 72	$ 23

Accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31, 2021	2020
Accounts payable	$ 1,786	$ 1,219
Accrued clinical expense	477	284
Accrued development expenses	109	184
Accrued regulatory expense	—	372
Accrued compensation	660	—
Other	75	75
Total	$ 3,107	$ 2,134

4. Licensing, Supply and Distribution Agreements

The Company has entered into collaboration and licensing agreements to license certain rights to ARS-1 to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; clinical, regulatory, and/or commercial milestone payments; payment for clinical and commercial supply and royalties or a transfer price on the net sales of licensed products.

Licenses of Intellectual Property. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, revenue is recognized from non-refundable, up-front payments allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If the license is not a distinct performance obligation, the Company evaluates the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments. At the inception of each arrangement that includes clinical, regulatory or commercial milestone payments, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within the Company's control, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized when the underlying performance obligation has been transferred to the customer.

Research and Development Revenues. For arrangements that contain research and development commitments, any arrangement consideration allocated to the research and development work is recognized as the underlying services are performed over the research and development term.

Clinical and Commercial Supply. Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.The Company has not earned revenues for clinical or commercial supply sales as of December 31, 2021.

Royalty/Transfer Price Revenues. For arrangements that include sales-based royalties or transfer price, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). The Company has not received any royalty or transfer price revenues as of December 31, 2021.

Alfresa Agreement

In March 2020, the Company signed a Letter of Intent (LOI) with Alfresa Pharma Corporation for the right to negotiate a definitive agreement for the exclusive license and sublicensable right to develop,

register, import, manufacture and commercialize ARS-1 in Japan in exchange for a non-refundable upfront payment of $2.0 million. In April 2020, the Company entered into a Collaboration and License Agreement for the rights pursuant to the LOI. Under the agreement, the Company delivered a license to the ARS-1 technology and is responsible for completion of a certain clinical study and for the manufacturing of development and commercial drug supply. The parties agreed to share the cost of any additional clinical studies required for approval of ARS-1 in Japan. Alfresa is solely responsible for regulatory and commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use in Japan. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue until the later of (i) expiration of the last-to-expire patent in Japan; or (ii) 10 years after the commercial sale of ARS-1 in Japan.

In addition to the $2.0 million received under the LOI, the Company is eligible to receive up to $13.0 million of milestone payments upon achievement of certain clinical and regulatory milestones. Further, the Company is eligible to receive a negotiable transfer price expected to be in the low double-digit percentage on net sales subject to the regulatory approval to commercialize ARS-1 in Japan. In July 2020, the Company earned a $5.0 million milestone payment upon the completion of a clinical milestone in Japan.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for ARS-1 and research and development services. The Company determined the initial transaction price to be the $7.0 million, which includes a clinical milestone as it was deemed not probable of significant reversal at the inception of the agreement. Due to the uncertainty in the achievement of the regulatory and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation. The Company recognized revenue of $0.2 million and $6.7 million for the years ended December 31, 2021 and 2020, respectively and had deferred revenue of $0.1 million and $0.3 million as of December 31, 2021 and 2020, respectively.

Recordati Agreement

In September 2020, the Company entered into a License and Supply Agreement with Recordati Ireland, Ltd. for the exclusive license and sublicensable right to develop, import, manufacture or have manufacture commercial product, file and hold regulatory approvals and commercialize ARS-1 in Europe and certain EFTA, CIS, Middle East and African countries. Under the agreement, the Company is responsible for completion of any clinical studies for ARS-1 required by the European Medicines Agency before granting EU Marketing Authorization (EMA), and by the Medicines and Healthcare products Regulatory Agency (MHRA) prior to granting UK Marketing Authorization. The Company will file the initial regulatory submissions to the EMA and MHRA for ARS-1 and is responsible for the manufacturing of commercial supply. Recordati is solely responsible all regulatory activities in the region after the Company's initial regulatory submissions to the EMA and MHRA, for any post-approval clinical studies and commercialization activities. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue as long as Recordati has commercial sale of ARS-1 the region.

Under the terms of the agreement, the Company received an upfront payment of $11.8 million and a regulatory milestone payment of $6.0 million during 2020. In addition, the Company is eligible to receive up to 90.0 million euros of milestone payments upon achievement of certain regulatory and commercial sales milestones. Subject to regulatory approval, the Company will earn tiered royalties in the low double digits on annual net sales in the region and will receive a per unit supply price for the sale of commercial supply to Recordati. The per unit commercial supply costs are subject to a cap. The combined tiered royalty and supply price have a low double-digit cap.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for ARS-1 in the defined territory, the research and development services. The Company determined the initial transaction price to be the $11.8 million. Due to the uncertainty in the achievement of all the developmental and commercial milestones, at inception of the contract, the variable consideration associated with future milestone payments was fully constrained and excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation. In November 2020, the Company earned a regulatory milestone of $6.0 million. The Company recognized revenue of $2.3 million and $11.1 million for the years ended December 31, 2021 and 2020, respectively, and had deferred revenue of $4.4 million and $6.7 millon as of December 31, 2021 and 2020 respectively.

Pediatrix Agreement

In March 2021, the Company entered into a Collaboration and Distribution Agreement with Pediatrix Therapeutics, Inc. for the exclusive license and sublicensable right to develop, import, manufacture or have manufactured commercial product, file and hold regulatory approvals and commercialize ARS-1 in the People's Republic of China, Taiwan, Macau, and Hong Kong. Under the agreement, Pediatrix is responsible, at its sole cost and expense, for all ongoing development work that is necessary for or otherwise supports regulatory approval in the defined territory, including all clinical trials, and activities related to post approval commitments and commercialization tests. In addition, Pediatrix is responsible for commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use. The Company is responsible for the manufacturing of product for clinical studies as well as commercial supply, all at a negotiated transfer price. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue as long as Pediatrix has commercial sale of ARS-1 the region, or 10 years after first commercial sale.

Under the terms of the agreement, the Company received an upfront payment of $3.0 million. In addition, the Company is eligible to receive up to $84.0 million of milestone payments upon achievement of certain regulatory and commercial sales milestones. Subject to regulatory approval, the Company will earn tiered royalties in the low double digits on annual net sales in the region and will receive a per unit supply price for the sale of commercial supply to Pediatrix.

At the commencement of this collaboration, the Company identified performance obligations related to the delivery of the license for ARS-1 in the defined territory and manufacturing of product for clinical studies and commercial supply. The Company concluded that the license was distinct from potential supply obligation. The supply provisions are effectively options granted to Pediatrix to purchase future

goods and would only constitute a performance obligation if they contain a material right. The Company determined the option to purchase the clinical and commercial supply was not at a significantly discounted price and does not represent a material right, therefore does not constitute a performance obligation. The Company determined the initial transaction price to be the $3.0 million. Due to the uncertainty in the achievement of all the developmental and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period. The Company recognized revenue of the full $3.0 million for the year ended December 31, 2021.

A reconciliation of deferred revenue from collaboration agreements was as follows (in thousands):

Balance at December 31, 2020	$ 6,960
Amounts received	—
Revenue recognized	(2,507)
Balance at December 31, 2021	$ 4,453

5. Commitments and Contingencies

Note Payable

In September 2019, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Silicon Valley Bank for working capital in the principal amount of $5.0 million (the "2019 Note"). The 2019 Note required interest only payment through September 30, 2020 followed by 36 monthly payments of principal and interest. Interest is payable at the greater of 0.75% above prime or 6.0%. In addition, there is a final payment ("Balloon Payment") of $0.3 million at maturity. In April 2020, the 2019 Note was amended to extend the interest only period to March 31, 2021 and the maturity date to March 1, 2024.

In December 2020, the Loan Agreement was further amended and the Company borrowed an additional $5.0 million for working capital (the "2020 Note"). The 2020 Note requires interest only payment through March 31, 2021 with a maturity date of March 1, 2024. Interest is payable at the greater of 0.75% above prime or 6.0%. In addition, there is a Balloon Payment of $0.3 million at maturity. In April 2021, the interest only payment period for the 2019 Note and the 2020 Note was extended to June 30, 2021. The Company accounted for the amendment as a debt modification.

The loan is collateralized by substantially all of the Company's assets other than intellectual property. The Loan Agreement includes customary affirmative and restrictive covenants and also includes standard events of default, including payment defaults. Upon the occurrence of an event of default, the lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. The Company was in compliance with all related covenants as of December 31, 2021. The loan may be prepaid without penalty.

In connection with the 2019 Note, the lender received warrants to purchase 19,230 shares of Series C preferred stock at $2.60 per share. The warrants are immediately exercisable and will expire on September 30, 2029. The estimated fair value of the warrants at issuance was $42,000 which was recorded as a debt discount. In addition, the Company recorded debt issuance costs totaling $47,000.

The Company estimated the fair value of the Series C preferred stock warrant utilizing the Black-Scholes option pricing model based on a risk-free rate of 1.68%; expected dividend rate of 0%, expected life of 10 years; and expected volatility of 85.68% of the underlying preferred stock.

In connection with the 2020 Note, the lender received warrants to purchase an additional 19,230 shares of Series C preferred stock at $2.60 per share. The warrants are immediately exercisable and will expire on September 30, 2029. The estimated fair value of the warrants at issuance was $44,000 which was recorded as a debt discount. The Company estimated the fair value of the Series C preferred stock warrant utilizing the Black-Scholes option pricing model based on a risk-free rate of 0.92%; expected dividend rate of 0%, expected life of 8.8 years; and expected volatility of 102.3% of the underlying preferred stock. No warrants were exercised as of December 31, 2021.

The debt discount, debt issuance costs and Balloon Payment are amortized to interest expense using the effective interest rate method over the loan term. The Company recorded $0.8 million in 2021 and $0.4 million in 2020 of interest expense including amortization of debt discount of $0.2 million in 2021 and $0.1 million in 2020.

Note payable and unamortized discount balance consisted of the following (in thousands):

	December 31, 2021	2020
Face value	$ 8,181	$10,000
Balloon payment	500	500
Total payments	8,681	10,500
Less: unamortized debt discount	(272)	(482)
Note payable, net of debt discount	8,409	10,018
Less: current portion	(3,479)	(2,558)
Total long-term note payable, net current portion	$ 4,930	$ 7,460

Future minimum payments were as follows (in thousands):

Year ended December 31:	
2022	$3,636
2023	3,636
2024	1,409
Total payments	8,681
Less: final payment fee	500
Total future principal payments due	$8,181

Leases

In October 2021, the Company entered into a 38 month noncancelable lease for its current headquarters location consisting of 4,047 rentable square feet of office space in San Diego, California. Under the terms of the agreement, there is no option to extend the lease, and the Company is subject to additional charges for common area maintenance and other costs. Monthly rental payments due

under the lease commenced on December 6, 2021 and escalate through the lease term. The Company prepaid the first month's rent upon execution of the lease, and the lease agreement provided full rent abatement for the second and third months of the rental term. The Company recorded $19,000 in operating lease expense and did not make any cash payments for amounts included in the measurement of lease liabilities for the year ended December 31, 2021. As of December 31, 2021, the remaining lease term of the Company's operating lease was 38 months, and the discount rate on the Company's operating lease was 8%. As there was not an implicit rate within the lease, the discount rate was determined by using a set of peer companies incremental borrowing rates. The adoption of ASC 842 resulted in the recognition of initial lease liability and right-of-use asset of $0.6 million as of December 31, 2021.

Future minimum noncancelable operating lease payments are as follows (in thousands):

Year ended December 31:	
2022	$190
2023	238
2024	245
2025	42
Total lease payments	715
Imputed interest	91
Lease liability	624
Less current portion of lease liability	144
Lease liability, net of current portion	$480

PPP Loan

In May 2020, the Company received a loan in the amount of $0.2 million (the "PPP Loan") pursuant to the Paycheck Protection Program ("PPP") of the Coronavirus Aid, Relief and Economic Security ("CARES") Act. The loan proceeds were used to offset qualified payroll costs and the loan amount was fully forgiven in December 2020.

6. License and Supply Agreements

In June 2018, the Company entered into a License Agreement (the "License Agreement") with Aegis Therapeutics, LLC ("Aegis"). Under the License Agreement, the Company licensed the exclusive, worldwide, royalty-bearing, sublicensable, rights to certain proprietary Aegis technology, patent rights and know-how to develop and commercialize epinephrine products. The Company utilizes this technology for the development of its lead product candidate, ARS-1. As consideration for the license, the Company paid an upfront license fee of $50,000, which was recorded in research and development expenses in the consolidated statement of operations.

The Company is required to make aggregate milestone payments of up to $20.0 million upon achievement of certain regulatory and commercial milestones. The regulatory milestone payments under the Agreement will be recognized as research and development expense upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. The Company made a $0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019. The Company will be required to pay Aegis a milestone payment of $1.0 million upon FDA's acceptance of an US NDA filing. The Company may be required to pay royalties based on

annual net product sales in the low to mid-single digits on its or its sublicensees' net sales of the Licensed Products on a country-by-country and product-by-product basis.

The Company is responsible for reimbursing Aegis for patent costs incurred in connection with prosecuting and maintaining patent rights that are specific to epinephrine or epinephrine products. Expenses recognized in connection with legal patent fees for the years ended December 31, 2021 and 2020 were below $0.1 million for each period.

The Company may terminate the Agreement with 30 days written notice or either party may terminate the Agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the License Agreement will continue until the final expiration of all royalty obligations under the agreement.

In conjunction with the License Agreement, the Company also entered into a Supply Agreement (the "Supply Agreement") with Aegis that allows the Company to purchase materials for preclinical, development and commercial use at predetermined prices. The Company may elect to have Aegis supply minimum quantities but there are no minimum or maximum purchase obligations under the Supply Agreement unless this election is made. The parties may terminate the Supply Agreement at any time by mutual agreement. In addition, the parties may terminate the Supply Agreement in the event of certain breaches of the agreement or upon the earlier of the expiration or termination of the License Agreement or June 2028. The Supply Agreement term may be extended by mutual written agreement. Expense recognized under the Supply Agreement was $0.2 million for each of the years ended December 31, 2021 and 2020.

Contingencies

From time to time, the Company may become subject to claims or suits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that the future expenditures will be made and such expenditures can be reasonably estimated.

7. Convertible Preferred Stock and Common Stock and Stockholders' Deficit

***Convertible Preferred* Stock**

In April 2016, the Company issued 3,600,000 shares of Series A preferred stock at $0.0833 per share for net cash proceeds of $0.3 million. Subsequently, in July 2017, an additional 1,164,000 shares of Series A preferred stock were issued at $0.0833 per share for net cash proceeds of $0.1 million.

In March, June and July 2018, the Company issued a total of 606,060 shares of Series B preferred stock at $1.65 per share for net cash proceeds of $1.0 million.

In September and December 2018, the Company issued 7,692,309 shares of Series C preferred stock at $2.60 per share for net cash proceeds of $19.8 million.

In August 2021, the Company issued 9,337,066 shares of Series D preferred stock at $5.89 per share for net cash proceeds of $54.8 million.

Collectively, the Series A, B, C and D preferred stock issuances will be referred to as "Series Convertible Preferred Stock."

The Company's convertible preferred stock has been classified as temporary equity in the accompanying balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of the Company's control, including liquidation, sale or transfer of control of the Company. The Company has determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

The preferred stock has the following characteristics:

Dividends

The holders of the Series Convertible Preferred Stock are entitled to receive noncumulative dividends at the rate of 8% per annum of the applicable original stock purchase price when and if declared by the Board of Directors, and in preference and in priority to any dividends on common stock. In the event dividends are paid on any share of common stock, the Company shall pay an additional dividend on all outstanding shares of Series Convertible Preferred Stock in a per share amount equal (on an as-if-converted to common stock basis) to the amount paid or set aside for each share of common stock. There have been no dividends declared by the board as of December 31, 2021.

Liquidation

In the event of any liquidation or deemed liquidation, dissolution, or winding up of the Company (Liquidation Event), the holders of Series A, Series B, Series C, and Series D convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds to the holders of common stock, an amount equal to the applicable Series A, Series B, Series C, and Series D purchase price per share then held plus an amount equal to any dividends declared but unpaid on such shares. If the assets and funds available to be distributed to the stockholders shall be insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to the Series A, Series B, Series C, and Series D convertible preferred stock shall be distributed among the holders of preferred stock in proportion to the amount each preferred holder is entitled to receive beginning with the Series D, followed by the Series C, then the Series B, then the Series A, and the common holders in this order. Each holder of shares of Series Convertible Preferred Stock is deemed to have converted such shares into shares of common stock if, as a result of such conversion, the convertible preferred stockholder would receive an amount greater than their preference rights.

Conversion

As of December 31, 2021, the shares of Series Convertible Preferred Stock are convertible into one share of common stock at any time, at the option of the holder, subject to certain antidilutive adjustments, including stock splits, combinations, common stock dividends and distributions, reclassification, recapitalization, merger, and consolidation. All of the shares of Series Convertible Preferred Stock will be automatically converted into shares of common stock upon the closing of an underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, at a price of at least $8.83575 per share resulting in gross proceeds of at least $70.0 million to the Company.

Voting

The holder of each share of Series Convertible Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters with the exception of those for which a Series A, B, C and/or D Preferred majority is required as defined per the Articles of Incorporation.

Anti-Dilution

The conversion price of Series Convertible Preferred Stock will be subject to a broad-based weighted average anti-dilution adjustment in the event that the Company issues additional equity securities (other than shares reserved under any employee incentive plan and certain other customary exceptions) at a purchase price less than the applicable conversion price.

Founder Common Stock

During 2015 and 2016, the Company issued 25,425,000 shares of common stock at $0.0033 and $0.0083 per share to its founders. No vesting conditions existed at the time of grant.

Concurrently with the issuance of Series C Convertible Preferred Stock in September 2018, 50% of the outstanding founder common stock, or 12,712,500 shares of common stock, became restricted common stock subject to vesting in equal monthly installments over 36 months commencing in September 2018. The restricted common stock is subject to repurchase at $0.0083 per share upon termination of the stockholders' services. The Company recorded a liability for the value associated with the restricted shares. The liability is reduced as the shares vest with the vested shares transferred into common stock and additional paid-in capital. As of December 31. 2021, all shares had fully vested.

A summary of the Company's unvested common stock was as follows (in thousands except share data):

	Shares	Unvested Stock Liability
Balance at December 31, 2020	3,178,125	$ 27
Vested shares	(3,178,125)	(27)
Balance at December 31, 2021	—	$ —

Equity Incentive Plan

In September 2018, the Company adopted the 2018 Equity Incentive Plan (as amended, the "2018 Plan") which provides for the grant of stock options, restricted stock awards, restricted stock unit and stock appreciation rights to its employees, members of its board of directors and consultants. As of December 31, 2021, there were 5,613,278 shares authorized for issuance under the 2018 Plan, of which 1,257,345 shares remained available for future issuance as of December 31, 2021. Recipients of stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2018 Plan is ten years and generally vest 25% one year from the vesting commencement dates and monthly thereafter over 36 months. The 2018 Plan allows for early exercise of stock option grants if authorized by the Board of Directors at the time of grant. The shares of

common stock issued from the early exercise of stock options are restricted and vest over time. The Company has the option to repurchase exercised and unvested shares at the lower of original purchase price or the then fair market value upon any voluntary or involuntary termination of services.

A summary of the Company's stock option activity issued under the 2018 Plan was as follows:

	Options Outstanding	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	2,193,933	$ 0.95		
Granted	2,062,000	$ 1.54		
Exercised	(170,416)	$ 0.99		
Forfeited	—			
Outstanding at December 31, 2021	4,085,517	$ 1.25	8.67	$ 1,856
Exercisable at December 31, 2021	3,883,434	$ 1.26	8.30	$ 1,712
Vested and expected to vest at December 31, 2021	3,885,517	$ 1.26	8.73	$ 1,714

Options totaling 200,000 shares are performance-based and will vest contingent on the closing of certain financing or strategic transactions. The performance condition was not considered probable of occurring as of December 31, 2021. Accordingly, no stock compensation has been recognized for the performance-based grants.

The weighted average fair value of options granted during the years ended December 31, 2021 and 2020 was $1.15 and $0.77, respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2021 was $121. The weighted average fair value of options vested for the years ended December 31, 2021 and 2020 was $0.70 and $0.69, respectively.

The total unrecognized compensation cost related to outstanding employee unvested stock-based awards as of December 31, 2021 was $2.8 million, which is expected to be recognized over a weighted-average period of 3.15 years.

For purposes of calculating the stock-based compensation, the Company estimates the fair value of stock options using the Black-Scholes option-pricing model. This model incorporates various assumptions, including the expected volatility, expected term, and interest rates. Stock-based compensation expense recognized in the consolidated statement of operations and comprehensive loss is based on the awards ultimately expected to vest. Forfeitures are recognized as they occur.

The weighted average underlying assumptions used to value employee and non-employee stock options granted using the Black-Scholes option-pricing model was as follows:

	For the year ended December 31,	
	2021	2020
Risk-free interest rate	1.2%	0.5%
Dividend yield	0%	0%
Expected life of options (years)	6.0	6.1
Volatility	91.6%	98.4%

Fair Value of Common Stock —Historically, the fair value of the shares of common stock underlying the stock options has been the responsibility of and determined by the Company's Board of Directors. Because there was no public market for the Company's common stock, the Board of Directors determined fair value of common stock at the time of grant of the option by considering a number of objective and subjective factors including independent third-party valuations of the Company's common stock, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and general and industry specific economic outlook, amongst other factors.

Expected Term—The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term, which calculates the expected term as the average time-to-vesting and the contractual life of the options for stock options issued to employees and non-employees.

Expected Volatility—Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

Risk-Free Interest Rate—The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.

Expected Dividend—The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

For the years ended December 31, 2021 and 2020, the Company recognized stock-based compensation expense related to stock option grants of $0.5 million and $0.4 million, respectively. In addition, the Company recognized stock-based compensation expense of $2.4 million and $3.1 million in connection with the vesting of restricted founder common stock awards for the years ended December 31, 2021 and 2020.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following:

	December 31,	
	2021	2020
Convertible preferred stock	22,399,435	13,062,369
Convertible preferred stock warrants	38,460	38,460
Common stock options granted and outstanding	4,085,517	2,193,933
Common stock reserved for future awards or option grants	1,257,345	1,982,441
	27,780,757	17,277,203

8. Income Taxes

A reconciliation of the federal statutory income tax rate to the Company's effective tax rate is as follows (in thousands):

	December 31, 2021	2021
Tax computed at federal statutory rate	$(4,251)	$ (224)
State income taxes, net of federal benefit	(9)	(1)
Other permanent items	(1)	(33)
Equity compensation	562	723
Research and development credits	(1,120)	(441)
Other	39	(66)
Valuation allowance	4,780	41
Provision for income taxes	$ —	$ —

Significant components of the Company's net deferred tax assets were as follows (in thousands):

	December 31, 2021	2020
Deferred tax assets:		
Net operating losses	$ 5,457	$ 2,814
Research and development credits	2,340	1,295
Lease liability	132	—
Amortized assets	219	176
Deferred revenue	943	—
Other	188	78
Total deferred tax assets	9,279	4,363
Deferred tax liabilities:		
ROU asset	(131)	—
Depreciable assets	(10)	(5)
Total deferred liabilities	(141)	(5)
Gross deferred tax assets		—
Valuation allowance	(9,138)	(4,358)
Net deferred tax assets	$ —	$ —

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred assets. At such time as it is determined that it is more likely than not that the deferred tax asset will be realized, the valuation allowance will be reduced. The change in the valuation allowance for the year ended December 31, 2021 was an increase of $4.8 million.

At December 31, 2021, the Company had federal and state net operating loss carryforwards (NOL) of $25.6 million, and $6.9 million, respectively. Federal NOL carryforwards of $25.6 million generated after 2017 may be carried forward indefinitely, but can only be utilized to offset 80% of future taxable income. The state NOL carryforwards begin expiring in 2036. State NOLs totaling $1.4 million may be carried forward indefinitely. In addition, the Company also has federal and California research and

development credit carryforwards totaling $2.6 million and $0.5 million, respectively. The federal research and development credit carryforwards will begin to expire in 2035 unless previously utilized. The California research credits do not expire.

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of the company's NOL and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company files income tax returns in the United States, California, Florida, Pennsylvania and Ireland. Due to the Company's losses incurred, the Company's federal and state tax returns are subject to the tax examination by authorities from inception. In addition, the Irish tax returns for 2020-2021 are subject to examination. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. As of December 31, 2021, there were no significant accruals for interest related to unrecognized tax benefits or tax penalties. The Company has not incurred any material interest or penalties as of the current reporting date with respect to income tax matters. The Company does not expect that there will be unrecognized tax benefits of a significant nature that will increase or decrease within 12 months of the reporting date.

Effective January 1, 2020, the Company adopted ASU 2019-12. Under ASU 2019-12, the Company, having a full valuation and a loss in continuing operations, will no longer include the impacts of items in other comprehensive income in determining intra-period allocation of tax expense for continuing operations. There was no cumulative effect to be recognized in connection with the adoption allocation rules of ASU 2019-12 to the unrealized gains on available-for-sale investments recognized in other comprehensive income.

On March 27, 2020, the CARES Act was signed into law. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which may impact the Company's future financial statements include removal of certain limitations on utilization of NOLs, increasing the loss carryback period for certain losses to five years, as well as amending certain provisions of the previously enacted JOBS Act. The Company has not recognized the provisional tax impacts related to the CARES Act in relation to its financial statements for the year ended December, 31, 2021.

9. Related-Party Transactions

In September 2015, the Company entered into a consulting agreement for regulatory and development services with Pacific-Link Consulting, LLC, an entity owned by the President/CEO/Board member and the Chief Medical Officer of the Company. The Company incurred consulting expense related to this agreement totaling $1.1 million and $1.3 million during the years ended December 31, 2021 and 2020, respectively.

In September 2018, the Company entered into a consulting agreement with Marlinspike Group, LLC ("Marlinspike Group") to provide management, business consulting services and business development support. In addition, Marlinspike Group provides the use of its facilities to the Company from time to time. The Company's Chairman of the Board of the Directors and investor is a managing member of Marlinspike Group. The Company incurred annual expenses related to this agreement totaling $0.2 million during the years ended December 31, 2021 and 2020.

10. Subsequent Events

The Company evaluated subsequent events through August 11, 2022, the date the financial statements were available to be issued. During this period, the Company did not have any material subsequent events other than those disclosed below.

Merger Transaction

On July 21, 2022, the Company entered into an agreement and plan of merger and reorganization (the Merger Agreement) with Silverback Therapeutics, Inc. (Silverback) and Sabre Merger Sub, Inc. (Merger Sub). Merger Sub will be merged into ARS with the Company surviving the merger as a wholly owned subsidiary of Silverback. The transaction will be accounted for as a reverse recapitalization, with the Company being treated as the acquirer for accounting purposes. Pursuant to the Merger Agreement, Silverback will effect a name change to ARS Pharmaceuticals, Inc., and is expected to list its securities on the Nasdaq Global Market under the symbol "SPRY". Following the completion of the merger, the newly combined company will be led by Richard Lowenthal., who will serve as the President and CEO.

Under the terms of the Merger Agreement, the Company will merge with a wholly owned subsidiary of Silverback, and stockholders of ARS will receive shares of newly issued Silverback common stock. The Company's stockholders are expected to own approximately 63% and Silverback stockholders will own approximately 37% of the combined company on a fully diluted basis using the treasury stock method. The percentage of the combined company that Silverback stockholders will own as of the close of the merger may be subject to adjustment based on Silverback's net cash at closing of the transaction. The transaction, which is expected to close in the fourth quarter of 2022, is subject to certain customary closing conditions, including Silverback and ARS shareholder approvals.

No assurance can be given that the required approvals will be obtained or that the required conditions to closing will be satisfied and, even if all such approvals are obtained and the conditions are satisfied, no assurance can be given as to the terms, conditions and timing of the approvals. The Merger Agreement contains certain termination rights for each of the Company and Silverback.

ARS Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share amounts)

	June 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 44,590	$ 60,063
Prepaid expense and other current assets	798	667
Total current assets	45,388	60,730
Right-of-use asset	536	621
Fixed assets, net	102	72
Other assets	23	23
Total assets	$ 46,049	$ 61,446
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $200 in 2022 and $159 in 2021)	$ 3,385	$ 3,107
Lease liability, current portion	227	144
Deferred revenue, current	344	1,457
Note payable, current	3,505	3,479
Total current liabilities	7,461	8,187
Lease liability, net of current portion	349	480
Deferred revenue	2,982	2,996
Note payable	3,170	4,930
Preferred stock warrant liability	80	83
Total liabilities	14,042	16,676
Commitments and contingencies		
Convertible preferred stock and stockholders' deficit:		
Series A convertible preferred stock, $0.01 par value, 4,764,000 shares authorized, issued and outstanding at June 30, 2022 and December 31, 2021. Liquidation preference of $397	365	365
Series B convertible preferred stock, $0.01 par value, 606,060 shares authorized, issued and outstanding at June 30, 2022 and December 31, 2021. Liquidation preference of $1,000	1,000	1,000
Series C convertible preferred stock, $0.01 par value, 7,749,999 shares authorized at June 30, 2022 and December 31, 2021, and 7,692,309 shares issued and outstanding at June 30, 2022 and December 31, 2021. Liquidation preference of $20,000	19,868	19,868
Series D convertible preferred stock, $0.01 par value, 9,337,066 shares authorized, issued and outstanding at June 30, 2022 and December 31, 2021. Liquidation preference of $55,000	54,806	54,806
Stockholders' deficit		
Common stock, $0.01 par value, 56,000,000 shares authorized at June 30, 2022 and December 31, 2021, 26,021,763 and 25,695,416 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	260	257
Additional paid-in capital	11,634	10,730
Accumulated deficit	(55,926)	(42,256)
Total stockholders' deficit	(44,032)	(31,269)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 46,049	$ 61,446

See accompanying notes.

ARS Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share information)
(unaudited)

	Six Months Ended June 30,	
	2022	2021
Revenue:		
Revenue under collaboration agreements	$ 1,127	$ 4,224
Total revenue		
Operating expenses:		
Research and development (including related party amounts of $1,112 in 2022 and $505 in 2021)	9,773	11,237
General and administrative (including related party amounts of $271 in 2022 and $127 in 2021)	4,797	1,864
Total operating expenses	14,570	13,101
Loss from operations	(13,443)	(8,877)
Other (expense) income, net	(227)	(416)
Net loss and comprehensive loss	$ (13,670)	$ (9,293)
Net loss per common share, basic and diluted	$ (0.53)	$ (0.40)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	25,796,385	23,433,564

See accompanying notes.

ARS Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)
(unaudited)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	4,764,000	$ 365	606,060	$ 1,000	7,692,309	$19,868	9,337,066	$54,806	25,695,416	$ 257	$ 10,730	$ (42,256)	$ (31,269)
Exercise of stock options	—	—	—	—	—	—	—	—	326,347	3	284	—	287
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	620	—	620
Net loss and comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	(13,670)	(13,670)
Balance at June 30, 2022	4,764,000	$ 365	606,060	$ 1,000	7,692,309	$19,868	9,337,066	$54,806	26,021,763	$ 260	$ 11,634	$ (55,926)	$ (44,032)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	4,764,000	$ 365	606,060	$ 1,000	7,692,309	$19,868	—	$ —	22,346,875	$ 223	$ 7,738	$ (22,013)	$ (14,052)
Vesting of restricted common stock	—	—	—	—	—	—	—	—	2,118,750	21	(3)	—	18
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	1,755	—	1,755
Net loss and comprehensive net loss	—	—	—	—	—	—	—	—	—	—	—	(9,293)	(9,293)
Balance at June 30, 2021	4,764,000	$ 365	606,060	$ 1,000	7,692,309	$19,868	—	$ —	24,465,625	$ 244	$ 9,490	$ (31,306)	$ (21,572)

See accompanying notes.

ARS Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Six Months Ended June 30, 2022	2021
Operating activities:		
Net loss	$ (13,670)	$ (9,293)
Non-cash adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	620	1,755
Non-cash interest expense	85	110
Change in fair value of warrant liability	(3)	(3)
Depreciation	13	3
Changes in operating assets and liabilities:		
Prepaid and other current assets	(132)	1,422
Other assets	—	—
Accounts payable and accrued liabilities (including related party amounts of $200 in 2022 and $159 in 2021)	279	(493)
Operating right-of-use assets and lease liabilities, net	36	—
Deferred revenue	(1,127)	(1,224)
Net cash used in operating activities	(13,899)	(7,723)
Investing activities:		
Purchase of property and equipment	(43)	—
Net cash used in investing activities	(43)	—
Financing activities:		
Repayment of bank note payable	(1,818)	—
Proceeds from exercise of common stock options	287	—
Net cash used in financing activities	(1,531)	—
Net increase (decrease) in cash and cash equivalents	(15,473)	(7,723)
Cash and cash equivalents at beginning of period	60,063	24,521
Cash and cash equivalents at end of period	$ 44,590	$ 16,799
Supplemental disclosures:		
Interest paid	$ 215	$ 274

See accompanying notes.

ARS Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

1. Organization and Basis of Presentation

ARS Pharmaceuticals, Inc. (the "Company"), is a privately-held company incorporated in Delaware in August 2015. In January 2020, the Company formed a wholly-owned subsidiary in Ireland, ARS Pharmaceuticals IRL, Limited, to facilitate the filing of regulatory approval for ARS-1 in European countries. The Company is focused on the development and commercialization of ARS-1 (brand name Neffy®), a proprietary product candidate for the needle-free intranasal delivery of epinephrine for the emergency treatment of type I allergic reactions including anaphylaxis.

Liquidity and Capital Resources

From August 5, 2015 (inception) through June 30, 2022, the Company has devoted substantially all of its efforts to acquiring its asset, developing intellectual property and conducting product development and clinical trials, raising capital, and building infrastructure. Since inception, the Company has funded its operations primarily with net proceeds from the issuance of convertible preferred stock, payments earned under collaboration agreements and bank debt. The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. The Company has experienced net losses and negative cash flows from operating activities and had an accumulated deficit of $55.9 million as of June 30, 2022.

The Company expects to continue to incur net losses into the foreseeable future and will need to obtain additional financing in order to initiate and complete clinical trials, complete process development and commercialize any product candidates for which it receives regulatory approval. The Company plans to continue to fund its losses from operations and capital funding needs through future public or private equity or debt financing or through collaborations or partnerships with other companies. The novel coronavirus-2019 ("COVID-19") pandemic and ongoing geopolitical events continue to rapidly evolve and have already resulted in a significant disruption of global financial markets. The Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and further disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the pandemic or geopolitical actions. If such further disruption occurs, the Company could experience an inability to access additional capital. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

Merger Transaction

On July 21, 2022, the Company entered into an agreement and plan of merger and reorganization (the Merger Agreement) with Silverback Therapeutics, Inc. (Silverback) and Sabre Merger Sub, Inc. (Merger Sub). Merger Sub will be merged into ARS with the Company surviving the merger as a wholly owned subsidiary of Silverback. The transaction will be accounted for as a reverse recapitalization, with the Company being treated as the acquirer for accounting purposes. Pursuant to the Merger Agreement, Silverback will effect a name change to ARS Pharmaceuticals, Inc., and is expected to list its securities on the Nasdaq Global Market under the symbol "SPRY". Following the completion of the merger, the newly combined company will be led by Richard Lowenthal., who will serve as the President and CEO.

Under the terms of the Merger Agreement, the Company will merge with a wholly owned subsidiary of Silverback, and stockholders of ARS will receive shares of newly issued Silverback common stock. The Company's stockholders are expected to own approximately 63% and Silverback stockholders will own approximately 37% of the combined company on a fully diluted basis using the treasury stock method. The percentage of the combined company that Silverback stockholders will own as of the close of the merger may be subject to adjustment based on Silverback's net cash at closing of the transaction. The transaction, which is expected to close in the fourth quarter of 2022, is subject to certain customary closing conditions, including Silverback and ARS shareholder approvals.

No assurance can be given that the required approvals will be obtained or that the required conditions to closing will be satisfied and, even if all such approvals are obtained and the conditions are satisfied, no assurance can be given as to the terms, conditions and timing of the approvals. The Merger Agreement contains certain termination rights for each of the Company and Silverback.

2. Summary of Significant Accounting Policies

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying unaudited condensed consolidated balance sheet as of June 30, 2022, the condensed consolidated statements of operations and comprehensive loss and condensed consolidated statements of convertible preferred stock and stockholders' deficit for the six months ended June 30, 2022 and 2021, and the condensed consolidated statements of cash flows for the six months ended June 30, 2022 and 2021, are unaudited. The balance sheet as of December 31, 2021 was derived from the audited financial statements as of and for the year ended December 31, 2021. The unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2021, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2022. The financial data and other information disclosed in these notes related to the six months ended June 30, 2022 and 2021 are also unaudited. The condensed consolidated results of operations for the six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the full year ending December 31, 2022 or any other period.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles (GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal accruals) considered necessary for a fair presentation have been included. These condensed consolidated financial statements should be read in conjunction with the financial statements for the year ended December 31, 2021 and related notes thereto included in this proxy statement filed with the United States Securities and Exchange Commission (SEC).

Significant Accounting Policies

There have been no material changes in the Company's accounting policies from those disclosed in the audited financial statements and related notes thereto as of and for the year ended December 31, 2021, which are included elsewhere in this proxy statement.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and limits its exposure to cash risk by placing its cash with high credit quality financial institutions.

Revenue Recognition

Our revenues generally consist of licenses and research services under license and collaboration agreements.

We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

Fair Value Measurements

The Company categorizes its assets and liabilities measured at fair value in accordance with the authoritative accounting guidance that establishes a consistent framework for measuring fair value, and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1—Quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2—Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and
- Level 3—Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The carrying values of the Company's current financial assets and current financial liabilities approximate their fair values due to the short-term nature of these instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, management believe the fair value of the note payable approximates its carrying value.

Assets measured at fair value on a recurring basis were as follows (in thousands):

	Fair Value Measurements Using			
	Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
June 30, 2022				
Cash equivalents				
Money market funds	$43,598	$ 43,598	$ —	$ —
December 31, 2021				
Cash equivalents				
Money market funds	$59,401	$ 59,401	$ —	$ —

Financial liabilities measured at fair value on a recurring basis include the preferred stock warrant liability described below. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

Liabilities measured at fair value on a recurring basis were as follows (in thousands):

	Fair Value Measurements Using			
	Balance as of December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
June 30, 2022				
Preferred stock warrant liability	$ 80	$ —	$ —	$ 80
December 31, 2021				
Preferred stock warrant liability	$ 83	$ —	$ —	$ 83

The estimated fair value of the preferred stock warrant liability at issuance was determined using the Black-Scholes valuation model that considered the fair value of the underlying Series C convertible preferred stock, the exercise price of the warrant, the assumed volatility of the Company utilizing a group of peers, an expected term equal to the contractual life of the instrument and a risk-free rate consistent with the term.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs:

	Preferred Stock Warrant Liability
Balance at December 31, 2021	$ 83
Change in fair value of preferred stock warrant liability	(3)
Balance at June 30, 2022	$ 80

Net Loss Per Common Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company. For purposes of this calculation, convertible preferred stock, stock options, and preferred stock warrants are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive.

	June 30, 2022	June 30, 2021
Convertible preferred stock	22,399,435	13,062,369
Warrants to purchase convertible preferred stock	38,460	38,460
Restricted common stock	—	1,059,375
Common stock options granted and outstanding	4,817,667	2,823,933
Total	27,255,562	16,984,137

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016 02, Leases (Topic 842) (“ASU 2016 02” or “ASC 842”). The new standard, while retaining two distinct types of leases, finance and operating, (i) requires lessees to record a right of use (“ROU”) asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and recognize lease expense based on straight line rent, (ii) eliminates current real estate specific lease provisions, (iii) modifies the lease classification criteria and (iv) aligns many of the underlying lessor model principles with those in the new revenue standard. ASU 2016-02 is effective for the Company’s annual periods beginning after December 15, 2021 and early adoption is permitted. The Company elected to early adopt ASU 2016 02 effective as of January 1, 2021 by applying the modified retrospective transition approach. The Company has elected to adopt the package of transition practical expedients, including combining lease and non-lease components into a single lease component and excluding leases with terms of 12 months or less from the recognition requirement. As of the date of adoption, the Company had no leases which required the Company to record a ROU asset and obligation as the company’s only lease was a month to

month lease, which qualified as a short-term lease. The adoption did not result in the recognition of any initial lease liabilities or right-of-use assets, and the Company was not required to adjust its comparative period financial information or make the new required lease disclosures for periods before the date of adoption. The Company applied the guidance to all new leases entered into during the year ended December 31, 2021, including its new facility lease.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The standard simplifies the accounting for income taxes, eliminates certain exceptions within ASC 740, *Income Taxes*, and clarifies certain aspects of the current guidance to promote consistency among reporting entities. The new guidance will be effective for the Company as of January 1, 2022. Most amendments within the standard are required to be applied on a prospective basis, while certain amendments must be applied on a retrospective or modified retrospective basis. The Company adopted this guidance in 2021; there was no material impact on the financial statements as a result of the adoption.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. This update is effective for the Company beginning January 1, 2023. The Company is currently evaluating the impact that the adoption of this guidance will have on its financial statements and related disclosures

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity's Own Equity*. The guidance, among other items, provides guidance on how to account for contracts on an entity's own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity's own equity (i) permits settlement in unregistered shares, (ii) whether counterparty rights rank higher than shareholder's rights, and (iii) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity's own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective or modified retrospective basis. The amendments in this ASU are effective for the Company on January 1, 2024. The Company is currently evaluating the impact that the adoption of this guidance will have on its financial statements and related disclosures.

3. Balance Sheet Details

Prepaid expenses and other current assets consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Prepaid expenses	$ 763	$ 666
Other receivable	35	1
Total	$ 798	$ 667

Property and equipment consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Equipment	$ 129	$ 86
Less: accumulated depreciation	(27)	(14)
Total	$ 102	$ 72

Accounts payable and accrued liabilities consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accounts payable	$ 1,937	$ 1,786
Accrued clinical expense	392	477
Accrued development expenses	235	109
Accrued compensation	472	660
Other	349	75
Total	$ 3,385	$ 3,107

4. Licensing, Supply and Distribution Agreements

The Company has entered into collaboration and licensing agreements to license certain rights to ARS-1 to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; clinical, regulatory, and/or commercial milestone payments; payment for clinical and commercial supply and royalties or a transfer price on the net sales of licensed products.

Licenses of Intellectual Property. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, revenue is recognized from non-refundable, up-front payments allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If the license is not a distinct performance obligation, the Company evaluates the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition

Milestone Payments. At the inception of each arrangement that includes clinical, regulatory or commercial milestone payments, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within the Company's control, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized when the underlying performance obligation has been transferred to the customer.

Research and Development Revenues. For arrangements that contain research and development commitments, any arrangement consideration allocated to the research and development work is recognized as the underlying services are performed over the research and development term.

Clinical and Commercial Supply. Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company has not earned revenues for clinical or commercial supply sales as of June 30, 2022.

Royalty/Transfer Price Revenues. For arrangements that include sales-based royalties or transfer price, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). The Company has not received any royalty or transfer price revenues as of June 30, 2022.

Alfresa Agreement

In March 2020, the Company signed a Letter of Intent (LOI) with Alfresa Pharma Corporation for the right to negotiate a definitive agreement for the exclusive license and sublicensable right to develop, register, import, manufacture and commercialize ARS-1 in Japan in exchange for a non-refundable upfront payment of $2.0 million. In April 2020, the Company entered into a Collaboration and License Agreement for the rights pursuant to the LOI. Under the agreement, the Company delivered a license to the ARS-1 technology and is responsible for completion of a certain clinical study and for the manufacturing of development and commercial drug supply. The parties agreed to share the cost of any additional clinical studies required for approval of ARS-1 in Japan. Alfresa is solely responsible for regulatory and commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use in Japan. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue until the later of (i) expiration of the last-to-expire patent in Japan; or (ii) 10 years after the commercial sale of ARS-1 in Japan.

In addition to the $2.0 million received under the LOI, the Company is eligible to receive up to $13.0 million of milestone payments upon achievement of certain clinical and regulatory milestones. Further, the Company is eligible to receive a negotiable transfer price expected to be in the low double-digit percentage on net sales subject to the regulatory approval to commercialize ARS-1 in Japan. In July 2020, the Company earned a $5.0 million milestone payment upon the completion of a clinical milestone in Japan.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for ARS-1 and research and development services. The Company determined the initial transaction price to be the $7.0 million, which includes a clinical milestone as it was deemed not probable of significant reversal at the inception of the agreement. Due to the uncertainty in the achievement of the regulatory and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period. The transaction price was allocated to

the performance obligations based on the estimated stand-alone selling price of each performance obligation. The Company recognized revenue of less than $0.1 million for each of the six months ended June 30, 2022 and 2021, and had deferred revenue of $0.1 million and $0.2 million as of June 30, 2022 and December 31, 2021, respectively.

Recordati Agreement

In September 2020, the Company entered into a License and Supply Agreement with Recordati Ireland, Ltd. for the exclusive license and sublicensable right to develop, import, manufacture or have manufacture commercial product, file and hold regulatory approvals and commercialize ARS-1 in Europe and certain EFTA, CIS, Middle East and African countries. Under the agreement, the Company is responsible for completion of any clinical studies for ARS-1 required by the European Medicines Agency before granting EU Marketing Authorization (EMA), and by the Medicines and Healthcare products Regulatory Agency (MHRA) prior to granting UK Marketing Authorization. The Company will file the initial regulatory submissions to the EMA and MHRA for ARS-1 and is responsible for the manufacturing of commercial supply. Recordati is solely responsible all regulatory activities in the region after the Company's initial regulatory submissions to the EMA and MHRA, for any post-approval clinical studies and commercialization activities. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue as long as Recordati has commercial sale of ARS-1 the region.

Under the terms of the agreement, the Company received an upfront payment of $11.8 million and a regulatory milestone payment of $6.0 million during 2020. In addition, the Company is eligible to receive up to 90.0 million euros of milestone payments upon achievement of certain regulatory and commercial sales milestones. Subject to regulatory approval, the Company will earn tiered royalties in the low double digits on annual net sales in the region and will receive a per unit supply price for the sale of commercial supply to Recordati. The per unit commercial supply costs are subject to a cap. The combined tiered royalty and supply price have a low double-digit cap.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for ARS-1 in the defined territory, the research and development services. The Company determined the initial transaction price to be the $11.8 million. Due to the uncertainty in the achievement of all the developmental and commercial milestones, at inception of the contract, the variable consideration associated with future milestone payments was fully constrained and excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation. In November 2020, the Company earned a regulatory milestone of $6.0 million. The Company recognized revenue of $1.1 million and $1.2 million for the six months ended June 30, 2022 and 2021, respectively, and had deferred revenue of $3.3 million and $4.4 million as of June 30, 2022 and December 31, 2021, respectively.

Pediatrix Agreement

In March 2021, the Company entered into a Collaboration and Distribution Agreement with Pediatrix Therapeutics, Inc. for the exclusive license and sublicensable right to develop, import, manufacture or have manufactured commercial product, file and hold regulatory approvals and commercialize ARS-1 in the People's Republic of China, Taiwan, Macau, and Hong Kong. Under the agreement, Pediatrix is

responsible, at its sole cost and expense, for all ongoing development work that is necessary for or otherwise supports regulatory approval in the defined territory, including all clinical trials, and activities related to post approval commitments and commercialization tests. In addition, Pediatrix is responsible for commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use. The Company is responsible for the manufacturing of product for clinical studies as well as commercial supply, all at a negotiated transfer price. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue as long as Pediatrix has commercial sale of ARS-1 the region, or 10 years after first commercial sale.

Under the terms of the agreement, the Company received an upfront payment of $3.0 million. In addition, the Company is eligible to receive up to $84.0 million of milestone payments upon achievement of certain regulatory and commercial sales milestones. Subject to regulatory approval, the Company will earn tiered royalties in the low double digits on annual net sales in the region and will receive a per unit supply price for the sale of commercial supply to Pediatrix.

At the commencement of this collaboration, the Company identified performance obligations related to the delivery of the license for ARS-1 in the defined territory territory and manufacturing of product for clinical studies and commercial supply. The Company concluded that the license was distinct from potential supply obligation. The supply provisions are effectively options granted to Pediatrix to purchase future goods and would only constitute a performance obligation if they contain a material right. The Company determined the option to purchase the clinical and commercial supply was not at a significantly discounted price and does not represent a material right, therefore does not constitute a performance obligation. The Company determined the initial transaction price to be the $3.0 million. Due to the uncertainty in the achievement of all the developmental and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period. The Company recognized revenue of the full $3.0 million during the six months ended June 30, 2021.

A reconciliation of deferred revenue from collaboration agreements was as follows (in thousands):

Balance at December 31, 2021	$ 4,453
Amounts received	—
Revenue recognized	(1,127)
Balance at June 30, 2022	$ 3,326

5. Commitments and Contingencies

Note Payable

In September 2019, the Company entered into a Loan and Security Agreement (“Loan Agreement”) with Silicon Valley Bank for working capital in the principal amount of $5.0 million (the “2019 Note”). The 2019 Note required interest only payment through September 30, 2020 followed by 36 monthly payments of principal and interest. Interest is payable at the greater of 0.75% above prime or 6.0%. In addition, there is a final payment (“Balloon Payment”) of $0.3 million at maturity. In April 2020, the 2019 Note was amended to extend the interest only period to March 31, 2021 and the maturity date to March 1, 2024.

ARS Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

In December 2020, the Loan Agreement was further amended and the Company borrowed an additional $5.0 million for working capital (the “2020 Note”). The 2020 Note requires interest only payment through March 31, 2021 with a maturity date of March 1, 2024. Interest is payable at the greater of 0.75% above prime or 6.0%. In addition, there is a Balloon Payment of $0.3 million at maturity. In April 2021, the interest only payment period for the 2019 Note and the 2020 Note was extended to June 30, 2021. The Company accounted for the amendment as a debt modification.

The loan is collateralized by substantially all of the Company’s assets other than intellectual property. The Loan Agreement includes customary affirmative and restrictive covenants and also includes standard events of default, including payment defaults. Upon the occurrence of an event of default, the lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. The Company was in compliance with all related covenants as of June 30, 2022. The loan may be prepaid without penalty.

In connection with the 2019 Note, the lender received warrants to purchase 19,230 shares of Series C preferred stock at $2.60 per share. The warrants are immediately exercisable and will expire on September 30, 2029. The estimated fair value of the warrants at issuance was $42,000 which was recorded as a debt discount. In addition, the Company recorded debt issuance costs totaling $47,000. The Company estimated the fair value of the Series C preferred stock warrant utilizing the Black-Scholes option pricing model based on a risk-free rate of 1.68%; expected dividend rate of 0%, expected life of 10 years; and expected volatility of 85.68% of the underlying preferred stock.

In connection with the 2020 Note, the lender received warrants to purchase an additional 19,230 shares of Series C preferred stock at $2.60 per share. The warrants are immediately exercisable and will expire on September 30, 2029. The estimated fair value of the warrants at issuance was $44,000 which was recorded as a debt discount. The Company estimated the fair value of the Series C preferred stock warrant utilizing the Black-Scholes option pricing model based on a risk-free rate of 0.92%; expected dividend rate of 0%, expected life of 8.8 years; and expected volatility of 102.3% of the underlying preferred stock. No warrants were exercised as of June 30, 2022.

The debt discount, debt issuance costs and Balloon Payment are amortized to interest expense using the effective interest rate method over the loan term. The Company recorded $0.3 million and $0.4 million of interest expense for the six months ended June 30, 2022 and 2021, respectively, including amortization of debt discount of $0.1 million and $0.1 million for the six months ended June 30, 2022 and 2021, respectively.

Note payable and unamortized discount balance consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Face value	$ 6,363	$ 8,181
Balloon payment	500	500
Total payments	6,863	8,681
Less: unamortized debt discount	(188)	(272)
Note payable, net of debt discount	6,675	8,409
Less: current portion	(3,505)	(3,479)
Total long-term note payable, net current portion	$ 3,170	$ 4,930

Future minimum payments were as follows (in thousands):

Year ended December 31:	
2022 (remaining 6 months)	$1,818
2023	3,636
2024	1,409
Total payments	6,863
Less: final payment fee	500
Total future principal payments due	$6,363

Leases

In October 2021, the Company entered into a 38 month noncancelable lease for its current headquarters location consisting of 4,047 rentable square feet of office space in San Diego, California. Under the terms of the agreement, there is no option to extend the lease, and the Company is subject to additional charges for common area maintenance and other costs. Monthly rental payments due under the lease commenced on December 6, 2021 and escalate through the lease term. The Company prepaid the first month's rent upon execution of the lease, and the lease agreement provided full rent abatement for the second and third months of the rental term. As of June 30, 2022, the remaining lease term of the Company's operating lease was 32 months, and the discount rate on the Company's operating lease was 8%. As there was not an implicit rate within the lease, the discount rate was determined by using a set of peer companies incremental borrowing rates.

Future minimum noncancelable operating lease payments are as follows (in thousands):

Year ended December 31:	
2022 (remaining 6 months)	$ 116
2023	238
2024	245
2025	42
Total lease payments	641
Imputed interest	65
Lease liability	576
Less current portion of lease liability	227
Lease liability, net of current portion	$349

6. License and Supply Agreements

In June 2018, the Company entered into a License Agreement (the "License Agreement") with Aegis Therapeutics, LLC ("Aegis"). Under the License Agreement, the Company licensed the exclusive, worldwide, royalty-bearing, sublicensable, rights to certain proprietary Aegis technology, patent rights and know-how to develop and commercialize epinephrine products. The Company utilizes this technology for the development of its lead product candidate, ARS-1. As consideration for the license, the Company paid an upfront license fee of $50,000, which was recorded in research and development expenses in the condensed consolidated statement of operations.

The Company is required to make aggregate milestone payments of up to $20.0 million upon achievement of certain regulatory and commercial milestones. The regulatory milestone payments under the Agreement will be recognized as research and development expense upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. The Company made a $0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019. The Company will be required to pay Aegis a milestone payment of $1.0 million upon FDA's acceptance of an US NDA filing. The Company may be required to pay royalties based on annual net product sales in the low to mid-single digits on its or its sublicensees' net sales of the Licensed Products on a country-by-country and product-by-product basis.

The Company is responsible for reimbursing Aegis for patent costs incurred in connection with prosecuting and maintaining patent rights that are specific to epinephrine or epinephrine products. There were no expenses recognized in connection with legal patent fees for the six months ended June 30, 2022 and 2021.

The Company may terminate the Agreement with 30 days written notice or either party may terminate the Agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the License Agreement will continue until the final expiration of all royalty obligations under the agreement.

In conjunction with the License Agreement, the Company also entered into a Supply Agreement (the "Supply Agreement") with Aegis that allows the Company to purchase materials for preclinical, development and commercial use at predetermined prices. The Company may elect to have Aegis supply minimum quantities but there are no minimum or maximum purchase obligations under the Supply Agreement unless this election is made. The parties may terminate the Supply Agreement at any time by mutual agreement. In addition, the parties may terminate the Supply Agreement in the event of certain breaches of the agreement or upon the earlier of the expiration or termination of the License Agreement or June 2028. The Supply Agreement term may be extended by mutual written agreement. Expense recognized under the Supply Agreement was zero and $0.1 million for the six months ended June 30, 2022 and 2021, respectively.

Contingencies

From time to time, the Company may become subject to claims or suits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that the future expenditures will be made and such expenditures can be reasonably estimated.

7. *Convertible Preferred Stock and Common Stock and Stockholders' Deficit*

***Convertible Preferred* Stock**

In April 2016, the Company issued 3,600,000 shares of Series A preferred stock at $0.0833 per share for net cash proceeds of $0.3 million. Subsequently, in July 2017, an additional 1,164,000 shares of Series A preferred stock were issued at $0.0833 per share for net cash proceeds of $0.1 million.

In March, June and July 2018, the Company issued a total of 606,060 shares of Series B preferred stock at $1.65 per share for net cash proceeds of $1.0 million.

In September and December 2018, the Company issued 7,692,309 shares of Series C preferred stock at $2.60 per share for net cash proceeds of $19.8 million.

In August 2021, the Company issued 9,337,066 shares of Series D preferred stock at $5.89 per share for net cash proceeds of $54.8 million.

Collectively, the Series A, B, C and D preferred stock issuances will be referred to as “Series Convertible Preferred Stock.”

The Company’s Series Convertible Preferred Stock has been classified as temporary equity in the accompanying balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of the Company’s control, including liquidation, sale or transfer of control of the Company. The Company has determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

The preferred stock has the following characteristics:

Dividends

The holders of the Series Convertible Preferred Stock are entitled to receive noncumulative dividends at the rate of 8% per annum of the applicable original stock purchase price when and if declared by the Board of Directors, and in preference and in priority to any dividends on common stock. In the event dividends are paid on any share of common stock, the Company shall pay an additional dividend on all outstanding shares of Series Convertible Preferred Stock in a per share amount equal (on an as-if-converted to common stock basis) to the amount paid or set aside for each share of common stock. There have been no dividends declared by the board as of June 30, 2022.

Liquidation

In the event of any liquidation or deemed liquidation, dissolution, or winding up of the Company (Liquidation Event), the holders of Series A, Series B, Series C, and Series D convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds to the holders of common stock, an amount equal to the applicable Series A, Series B, Series C, and Series D purchase price per share then held plus an amount equal to any dividends declared but unpaid on such shares. If the assets and funds available to be distributed to the stockholders shall be insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to the Series A, Series B, Series C, and Series D convertible preferred stock shall be distributed among the holders of preferred stock in proportion to the amount each preferred holder is entitled to receive beginning with the Series D, followed by the Series C, then the Series B, then the Series A, and the common holders in this order. Each holder of shares of Series Convertible Preferred Stock is deemed to have converted such shares into shares of common stock if, as a result of such conversion, the convertible preferred stockholder would receive an amount greater than their preference rights.

Conversion

In connection with the merger, all of the shares of Series Convertible Preferred Stock will be automatically converted into shares of common stock upon: (i) the closing of an underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, at a price of at least $8.83575 per share resulting in gross proceeds of at least $70.0 million to the Company or (ii) the election by the requisite holders of the shares of Series Convertible Preferred Stock. In connection with the Merger, on July 21, 2022 the requisite holders of the shares of Series Convertible Preferred Stock have elected to convert all shares of Series Convertible Preferred Stock into common stock in connection with the Merger.

Voting

The holder of each share of Series Convertible Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters with the exception of those for which a Series A, B, C and/or D Preferred majority is required as defined per the Articles of Incorporation.

Anti-Dilution

The conversion price of Series Convertible Preferred Stock will be subject to a broad-based weighted average anti-dilution adjustment in the event that the Company issues additional equity securities (other than shares reserved under any employee incentive plan and certain other customary exceptions) at a purchase price less than the applicable conversion price.

Founder Common Stock

During 2015 and 2016, the Company issued 25,425,000 shares of common stock at $0.0033 and $0.0083 per share to its founders. No vesting conditions existed at the time of grant.

Concurrently with the issuance of Series C Convertible Preferred Stock in September 2018, 50% of the outstanding founder common stock, or 12,712,500 shares of common stock, became restricted common stock subject to vesting in equal monthly installments over 36 months commencing in September 2018. The restricted common stock is subject to repurchase at $0.0083 per share upon termination of the stockholders' services. The Company recorded a liability for the value associated with the restricted shares. The liability is reduced as the shares vest with the vested shares transferred into common stock and additional paid-in capital. As of December 31. 2021, all shares had fully vested.

Equity Incentive Plan

In September 2018, the Company adopted the 2018 Equity Incentive Plan (as amended, the "2018 Plan") which provides for the grant of stock options, restricted stock awards, restricted stock unit and stock appreciation rights to its employees, members of its board of directors and consultants. As of June 30, 2022, there were 5,613,278 shares authorized for issuance under the 2018 Plan, of which 198,848 shares remained available for future issuance. Recipients of stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2018 Plan is ten years and generally vest 25% one year from the vesting commencement dates and monthly

thereafter over 36 months. The 2018 Plan allows for early exercise of stock option grants if authorized by the Board of Directors at the time of grant. The shares of common stock issued from the early exercise of stock options are restricted and vest over time. The Company has the option to repurchase exercised and unvested shares at the lower of original purchase price or the then fair market value upon any voluntary or involuntary termination of services.

A summary of the Company's stock option activity issued under the 2018 Plan for the six months ended June 30, 2022 was as follows, except share and per share data):

	Options Outstanding	Weighted - Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	4,085,517	$ 1.25		
Granted	1,246,000	$ 1.77		
Exercised	(326,349)	$ 0.88		
Forfeited	(187,501)	$ 1.14		
Outstanding at June 30, 2022	4,817,667	$ 1.41	8.70	$ 14,837
Exercisable at June 30, 2022	4,616,209	$ 1.42	8.70	$ 14,132
Vested and expected to vest at June 30, 2022	4,617,667	$ 1.43	8.40	$ 14,137

Options totaling 200,000 shares are performance-based and will vest contingent on the closing of certain financing or strategic transactions. The performance condition was not considered probable of occurring as of June 30, 2022. Accordingly, no stock compensation has been recognized for the performance-based grants.

The weighted average fair value of options granted during the six months ended June 30, 2022 and 2021 was $2.74 and $0.93, respectively. The total intrinsic value of stock options exercised for the six months ended June 30, 2022 was $1.2 million. The weighted average fair value of options vested for the six months ended June 30, 2022 and 2021 was $0.86 and $0.70, respectively.

The total unrecognized compensation cost related to outstanding employee unvested stock-based awards as of June 30, 2022 was $4.5 million, which is expected to be recognized over a weighted-average period of 3.16 years.

For purposes of calculating the stock-based compensation, the Company estimates the fair value of stock options using the Black-Scholes option-pricing model. This model incorporates various assumptions, including the expected volatility, expected term, and interest rates. Stock-based compensation expense recognized in the condensed consolidated statement of operations and comprehensive loss is based on the awards ultimately expected to vest. Forfeitures are recognized as they occur.

The weighted average underlying assumptions used to value employee and non-employee stock options granted using the Black-Scholes option-pricing model was as follows:

	For the six months ended June 30,	
	2022	2021
Risk-free interest rate	2.13%	1.00%
Dividend yield	0%	0%
Expected life of options (years)	6.1	6.1
Volatility	91.3%	98.2%

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following:

	June 30, 2022	December 31, 2021
Convertible preferred stock	22,399,435	22,399,435
Convertible preferred stock warrants	38,460	38,460
Common stock options granted and outstanding	4,817,667	4,085,517
Common stock reserved for future awards or option grants	198,848	1,257,345
	27,454,410	27,780,757

8. Related-Party Transactions

In September 2015, the Company entered into a consulting agreement for regulatory and development services with Pacific-Link Consulting, LLC, an entity owned by the President/CEO/Board member and the Chief Medical Officer of the Company. The Company incurred consulting expense related to this agreement totaling $1.1 million and $0.5 million during the six months ended June 30, 2022 and 2021, respectively.

In September 2018, the Company entered into a consulting agreement with Marlinspike Group, LLC (“Marlinspike Group”) to provide management, business consulting services and business development support. In addition, Marlinspike Group provides the use of its facilities to the Company from time to time. The Company’s Chairman of the Board of the Directors and investor is a managing member of Marlinspike Group. The Company incurred annual expenses related to this agreement totaling $0.1 million during the six months ended June 30, 2022 and 2021.

9. Subsequent Events

The Company evaluated subsequent events through August 11, 2022, the date the financial statements were available to be issued. During this period, the Company did not have any material subsequent events other than those disclosed above.

Annex A

AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

among:

SILVERBACK THERAPEUTICS, INC.,
a Delaware corporation;

SABRE MERGER SUB, INC.,
a Delaware corporation; and

ARS PHARMACEUTICALS, INC.,
a Delaware corporation

Dated as of July 21, 2022

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Exhibits:

AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

THIS AGREEMENT AND PLAN OF MERGER AND REORGANIZATION (this "***Agreement***") is made and entered into as of July 21, 2022, by and among **SILVERBACK THERAPEUTICS, INC.**, a Delaware corporation ("***Parent***"), **SABRE MERGER SUB, INC.** a Delaware corporation and wholly owned subsidiary of Parent ("***Merger Sub***"), and **ARS PHARMACEUTICALS, INC.**, a Delaware corporation (the "***Company***"). Certain capitalized terms used in this Agreement are defined in **Exhibit A**.

RECITALS

A. Parent and the Company intend to effect a merger of Merger Sub with and into the Company (the "***Merger***") in accordance with this Agreement and the DGCL. Upon consummation of the Merger, Merger Sub will cease to exist and the Company will become a wholly owned subsidiary of Parent.

B. The Parties intend that the Merger qualify as a "reorganization" within the meaning of Section 368(a) of the Code (the "***Intended Tax Treatment***"), and by executing this Agreement, the Parties hereby adopt a plan of reorganization within the meaning of Treasury Regulations Sections 1.368-2(g) and 1.368-3.

C. The Parent Board has unanimously (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions, including the issuance of shares of Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement, the change of control of Parent and other actions contemplated by this Agreement, and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters and the Other Parent Stockholder Matters.

D. The Merger Sub Board has unanimously (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Merger Sub and its sole stockholder, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the sole stockholder of Merger Sub vote to adopt this Agreement and thereby approve the Contemplated Transactions.

E. The Company Board has unanimously (i) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions and (iii) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote to approve the Company Stockholder Matters.

F. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to Parent's willingness to enter into this Agreement, (a) the officers, directors and stockholders of the Company listed in Section A-1 of the Company Disclosure Schedule (the "***Company Signatories***") (solely in their capacity as stockholders of the Company), which represent at least seventy-five percent (75%) of the voting securities of the Company, are executing support agreements in favor of Parent in substantially the form attached hereto as **Exhibit B-1** (the "***Company Stockholder Support Agreement***") and (b) the officers, directors and stockholders of the Company listed in Section A-2 of the Company Disclosure Schedule (the **"*Company Lock-Up Signatories***")

(solely in their capacity as stockholders of the Company) are executing lock-up agreements in substantially the form attached hereto as **Exhibit C-1** (the "***Company Lock-Up Agreement***").

G. Concurrently with the execution and delivery of this Agreement and as a condition and inducement to the Company's willingness to enter into this Agreement, (a) the officers, directors and stockholders of Parent listed in Section A-1 of the Parent Disclosure Schedule (solely in their capacity as stockholders of Parent), which represent at least twenty-five percent (25%) of the voting securities of Parent, are executing support agreements in favor of the Company in substantially the form attached hereto as **Exhibit B-2** (the "***Parent Stockholder Support Agreement***") and (b) the officers, directors and stockholders of Parent listed in Section A-2 of the Parent Disclosure Schedule (solely in their capacity as stockholders of Parent) are executing lock-up agreements in substantially the form attached hereto as **Exhibit C-2** (the "***Parent Lock-Up Agreement***").

H. It is expected that within one (1) Business Day after the execution and delivery of this Agreement (a) no less than seventy-five percent (75%) of the stockholders of the Company will execute and deliver an action by written consent in substantially the form attached hereto as **Exhibit F** (each, a "***Company Stockholder Written Consent***" and collectively, the "***Company Stockholder Written Consents***") and (b) each of the Company Signatories that is a stockholder in the Company will execute an investor questionnaire in substantially the form attached hereto as **Exhibit G** (the "***Investor Questionnaire***"); *provided*, that no more than ten (10) such Persons do not represent that they are "accredited investors" as defined in Regulation D under the Securities Act ("***Regulation D***").

AGREEMENT

The Parties, intending to be legally bound, agree as follows:

Section 1. DESCRIPTION OF TRANSACTION

1.1 **The Merger**. Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time, Merger Sub shall be merged with and into the Company, and the separate existence of Merger Sub shall cease. The Company will continue as the surviving corporation in the Merger (the "***Surviving Corporation***").

1.2 **Effects of the Merger**. The Merger shall have the effects set forth in this Agreement, the Certificate of Merger and in the applicable provisions of the DGCL. As a result of the Merger, the Company will become a wholly owned subsidiary of Parent.

1.3 **Closing; Effective Time**. Unless this Agreement is earlier terminated pursuant to the provisions of Section 9.1, and subject to the satisfaction or waiver of the conditions set forth in Sections 6, 7 and 8, the consummation of the Merger (the "***Closing***") shall take place remotely as promptly as practicable (but in no event later than the second (2nd) Business Day following the satisfaction or waiver of the last to be satisfied or waived of the conditions set forth in Sections 6, 7 and 8, other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of each of such conditions), or at such other time, date and place as Parent and the Company may mutually agree in writing. The date on which the Closing actually takes place is referred to as the "***Closing Date***." At the Closing, the Parties shall cause the Merger to be consummated by executing and filing with the Secretary of State of the State of Delaware a certificate of merger with respect to the Merger, satisfying the applicable requirements of the DGCL and in a form reasonably acceptable to Parent and the Company (the "***Certificate of Merger***"). The Merger shall become effective at the time of the filing of such Certificate of Merger with the Secretary of State of the State of Delaware or at such later time as may be specified in such Certificate of Merger with the consent of Parent and the Company (the time as of which the Merger becomes effective being referred to as the "***Effective Time***").

1.4 **Certificate of Incorporation and Bylaws; Directors and Officers**. At the Effective Time:

(a) the certificate of incorporation of the Surviving Corporation shall be amended and restated in its entirety to read identically to the certificate of incorporation of Merger Sub as in effect immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation; *provided*, *however*, that at or immediately prior to the Effective Time, the Surviving Corporation shall file an amendment to its certificate of incorporation to change the name of the Surviving Corporation to ARS Subsidiary, Inc. or such other name as shall be mutually agreed upon by Parent and the Company prior to filing such amendment;

(b) the certificate of incorporation of Parent shall be identical to the certificate of incorporation of Parent immediately prior to the Effective Time, until thereafter amended as provided by the DGCL and such certificate of incorporation; *provided, however,* that at or immediately prior to the Effective Time, Parent shall file an amendment to its certificate of incorporation to (i) change the name of Parent to ARS Pharmaceuticals, Inc. and (ii) make such other changes as shall be mutually agreed upon by Parent and the Company prior to filing such amendment;

(c) the bylaws of the Surviving Corporation shall be amended and restated in their entirety to read identically to the bylaws of Merger Sub as in effect immediately prior to the Effective Time (except that the name of the Surviving Corporation in such bylaws shall reflect the name identified in Section 1.4(a)), until thereafter amended as provided by the DGCL and such bylaws;

(d) the directors and officers of Parent, each to hold office in accordance with the certificate of incorporation and bylaws of Parent, shall be as set forth in Section 5.13 after giving effect to the provisions of Section 5.13, or such other persons as shall be mutually agreed upon by Parent and the Company; and

(e) the directors and officers of the Surviving Corporation, each to hold office in accordance with the certificate of incorporation and bylaws of the Surviving Corporation, shall be determined prior to Closing by the Company.

1.5 **Conversion of Shares.**

(a) At the Effective Time, by virtue of the Merger and without any further action on the part of Parent, Merger Sub, the Company or any stockholder of the Company or Parent:

(i) any shares of Company Capital Stock held as treasury stock by the Company or held or owned by Parent, Merger Sub or any Subsidiary of Parent or the Company immediately prior to the Effective Time shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor; and

(ii) subject to Section 1.5(c), each share of Company Capital Stock outstanding immediately prior to the Effective Time (excluding shares to be canceled pursuant to Section 1.5(a)(i) and excluding Dissenting Shares), after giving effect to the Preferred Stock Conversion, shall be automatically converted solely into the right to receive a number of shares of Parent Common Stock equal to the Exchange Ratio (the "***Merger Consideration***").

(b) If any shares of Company Capital Stock outstanding immediately prior to the Effective Time are unvested or are subject to a repurchase option or a risk of forfeiture under any applicable restricted stock purchase agreement or other similar agreement with the Company, then the shares of Parent Common Stock issued in exchange for such shares of Company Capital Stock at the Effective Time will to the same extent be unvested and subject to the same repurchase option or risk of

forfeiture, and such shares of Parent Common Stock shall accordingly be marked with appropriate legends. The Company shall use commercially reasonable efforts to take all actions that may be reasonably necessary to ensure that, from and after the Effective Time, Parent is entitled to exercise any such repurchase option or other right set forth in any such restricted stock purchase agreement or other agreement in accordance with its terms.

(c) No fractional shares of Parent Common Stock shall be issued in connection with the Merger, no certificates or scrip for any such fractional shares shall be issued and no cash shall be paid for any such fractional shares. Any fractional shares of Parent Common Stock that a holder of Company Capital Stock would otherwise be entitled to receive shall be aggregated with all fractional shares of Parent Common Stock issuable to such holder and any remaining fractional shares shall be rounded up to the nearest whole share.

(d) All Company Options outstanding immediately prior to the Effective Time under the Company Plan shall be treated in accordance with Section 5.5(a).

(e) All Company Warrants outstanding immediately prior to the Effective Time shall be treated in accordance with Section 5.5(c).

(f) Each share of common stock, $0.001 par value per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be converted into and exchanged for one validly issued, fully paid and nonassessable share of common stock, $0.001 par value per share, of the Surviving Corporation. Each stock certificate of Merger Sub evidencing ownership of any such shares shall, as of the Effective Time, evidence ownership of such shares of common stock of the Surviving Corporation.

(g) If, between the time of calculating the Exchange Ratio and the Effective Time, the outstanding shares of Company Capital Stock or Parent Common Stock shall have been changed into, or exchanged for, a different number of shares or a different class, by reason of any stock dividend, subdivision, reclassification, recapitalization, split, combination or exchange of shares or other like change, the Exchange Ratio shall, to the extent necessary, be equitably adjusted to reflect such change to the extent necessary to provide the holders of Company Capital Stock, Parent Common Stock, Company Options and Company Warrants with the same economic effect as contemplated by this Agreement prior to such stock dividend, subdivision, reclassification, recapitalization, split, combination or exchange of shares or other like change; *provided, however*, that nothing herein will be construed to permit the Company or Parent to take any action with respect to Company Capital Stock or Parent Common Stock, respectively, that is prohibited or not expressly permitted by the terms of this Agreement.

1.6 **Calculation of Parent Net Cash**.

(a) For the purposes of this Agreement, the "***Anticipated Closing Date***" shall be the date, as agreed upon by Parent and the Company at least ten (10) calendar days prior to the Parent Stockholders' Meeting, to be the anticipated date for Closing. At least five (5) calendar days prior to the Anticipated Closing Date, Parent shall deliver to the Company a schedule (the "***Net Cash Schedule***") setting forth, in reasonable detail, Parent's good faith, estimated calculation of Parent Net Cash (the "***Net Cash Calculation***") as of the Anticipated Closing Date, prepared and certified by an executive officer of Parent. Parent shall make available to the Company the work papers and back-up materials used or useful in preparing the Net Cash Schedule, as reasonably requested by the Company.

(b) Within three (3) calendar days after delivery of the Net Cash Schedule (the "***Response Date***"), the Company will have the right to dispute any part of the Net Cash Schedule by

delivering a written notice to that effect to Parent (a "***Dispute Notice***"). Any Dispute Notice shall identify in reasonable detail the nature of any proposed revisions to the Net Cash Calculation.

(c) If on or prior to the Response Date, the Company (i) notifies Parent in writing that it has no objections to the Net Cash Calculation or (ii) fails to deliver a Dispute Notice as provided in Section 1.6(b) then the Net Cash Calculation as set forth in the Net Cash Schedule shall be deemed to have been finally determined for purposes of this Agreement and to represent Parent Net Cash at the Anticipated Closing Date for purposes of this Agreement.

(d) If the Company delivers a Dispute Notice on or prior to the Response Date, then Representatives of both Parties shall promptly meet and attempt in good faith to resolve the disputed item(s) and negotiate an agreed-upon determination of Parent Net Cash, which agreed upon Parent Net Cash amount shall be deemed to have been finally determined for purposes of this Agreement and to represent Parent Net Cash at the Anticipated Closing Date for purposes of this Agreement.

(e) If Parent and the Company are unable to negotiate an agreed-upon determination of Parent Net Cash at the Anticipated Closing Date pursuant to Section 1.6(d) within three (3) calendar days after delivery of the Dispute Notice (or such other period as Parent and the Company may mutually agree upon), then Parent and the Company shall jointly select an independent auditor of recognized national standing (the "***Accounting Firm***") to resolve any remaining disagreements as to the Net Cash Calculation. Parent shall promptly deliver to the Accounting Firm the work papers and back-up materials used in preparing the Net Cash Schedule, and Parent and the Company shall use commercially reasonable efforts to cause the Accounting Firm to make its determination within ten (10) calendar days of accepting its selection. The Company and Parent shall be afforded the opportunity to present to the Accounting Firm any material related to the unresolved disputes and to discuss the issues with the Accounting Firm; *provided, however*, that no such presentation or discussion shall occur without the presence of a Representative of each of the Company and Parent. The determination of the Accounting Firm shall be limited to the disagreements submitted to the Accounting Firm. The determination of the amount of Parent Net Cash made by the Accounting Firm shall be deemed to have been finally determined for purposes of this Agreement and to represent Parent Net Cash at the Anticipated Closing Date for purposes of this Agreement, and the Parties shall delay the Closing until the resolution of the matters described in this Section 1.6(e). The fees and expenses of the Accounting Firm shall be allocated between Parent and the Company in the same proportion that the disputed amount of Parent Net Cash that was unsuccessfully disputed by such Party (as finally determined by the Accounting Firm) bears to the total disputed amount of Parent Net Cash (and for the avoidance of doubt, such fees and expenses of the Accounting Firm allocated to Parent shall reduce Parent Net Cash). If this Section 1.6(e) applies as to the determination of Parent Net Cash at the Anticipated Closing Date described in Section 1.6(a), upon resolution of the matter in accordance with this Section 1.6(e), the Parties shall not be required to determine Parent Net Cash again even though the Closing Date may occur later than the Anticipated Closing Date, except that either Party may request a re-determination of Parent Net Cash if the Closing Date is more than five (5) Business Days after the Anticipated Closing Date.

1.7 **Closing of the Company's Transfer Books**. At the Effective Time: (a) all shares of Company Capital Stock outstanding immediately prior to the Effective Time shall be treated in accordance with Section 1.5(a), and all holders of certificates or book-entry shares representing shares of Company Capital Stock that were outstanding immediately prior to the Effective Time shall cease to have any rights as stockholders of the Company; and (b) the stock transfer books of the Company shall be closed with respect to all shares of Company Capital Stock outstanding immediately prior to the Effective Time. No further transfer of any such shares of Company Capital Stock shall be made on such stock transfer books after the Effective Time. If, after the Effective Time, a valid certificate previously representing any shares of Company Capital Stock outstanding immediately prior to the

Effective Time (a "***Company Stock Certificate***") is presented to the Exchange Agent or to the Surviving Corporation, such Company Stock Certificate shall be canceled and shall be exchanged as provided in Sections 1.5 and 1.8.

1.8 **Surrender of Certificates.**

(a) On or prior to the Closing Date, Parent and the Company shall agree upon and select a reputable bank, transfer agent or trust company to act as exchange agent in the Merger (the "***Exchange Agent***"). At the Effective Time, Parent shall deposit with the Exchange Agent evidence of book-entry shares representing the Parent Common Stock issuable pursuant to Section 1.5(a). The Parent Common Stock so deposited with the Exchange Agent, together with any dividends or distributions received by the Exchange Agent with respect to such shares, are referred to collectively as the "***Exchange Fund***."

(b) Promptly after the Effective Time, the Parties shall cause the Exchange Agent to mail to the Persons who were record holders of shares of Company Capital Stock that were converted into the right to receive the Merger Consideration: (i) a letter of transmittal in customary form and containing such provisions as Parent may reasonably specify (including a provision confirming that delivery of Company Stock Certificates shall be effected, and risk of loss and title to Company Stock Certificates shall pass, only upon proper delivery of such Company Stock Certificates to the Exchange Agent); and (ii) instructions for effecting the surrender of Company Stock Certificates in exchange for shares of Parent Common Stock. Holders of Company Preferred Stock shall surrender Company Stock Certificates representing the shares of Company Preferred Stock that were converted in connection with the Preferred Stock Conversion. Upon surrender of a Company Stock Certificate to the Exchange Agent for exchange, together with a duly executed letter of transmittal and such other documents as may be reasonably required by the Exchange Agent or Parent (including a properly completed IRS Form W-9 or the appropriate version of IRS Form W-8, as applicable): (A) the holder of such Company Stock Certificate shall be entitled to receive in exchange therefor book-entry shares representing the Merger Consideration (in a number of whole shares of Parent Common Stock) that such holder has the right to receive pursuant to the provisions of Section 1.5(a); and (B) the Company Stock Certificate so surrendered shall be canceled. Until surrendered as contemplated by this Section 1.8(b), each Company Stock Certificate shall be deemed, from and after the Effective Time, to represent only the right to receive book-entry shares of Parent Common Stock representing the Merger Consideration. If any Company Stock Certificate shall have been lost, stolen or destroyed, Parent may, in its reasonable discretion and as a condition precedent to the delivery of any shares of Parent Common Stock, require the owner of such lost, stolen or destroyed Company Stock Certificate to provide an applicable affidavit with respect to such Company Stock Certificate that includes an obligation of such owner to indemnify Parent against any claim suffered by Parent related to the lost, stolen or destroyed Company Stock Certificate as Parent may reasonably request. In the event of a transfer of ownership of a Company Stock Certificate that is not registered in the transfer records of the Company, payment of the Merger Consideration may be made to a Person other than the Person in whose name such Company Stock Certificate so surrendered is registered if such Company Stock Certificate shall be properly endorsed or otherwise be in proper form for transfer and the Person requesting such payment shall pay any transfer or other Taxes required by reason of the transfer or establish to the reasonable satisfaction of Parent that such Taxes have been paid or are not applicable. The Merger Consideration and any dividends or other distributions as are payable pursuant to Section 1.8(c) shall be deemed to have been in full satisfaction of all rights pertaining to Company Capital Stock formerly represented by such Company Stock Certificates.

(c) No dividends or other distributions declared or made with respect to Parent Common Stock with a record date on or after the Effective Time shall be paid to the holder of any unsurrendered Company Stock Certificate with respect to the shares of Parent Common Stock that

such holder has the right to receive in the Merger until such holder surrenders such Company Stock Certificate or provides an affidavit of loss, theft or destruction in lieu thereof in accordance with this Section 1.8 together with a duly executed letter of transmittal and such other documents as may be reasonably required by the Exchange Agent or Parent (at which time (or, if later, on the applicable payment date) such holder shall be entitled, subject to the effect of applicable abandoned property, escheat or similar Laws, to receive all such dividends and distributions, without interest).

(d) Any portion of the Exchange Fund that remains undistributed to holders of Company Stock Certificates as of the date that is one (1) year after the Closing Date shall be delivered to Parent upon demand, and any holders of Company Stock Certificates who have not theretofore surrendered their Company Stock Certificates in accordance with this Section 1.8 shall thereafter look only to Parent for satisfaction of their claims for Parent Common Stock and any dividends or distributions with respect to shares of Parent Common Stock.

(e) No Party to this Agreement shall be liable to any holder of any Company Stock Certificate or to any other Person with respect to any shares of Parent Common Stock (or dividends or distributions with respect thereto) or for any cash amounts delivered to any public official pursuant to any applicable abandoned property Law, escheat Law or similar Law.

(f) All shares of Parent Common Stock issued pursuant to this Agreement shall bear a legend (and Parent will make a notation on its transfer books to such effect) prominently stamped or printed thereon or the substance of which will otherwise be reflected on the books and records of the transfer agent for Parent Common Stock with respect to book-entry shares, in each case reading substantially as follows:

> "THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT PURPOSES AND NOT WITH A VIEW TO RESALE IN CONNECTION WITH A DISTRIBUTION AND MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS, OR AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT."

1.9 **Appraisal Rights.**

(a) Notwithstanding any provision of this Agreement to the contrary, shares of Company Capital Stock that are outstanding immediately prior to the Effective Time and which are held by stockholders who have exercised and perfected appraisal rights for such shares of Company Capital Stock in accordance with the DGCL or California Law, as applicable (collectively, the "***Dissenting Shares***") shall not be converted into or represent the right to receive the Merger Consideration described in Section 1.5 attributable to such Dissenting Shares. Such stockholders shall be entitled to receive payment of the appraised value of such shares of Company Capital Stock held by them in accordance with the DGCL or California Law, as applicable, unless and until such stockholders fail to perfect or effectively withdraw or otherwise lose their appraisal rights under the DGCL or California Law, as applicable. All Dissenting Shares held by stockholders who shall have failed to perfect or shall have effectively withdrawn or lost their right to appraisal of such shares of Company Capital Stock under the DGCL or California Law, as applicable (whether occurring before, at or after the Effective Time) shall thereupon be deemed to be converted into and to have become exchangeable for, as of the Effective Time, the right to receive the Merger Consideration, without interest, attributable to such Dissenting Shares upon their surrender in the manner provided in Sections 1.5 and 1.8.

(b) The Company shall give Parent prompt written notice of any demands by dissenting stockholders received by the Company, withdrawals of such demands and any other instruments served on the Company and any material correspondence received by the Company in connection with such demands, and the Company shall have the right to direct all negotiations and proceedings with respect to such demands; *provided* that Parent shall have the right to participate in such negotiations and proceedings. The Company shall not, except with Parent's prior written consent, not to be unreasonably withheld, delayed or conditioned, make any payment with respect to, or settle or offer to settle, any such demands, or approve any withdrawal of any such demands or agree to do any of the foregoing.

1.10 **Further Action**. If, at any time after the Effective Time, any further action is determined by the Surviving Corporation to be necessary or desirable to carry out the purposes of this Agreement or to vest the Surviving Corporation with full right, title and possession of and to all rights and property of the Company, then the officers and directors of the Surviving Corporation shall be fully authorized, and shall use their and its commercially reasonable efforts (in the name of the Company, in the name of Merger Sub, in the name of the Surviving Corporation and otherwise) to take such action.

1.11 **Withholding**. The Parties and the Exchange Agent shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to any holder of Company Capital Stock or any other Person such amounts as such Party or the Exchange Agent reasonably determines it is required to deduct and withhold under the Code or any other Law with respect to the making of such payment. To the extent that amounts are so withheld and paid to the appropriate Governmental Body, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction and withholding was made.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Subject to Section 10.13(h), except as set forth in the disclosure schedule delivered by the Company to Parent (the "***Company Disclosure Schedule***"), the Company represents and warrants to Parent and Merger Sub as follows:

2.1 **Due Organization; Subsidiaries.**

(a) The Company is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions.

(b) The Company is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Company Material Adverse Effect.

(c) The Company has no Subsidiaries, except for the Entities identified in Section 2.1(c) of the Company Disclosure Schedule; and neither the Company nor any of the Entities identified in Section 2.1(c) of the Company Disclosure Schedule owns any capital stock of, or any equity, ownership or profit sharing interest of any nature in, or controls directly or indirectly, any other

Entity other than the Entities identified in Section 2.1(c) of the Company Disclosure Schedule. Each of the Company's Subsidiaries is a corporation or other legal entity duly organized, validly existing and, if applicable, in good standing under the Laws of the jurisdiction of its organization and has all necessary corporate or other power and authority to conduct its business in the manner in which its business is currently being conducted and to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used, except where the failure to have such power or authority would not be reasonably expected to have a Company Material Adverse Effect.

(d) Neither the Company nor any of its Subsidiaries is or has otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Neither the Company nor any of its Subsidiaries has agreed or is obligated to make, or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Neither the Company nor any of its Subsidiaries has, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

2.2 **Organizational Documents**. The Company has made available to Parent accurate and complete copies of the Organizational Documents of the Company and each of its Subsidiaries in effect as of the date of this Agreement. Neither the Company nor any of its Subsidiaries is in material breach or violation of its respective Organizational Documents.

2.3 **Authority; Binding Nature of Agreement.** The Company and each of its Subsidiaries have all necessary corporate power and authority to enter into this Agreement and, subject, with respect to the Company, to receipt of the Required Company Stockholder Vote, to perform its obligations under this Agreement and to consummate the Contemplated Transactions. The Company Board (at meetings duly called and held or by written consent in lieu of a meeting) has unanimously: (a) determined that the Contemplated Transactions are fair to, advisable and in the best interests of the Company and its stockholders; (b) approved and declared advisable this Agreement and the Contemplated Transactions; and (c) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of the Company vote to approve the Company Stockholder Matters.

This Agreement has been duly executed and delivered by the Company and assuming the due authorization, execution and delivery by Parent and Merger Sub, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to the Enforceability Exceptions. Prior to the execution of the Company Stockholder Support Agreements, the Company Board approved the Company Stockholder Support Agreements and the transactions contemplated thereby.

2.4 **Vote Required.** The affirmative vote (or written consent) of (a) the holders of a majority of the issued and outstanding shares of Company Common Stock; (b) the holders of a majority of the issued and outstanding shares of Company Common Stock and Company Preferred Stock, voting together as a single class with each holder of shares of Company Preferred Stock having the number of votes equal to the number of shares of Company Common Stock into which such shares of Company Preferred Stock could be converted; (c) the holders of a majority of the issued and outstanding shares of Company Preferred Stock, voting together as a separate class on an as-if-converted to Company Common Stock basis, which majority must include the holders of a majority of the issued and outstanding shares of the Company's Series D Preferred Stock, on an as-if-converted to Company Common Stock basis; (d) solely with respect to the termination of the Amended and Restated Voting Agreement described in Section 2.22(b) of the Company Disclosure Schedule (the "***Voting Agreement***"), the holders of a majority of the Key Holder Shares (as defined in the Voting Agreement); and (e) solely with respect to the termination of the Amended and Restated

Right of First Refusal and Co-Sale Agreement described in Section 2.22(b) of the Company Disclosure Schedule (the "***ROFR Agreement***"), the holders of a majority of the Key Holder Stock (as defined in the ROFR Agreement) (collectively, the "***Required Company Stockholder Vote***"), is the only vote (or written consent) of the holders of any class or series of Company Capital Stock necessary to adopt and approve this Agreement and approve the Contemplated Transactions.

2.5 **Non-Contravention; Consents.** Subject to obtaining the Required Company Stockholder Vote and the filing of the Certificate of Merger required by the DGCL and subject to making all filings and notifications as may be required in connection with the transactions described herein under the HSR Act and any other Antitrust Laws and obtaining all consents, authorizations, clearances, approvals and waiting period expirations or terminations as may be required in connection with the transactions described herein under the HSR Act and other Antitrust Laws, neither (x) the execution, delivery or performance of this Agreement by the Company, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of the Company or any of its Subsidiaries;

(b) contravene, conflict with or result in a violation of, or give any Governmental Body the right to challenge the Contemplated Transactions or to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which the Company or its Subsidiaries, or any of the assets owned or used by the Company or its Subsidiaries, is subject, except as would not reasonably be expected to be material to the Company or its business;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by the Company or its Subsidiaries, except as would not reasonably be expected to be material to the Company or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Company Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Company Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Company Material Contract; (iii) accelerate the maturity or performance of any Company Material Contract; or (iv) cancel, terminate or modify any term of any Company Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by the Company or its Subsidiaries (except for Permitted Encumbrances).

Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, and (ii) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, the HSR Act or other Antitrust Laws, neither the Company nor any of its Subsidiaries is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Governmental Body in connection with (x) the execution, delivery or performance of this Agreement, or (y) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of the Company to consummate the Contemplated Transactions. The Company Board has taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Company Stockholder Support Agreements, the Company Lock-Up Agreements

and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Company Stockholder Support Agreements, the Company Lock-Up Agreements or any of the Contemplated Transactions.

2.6 **Capitalization.**

(a) The authorized Company Capital Stock as of the date of this Agreement consists of (i) 56,000,000 shares of Company Common Stock, of which 26,021,763 shares have been issued and are outstanding as of the date of this Agreement, and (ii) 22,457,125 shares of Company Preferred Stock, of which 22,399,435 have been issued and are outstanding as of the date of this Agreement, consisting of 4,764,000 shares of Series A Preferred Stock, 606,060 shares of Series B Preferred Stock, 7,692,309 shares of Series C Preferred Stock, and 9,337,066 shares of Series D Preferred Stock. In addition, there are Company Warrants to acquire 38,460 shares of Series C Preferred Stock. The Company does not hold any shares of its capital stock in its treasury. Section 2.6(a) of the Company Disclosure Schedule lists, as of the date of this Agreement (A) each record holder of issued and outstanding Company Capital Stock and the number and type of shares of Company Capital Stock held by such holder; and (B)(1) each holder of issued and outstanding Company Warrants, (2) the number and type of shares subject to each Company Warrant, (3) the exercise price of each Company Warrant and (4) the termination date of each Company Warrant.

(b) All of the outstanding shares of Company Common Stock and Company Preferred Stock have been duly authorized and validly issued, and are fully paid and nonassessable. Except as set forth in the Investor Agreements, none of the outstanding shares of Company Capital Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Company Capital Stock is subject to any right of first refusal in favor of the Company. Except as contemplated herein and in the Investor Agreements, there is no Company Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Company Capital Stock. The Company is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Company Capital Stock or other securities. Section 2.6(b) of the Company Disclosure Schedule accurately and completely lists all repurchase rights held by the Company with respect to shares of Company Capital Stock (including shares issued pursuant to the exercise of stock options) and specifies which of those repurchase rights are currently exercisable and whether the holder of such shares of Company Capital Stock timely filed an election with the relevant Governmental Bodies under Section 83(b) of the Code with respect to such shares. Each share of Company Preferred Stock is convertible into one share of Company Common Stock.

(c) Except for the Company Plan, the Company does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the date of this Agreement, the Company has reserved 5,613,278 shares of Company Common Stock for issuance under the Company Plan, of which 596,763 shares have been issued and are currently outstanding, 4,767,667 shares have been reserved for issuance upon exercise of Company Options previously granted and currently outstanding under the Company Plan, and 248,848 shares of Company Common Stock remain available for future issuance of awards pursuant to the Company Plan. Section 2.6(c) of the Company Disclosure Schedule sets forth the following information with respect to each Company Option outstanding as of the date of this Agreement: (i) the name of the optionee; (ii) the number of shares of Company Common Stock subject to such Company Option at the time of grant; (iii) the number of shares of Company Common Stock subject to such Company Option as of the date of this Agreement; (iv) the exercise price of such Company Option; (v) the date on which such Company Option was granted; (vi) the applicable vesting schedule, including the number of vested and unvested shares as of the date of this Agreement and

any acceleration provisions; (vii) the date on which such Company Option expires; and (viii) whether such Company Option is intended to constitute an "incentive stock option" (as defined in the Code) or a non-qualified stock option. The Company has made available to Parent accurate and complete copies of the Company Plan and the form of the stock option agreements evidencing outstanding Company Options granted thereunder. All stock option agreements evidencing outstanding Company Options are consistent with the Company's standard form of stock option agreements. No vesting of Company Options will accelerate in connection with the closing of the Contemplated Transactions.

(d) Except for Company Warrants and the Company Options set forth in Section 2.6(c) of the Company Disclosure Schedule, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of the Company or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of the Company or any of its Subsidiaries; or (iii) condition or circumstance that could be reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of the Company or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to the Company or any of its Subsidiaries.

(e) All outstanding shares of Company Common Stock, Company Preferred Stock, Company Options, Company Warrants and other securities of the Company have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts.

(f) The Company does not have more than ten (10) stockholders that are not "accredited investors" as defined in Regulation D and each stockholder who is not an accredited investor either alone or with such stockholder's purchaser representative(s) has such knowledge and experience in financial and business matters that such stockholder is capable of evaluating the merits and risks of the Merger.

2.7 **Financial Statements.**

(a) Concurrently with the execution hereof, the Company has provided to Parent true and complete copies of (i) the Company's audited consolidated balance sheets at December 31, 2021, 2020 and 2019, together with related audited consolidated statements of income, stockholders' equity and cash flows, and notes thereto, of the Company for the fiscal years then ended and (ii) the Company Unaudited Interim Balance Sheet, together with the unaudited consolidated statements of income, stockholders' equity and cash flows of the Company for the period reflected in the Company Unaudited Interim Balance Sheet (collectively, the "***Company Financials***"). The Company Financials were prepared in accordance with GAAP applied on a consistent basis throughout the periods covered thereby (except as may be indicated in the notes to such financial statements and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments, none of which are material) and fairly present, in all material respects, the financial position and operating results of the Company and its consolidated Subsidiaries as of the dates and for the periods indicated therein.

(b) The Company and each of its Subsidiaries maintains accurate books and records reflecting its assets and liabilities and maintains a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of the financial statements of the Company and its Subsidiaries and to maintain accountability of the Company's and its Subsidiaries' assets; (iii) access to the Company's and its Subsidiaries' assets is

permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for the Company's and its Subsidiaries' assets is compared with the existing assets at regular intervals and appropriate action is taken with respect to any differences; and (v) accounts, notes and other receivables and inventory are recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis. The Company and each of its Subsidiaries maintains internal control over financial reporting that provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes.

(c) Section 2.7(c) of the Company Disclosure Schedule lists, and the Company has delivered to Parent accurate and complete copies of the documentation creating or governing, all securitization transactions and "off-balance sheet arrangements" (as described in Instruction 8 to Item 303(b) of Regulation S-K as promulgated under the Securities Act) effected by the Company or any of its Subsidiaries since January 1, 2019, if any.

(d) Since January 1, 2019, there have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer or general counsel of the Company, the Company Board or any committee thereof. Since January 1, 2019, neither the Company nor its independent auditors have identified (i) any significant deficiency or material weakness in the design or operation of the system of internal accounting controls utilized by the Company and its Subsidiaries, (ii) any fraud, whether or not material, that involves the Company, any of its Subsidiaries, the Company's management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by the Company and its Subsidiaries or (iii) any claim or allegation regarding any of the foregoing.

2.8 **Absence of Changes**. Except as set forth in Section 2.8 of the Company Disclosure Schedule and reasonable and good faith actions or omissions taken to comply with applicable Law or guidance by a Governmental Body in connection with the COVID-19 pandemic, between the date of the Company Unaudited Interim Balance Sheet and the date of this Agreement, the Company has conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions) and there has not been any (a) Company Material Adverse Effect or (b) action, event or occurrence that would have required the consent of Parent pursuant to Section 4.2(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

2.9 **No Competitive Products**. The Company has no current products, or products in development, for the treatment of chronic hepatitis.

2.10 **Absence of Undisclosed Liabilities**. As of the date hereof, neither the Company nor any of its Subsidiaries has any liability, indebtedness, obligation or expense of any kind, whether accrued, absolute, contingent, matured or unmatured (whether or not required to be reflected in the financial statements in accordance with GAAP) (each a "***Liability***"), individually or in the aggregate, of a type required to be recorded or reflected on a balance sheet or disclosed in the footnotes thereto under GAAP except for: (a) Liabilities disclosed, reflected or reserved against in the Company Unaudited Interim Balance Sheet; (b) Liabilities that have been incurred by the Company or its Subsidiaries since the date of the Company Unaudited Interim Balance Sheet in the Ordinary Course of Business; (c) Liabilities for performance of obligations of the Company or any of its Subsidiaries under Company Material Contracts which have not resulted from a breach of such Company Material Contracts or violation of Law; (d) Liabilities incurred in connection with the Contemplated Transactions; (e) Liabilities which would not, individually or in the aggregate, reasonably be expected to be material to the Company; and (f) Liabilities described in Section 2.10 of the Company Disclosure Schedule.

2.11 **Title to Assets**. The Company and each of its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it, including: (a) all tangible assets reflected on the Company Unaudited Interim Balance Sheet; and (b) all other tangible assets reflected in the books and records of the Company or any of its Subsidiaries as being owned by the Company or such Subsidiary. All of such assets are owned or, in the case of leased assets, leased by the Company or its applicable Subsidiary free and clear of any Encumbrances, other than Permitted Encumbrances.

2.12 **Real Property; Leasehold**. Neither the Company nor any of its Subsidiaries owns or has ever owned any real property. The Company has made available to Parent (a) an accurate and complete list of all real properties with respect to which the Company directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by the Company or any of its Subsidiaries, and (b) copies of all leases under which any such real property is possessed (the "***Company Real Estate Leases***"), each of which is in full force and effect, with no existing material default thereunder. The Company's use and operation of each such leased property conforms to all applicable Laws in all material respects, and the Company has exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Encumbrances other than Permitted Encumbrances.

2.13 **Intellectual Property.**

(a) Section 2.13(a) of the Company Disclosure Schedule identifies (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application or registration number and (iv) any other co-owners, for each item of Registered IP owned in whole or in part by the Company or its Subsidiaries (the "***Company Owned Registered IP***"). Each of the patents and patent applications included in the Company Owned Registered IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. Except as set forth in Section 2.13(a) of the Company Disclosure Schedule: (A) The Company Owned Registered IP is valid, enforceable and subsisting, (B) none of the Company Owned Registered IP has been misused, withdrawn, cancelled or abandoned, and (C) all application, registration, issuance, renewal and maintenance fees due for the Company Owned Registered IP having a due date on or before the date hereof have been paid in full and are current. To the Company's Knowledge, with respect to each item of Company Owned Registered IP and each patent application from which such Company Owned Registered IP claims priority, all statements made and information presented to the applicable patent office by or on behalf of the Company or its Subsidiaries or any inventor thereof, or their respective patent counsel, during the prosecution thereof are accurate and complete and comply with 37 CFR 1.56. As of the date of this Agreement, except as set forth in Section 2.13(a) of the Company Disclosure Schedule, no interference, opposition, reissue, reexamination or other proceeding of any nature (other than initial examination proceedings) is pending or, to the Company's Knowledge, threatened in writing, in which the scope, validity, enforceability or ownership of any Company Owned Registered IP is being or has been contested or challenged.

(b) To the Company's Knowledge, Section 2.13(b) of the Company Disclosure Schedule identifies all Encumbrances of Company IP. Except as set forth in Section 2.13(a) of the Company Disclosure Schedule, the Company or its applicable Subsidiary solely owns all right, title and interest in and to all material Company IP, free and clear of all Encumbrances other than Permitted Encumbrances and, to the Company's Knowledge, has the right, pursuant to a Company In-bound License to use all other material Intellectual Property Rights used by the Company or its Subsidiaries in their respective businesses as currently conducted. The Company IP and the Intellectual Property Rights licensed to the Company or its Subsidiaries pursuant to a Company In-bound License (the

"***Company In-Licensed IP***") are all the Intellectual Property Rights necessary to operate the business of the Company and its Subsidiaries as currently conducted and as proposed to be conducted as of the date hereof. No Company Associate owns or has any claim, right (whether or not currently exercisable) or interest to or in any Company IP, and each Company Associate involved in the creation or development of any material Company IP, pursuant to such Company Associate's activities on behalf of the Company or its Subsidiaries, has signed a valid, enforceable written agreement containing a present assignment of all of such Company Associate's rights in such Company IP to the Company or its Subsidiaries (without further payment being owed to any such Company Associate and without any restrictions or obligations on the Company's or its Subsidiaries' ownership or use thereof) and confidentiality provisions protecting the Company IP, which, to the Company's Knowledge, has not been breached by such Company Associate. Without limiting the foregoing, the Company and its Subsidiaries have taken commercially reasonable steps to protect, maintain and enforce all Company IP and Company In-Licensed IP, including the secrecy, confidentiality and value of trade secrets and other confidential information therein, and to the Company's Knowledge there have been no authorized disclosures of any Company IP or Company In-Licensed IP. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will conflict with, alter or impair any of the Company's or its Subsidiaries' rights in or to any Company IP or Company In-Licensed IP or cause any payments of any kind to be due or payable to any Person.

(c) To the Company's Knowledge, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational or academic institution has been used, in whole or in part, to create any Company IP or any Company In-Licensed IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership or other rights (including any "march in" rights or a right to direct the location of manufacturing of products) to such Company IP or the right to receive royalties or other consideration for the practice of such Company IP.

(d) Section 2.13(d) of the Company Disclosure Schedule sets forth each license agreement pursuant to which the Company or any of its Subsidiaries (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by the Company or any of its Subsidiaries in its business as currently conducted (each a "***Company In-bound License***") or (ii) grants to any third party a license, option, covenant not to sue or other right under any material Company IP or any material Company In-Licensed IP (each a "***Company Out-bound License***") (*provided*, that, Company In-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, commercially available Software-as-a-Service offerings, off-the-shelf software licenses or generally available patent license agreements, in each case entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of the Company or its Subsidiaries; and Company Out-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses, in each case entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of the Company or its Subsidiaries). Neither the Company nor its Subsidiaries nor, to the Company's Knowledge, any other party to any Company In-bound License or Company Out-bound License has breached or is in breach of any of its obligations under any Company In-bound License or Company Out-bound License.

(e) To the Company's Knowledge: (i) the operation of the businesses of the Company and its Subsidiaries as currently conducted or as proposed to be conducted as of the date hereof does not infringe or misappropriate or otherwise violate any valid and enforceable Intellectual Property Right owned by any other Person; and (ii) no other Person is infringing, misappropriating or otherwise violating any Company IP or any Company In-Licensed IP. As of the date of this Agreement, no Legal Proceeding is pending (or, to the Company's Knowledge, is threatened in writing) (A) against the

Company or its Subsidiaries alleging that the operation of the businesses of the Company or its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by the Company or its Subsidiaries alleging that another Person has infringed, misappropriated or otherwise violated any of the Company IP or any Company In-Licensed IP. Since January 1, 2019, neither the Company nor any of its Subsidiaries has received any written notice or other written communication alleging that the operation of the business of the Company or its Subsidiaries infringes or constitutes the misappropriation or other violation of any Intellectual Property Right of another Person.

(f) None of the Company IP or, to the Company's Knowledge, any Company In-Licensed IP is subject to any pending or outstanding injunction, directive, order, decree, settlement, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by the Company or its Subsidiaries of any such Company IP or Company In-Licensed IP or otherwise would reasonably be expected to adversely affect the validity, scope, use, registrability, or enforceability of any Company IP or Company In-Licensed IP.

(g) To the Company's Knowledge, the Company, its Subsidiaries and the operation of the Company's and its Subsidiaries' business are in substantial compliance with all applicable Laws pertaining to data privacy and data security of any personally identifiable information and sensitive business information (collectively, "***Sensitive Data***") except to the extent that such noncompliance has not and would not reasonably be expected to have a Company Material Adverse Effect. To the Company's Knowledge, since January 1, 2019, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of the Company or its Subsidiaries, (ii) no violations of any security policy of the Company or its Subsidiaries regarding any such Sensitive Data, (iii) no unauthorized access or unauthorized use of any Sensitive Data used in the business of the Company or its Subsidiaries and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of the Company or its Subsidiaries, or a contractor or agent acting on behalf of the Company or its Subsidiaries, in each case of (i) through (iv), except as would not reasonably be expected to, individually or in the aggregate, have a Company Material Adverse Effect.

(h) None of the Company or its Subsidiaries is now nor has ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that would reasonably be expected to require or obligate any of the Company or its Subsidiaries to grant or offer to any other Person any license or right to any Company IP or Company In-Licensed IP.

2.14 **Agreements, Contracts and Commitments.**

(a) Section 2.14(a) of the Company Disclosure Schedule lists the following Company Contracts in effect as of the date of this Agreement (other than any Company Benefit Plans) (each, a "***Company Material Contract***" and collectively, the "***Company Material Contracts***"):

(i) each Contract that would be a material contract as defined in Item 601(b)(10) of Regulation S-K as promulgated under the Securities Act (assuming the Company was subject to the public reporting requirements of the Exchange Act);

(ii) each Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;

(iii) each Contract containing (A) any covenant limiting the freedom of the Company, its Subsidiaries or the Surviving Corporation to engage in any line of business or compete with any Person, (B) any "most-favored nations" pricing provisions or marketing or distribution rights related to any products or territory, (C) any exclusivity provision, (D) any agreement to purchase minimum quantity of goods or services, or (E) any material non-solicitation provisions applicable to the Company or any of its Subsidiaries;

(iv) each Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of $200,000 pursuant to its express terms and not cancelable without penalty;

(v) each Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity;

(vi) each Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit or creating any material Encumbrances with respect to any assets of the Company or any of its Subsidiaries or any loans or debt obligations with officers or directors of the Company or any of its Subsidiaries;

(vii) each Contract requiring payment by or to the Company or any of its Subsidiaries after the date of this Agreement in excess of $200,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of the Company or any of its Subsidiaries; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, collaboration, development or other agreement currently in force under which the Company or any of its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which the Company or any of its Subsidiaries has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by the Company or any of its Subsidiaries; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of the Company or any of its Subsidiaries or any Contract to sell, distribute or commercialize any products or service of the Company or any of its Subsidiaries, in each case, except for Contracts entered into in the Ordinary Course of Business;

(viii) each Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to the Company in connection with the Contemplated Transactions;

(ix) each Company Real Estate Lease;

(x) each Contract with any Governmental Body;

(xi) each Company Out-bound License and Company In-bound License;

(xii) each Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of the Company or any of its Subsidiaries; or

(xiii) any other Contract that is not terminable at will (with no penalty or payment) by the Company or its Subsidiaries, as applicable, and (A) which involves payment or receipt by the Company or its Subsidiaries after the date of this Agreement under any such agreement, contract or commitment of more than $200,000 in the aggregate, or obligations after the date of this Agreement in excess of $500,000 in the aggregate, or (B) that is material to the business or operations of the Company and its Subsidiaries, taken as a whole.

(b) The Company has delivered or made available to Parent accurate and complete copies of all Company Material Contracts, including all amendments thereto. Except as set forth in Section 2.14(b) of the Company Disclosure Schedule, there are no Company Material Contracts that are not in written form. As of the date of this Agreement, none of the Company, any of its Subsidiaries, nor, to the Company's Knowledge, any other party to a Company Material Contract, has breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Company Material Contract in such manner as would permit any other party to cancel or terminate any such Company Material Contract, or would permit

any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to the Company or its business or operations. As to the Company and its Subsidiaries, as of the date of this Agreement, each Company Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Company Material Contract to change, any material amount paid or payable to the Company or any of its Subsidiaries under any Company Material Contract or any other material term or provision of any Company Material Contract.

2.15 **Compliance; Permits; Restrictions.**

(a) The Company and each of its Subsidiaries are, and since January 1, 2019 have been, in compliance in all material respects with all applicable Laws, including the Federal Food, Drug, and Cosmetic Act ("***FDCA***"), the U.S. Food and Drug Administration ("***FDA***") regulations adopted thereunder, the Public Health Service Act and any other similar Law administered or promulgated by the FDA or other comparable Governmental Body responsible for regulation of the development, clinical testing, manufacturing, sale, marketing, distribution and importation or exportation of drug and biopharmaceutical products (each, a "***Drug Regulatory Agency***"), except for any noncompliance, either individually or in the aggregate, which would not be material to the Company. No investigation, claim, suit, proceeding, audit or other action by any Governmental Body is pending or, to the Company's Knowledge, threatened against the Company or any of its Subsidiaries. There is no agreement, judgment, injunction, order or decree binding upon the Company or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of the Company or any of its Subsidiaries, any acquisition of material property by the Company or any of its Subsidiaries or the conduct of business by the Company or any of its Subsidiaries as currently conducted, (ii) is reasonably likely to have an adverse effect on the Company's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions. Notwithstanding the foregoing, for all purposes of this Agreement, the Company does not make any representation or warranty (pursuant to this Section 2.15 or elsewhere) regarding the effect of any applicable Antitrust Laws on the Company's ability to execute, deliver or perform its obligations under this Agreement or to consummate the Contemplated Transactions as a result of any enactment, promulgation, application or threatened or actual judicial or administrative investigation or litigation under, or enforcement of, any Antitrust Laws with respect to the consummation of the Contemplated Transactions.

(b) The Company and its Subsidiaries hold all required Governmental Authorizations which are material to the operation of the business of the Company and its Subsidiaries as currently conducted (the "***Company Permits***"). Section 2.15(b) of the Company Disclosure Schedule identifies each Company Permit. The Company and its Subsidiaries hold all right, title and interest in and to all Company Permits free and clear of any Encumbrance. The Company and each of its Subsidiaries is in material compliance with the terms of the Company Permits. No Legal Proceeding is pending or, to the Company's Knowledge, threatened, which seeks to revoke, limit, suspend, or materially modify any Company Permit. The rights and benefits of each Company Permit will be available to the Surviving Corporation or its Subsidiaries, as applicable, immediately after the Effective Time on terms substantially identical to those enjoyed by the Company and its Subsidiaries as of the date of this Agreement and immediately prior to the Effective Time.

(c) There are no proceedings pending or, to the Company's Knowledge, threatened with respect to an alleged material violation by the Company or any of its Subsidiaries of the FDCA, FDA regulations adopted thereunder, the Public Health Service Act or any other similar Law administered or promulgated by any Drug Regulatory Agency. The Company is not currently conducting or addressing, and to the Company's Knowledge there is no basis to expect that it will be

required to conduct or address, any corrective actions, including, without limitation, product recalls or clinical holds.

(d) To the Company's Knowledge, all clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, the Company or its Subsidiaries, or in which the Company or its Subsidiaries or their respective current products or product candidates have participated, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, including 21 C.F.R. Parts 50, 54, 56, 58 and 312. Since January 1, 2019, neither the Company nor any of its Subsidiaries has received any notices, correspondence, or other communications from any Drug Regulatory Agency requiring, or, to the Company's Knowledge, threatening to initiate, the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, the Company or any of its Subsidiaries or in which the Company or any of its Subsidiaries or their respective current products or product candidates have participated.

(e) Neither the Company nor any of its Subsidiaries is the subject of any pending or, to the Company's Knowledge, threatened investigation in respect of its business or products by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To the Company's Knowledge, neither the Company nor any of its Subsidiaries has committed any acts, made any statement, or failed to make any statement, in each case in respect of its business or products that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. None of the Company, any of its Subsidiaries or any of their respective officers, employees or agents has been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of their business or products are pending or, to the Company's Knowledge, threatened against the Company, any of its Subsidiaries or any of their respective officers, employees or agents.

2.16 **Legal Proceedings; Orders.**

(a) As of the date of this Agreement, there is no pending Legal Proceeding and, to the Company's Knowledge, no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) the Company, (B) any of its Subsidiaries, (C) any Company Associate (in his or her capacity as such) or (D) any of the material assets owned or used by the Company or its Subsidiaries; or (ii) that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Except as set forth in Section 2.16(b) of the Company Disclosure Schedule, since January 1, 2019, no Legal Proceeding has been pending against the Company or any of its Subsidiaries that resulted in material liability to the Company or any of its Subsidiaries.

(c) There is no order, writ, injunction, judgment or decree to which the Company or any of its Subsidiaries, or any of the material assets owned or used by the Company or any of its Subsidiaries, is subject. To the Company's Knowledge, no officer or employee of the Company or any of its Subsidiaries is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of the Company or any of its Subsidiaries or to any material assets owned or used by the Company or any of its Subsidiaries.

2.17 **Tax Matters.**

(a) Except as set forth in Section 2.17(a) of the Company Disclosure Schedule, the Company and each of its Subsidiaries have timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Body in any jurisdiction where the Company or any of its Subsidiaries does not file a particular Tax Return or pay a particular Tax that the Company or such Subsidiary is subject to taxation by that jurisdiction.

(b) All material amounts of income and other Taxes due and owing by the Company or any of its Subsidiaries on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of the Company and its Subsidiaries did not, as of the date of the Company Unaudited Interim Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Company Unaudited Interim Balance Sheet. Since the date of the Company Unaudited Interim Balance Sheet, neither the Company nor any of its Subsidiaries has incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All material amounts of Taxes that the Company or any of its Subsidiaries are or were required by Law to withhold or collect on behalf of their respective employees, independent contractors, equityholders, lenders, customers, or other third parties have been duly and timely withheld or collected and have been timely paid to the proper Governmental Body or other Person or properly set aside in accounts for this purpose.

(d) There are no Encumbrances for material Taxes (other than Taxes not yet due and payable) upon any of the assets of the Company or any of its Subsidiaries.

(e) No deficiencies for income or other material Taxes with respect to the Company or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received written notice threatening any such audit, assessment or other action. Neither the Company nor any of its Subsidiaries (or any of their predecessors) has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) Neither the Company nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Neither the Company nor any of its Subsidiaries is a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) None of Parent, the Company nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) “closing agreement” as described in Section 7121 of the Code (or any similar provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in

Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; (vii) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date; (viii) application of Sections 951 or 951A of the Code (or any similar provision of state, local or foreign Law) to any income received or accrued on or prior to the Closing Date; or (ix) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. The Company has not made any election under Section 965(h) of the Code.

(i) Neither the Company nor any of its Subsidiaries has ever been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is the Company) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Neither the Company nor any of its Subsidiaries has any Liability for any material Taxes of any Person (other than the Company and any of its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Neither the Company nor any of its Subsidiaries (i) is a "controlled foreign corporation" as defined in Section 957 of the Code, (ii) is a "passive foreign investment company" within the meaning of Section 1297 of the Code, or (iii) has ever had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) Neither the Company nor any of its Subsidiaries has participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(l) Neither the Company nor any of its Subsidiaries has taken any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(m) Neither the Company nor any of its Subsidiaries has availed itself of any Tax relief pursuant to any Pandemic Response Laws that could reasonably be expected to materially impact the Tax payment and/or Tax reporting obligations of Parent and its Affiliates (including the Company and its Subsidiaries) after the Closing Date.

For purposes of this Section 2.17, each reference to the Company or any of its Subsidiaries shall be deemed to include any Person that was liquidated into, merged with, or otherwise a predecessor to, the Company or any of its Subsidiaries.

2.18 **Employee and Labor Matters; Benefit Plans.**

(a) Section 2.18(a) of the Company Disclosure Schedule lists all material Company Benefit Plans, including, without limitation, each Company Benefit Plan that provides for retirement, change in control, stay or retention, deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. "***Company Benefit Plan***" means each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based, phantom equity, employment (other than at-will employment offer letters on the Company's standard form that may be terminated without notice and with no penalty to the Company or any of its Subsidiaries and other than individual

Company Options or other compensatory equity award agreements made pursuant to the Company's standard forms, in which case only representative standard forms of such agreements shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in any case, maintained, contributed to, or required to be contributed to, by the Company or any of its Subsidiaries or Company ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of the Company or any of its Subsidiaries or under which the Company or any of its Subsidiaries has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Sections 414(b) or 414(c) of the Code with any other person).

(b) As applicable with respect to each material Company Benefit Plan, the Company has made available to Parent, true and complete copies of (i) each material Company Benefit Plan, including all amendments thereto, and in the case of an unwritten material Company Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Body (*e.g.*, Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, (vii) all records, notices and filings concerning IRS or United States Department of Labor or other Governmental Body examinations, audits or investigations, voluntary compliance programs or policies, or "prohibited transactions" within the meaning of Section 406 of ERISA or Section 4975 of the Code, and (viii) any written reports constituting a valuation of the Company's capital stock for purposes of Sections 409A or 422 of the Code, whether prepared internally by the Company or by an outside, third-party valuation firm.

(c) Each Company Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Company Benefit Plans which are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and, to the Company's Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Company Benefit Plan or the tax exempt status of the related trust.

(e) Neither the Company, any of its Subsidiaries nor any Company ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code) or (iv) any "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Body involving any Company Benefit Plan, and no pending or, to the Company's Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Company Benefit

Plans), suits or proceedings involving any Company Benefit Plan, any fiduciary thereof or service provider thereto, in any case except as would not be reasonably expected to result in material liability to the Company. All contributions and premium payments required to have been made under any of the Company Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made and neither the Company nor any Company ERISA Affiliate has any liability for any unpaid contributions with respect to any Company Benefit Plan.

(g) Neither the Company, any of its Subsidiaries or Company ERISA Affiliates, nor, to the Company's Knowledge, any fiduciary, trustee or administrator of any Company Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Company Benefit Plan which would subject any such Company Benefit Plan, the Company, any of its Subsidiaries or Company ERISA Affiliates or Parent to a material Tax, material penalty or material liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Company Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law and neither the Company nor any of its Subsidiaries or Company ERISA Affiliates has made a written or oral representation promising the same.

(i) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will, either alone or in connection with any other event(s), (i) result in any payment becoming due to any current or former employee, director, officer, independent contractor or other service provider of the Company or any Subsidiary thereof, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of the Company or any Subsidiary thereof, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Company Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Company Benefit Plan or (v) limit the right to merge, amend or terminate any Company Benefit Plan.

(j) Neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any person who is a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to the Company and its Subsidiaries of any payment or benefit that is or could be characterized as a "parachute payment" (within the meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) Each Company arrangement providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder in all material respects.

(l) No current or former employee, officer, director or independent contractor of the Company has any "gross up" agreements with the Company or any of its Subsidiaries or other assurance of reimbursement or compensation by the Company or any of its Subsidiaries for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) The Company does not have any Company Benefit Plan that is maintained for service providers located outside of the United States.

(n) There has been no amendment to, announcement by Company or any Company ERISA Affiliate relating to, or change in employee participation or coverage under, any Company Benefit Plan or collective bargaining agreement that would increase the annual expense of maintaining such plan above the level of the expense incurred for the most recently completed fiscal year (other than on a de minimis basis) with respect to any director, officer, employee, independent contractor or consultant, as applicable. Neither the Company nor any Company ERISA Affiliate has any commitment or obligation or has made any representations to any director, officer, employee, independent contractor or consultant, whether or not legally binding, to adopt, amend, modify or terminate any Company Benefit Plan or any collective bargaining agreement.

(o) Neither the Company nor any of its Subsidiaries is a party to, bound by, or has a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or, to the Company's Knowledge, purporting to represent or seeking to represent any employees of the Company or its Subsidiaries, including through the filing of a petition for representation election.

(p) The Company and each of its Subsidiaries is, and since January 1, 2018 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including without limitation worker classification, discrimination, wrongful termination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, wages (including overtime wages, timely payment of wages, and legally compliant wage statements), unemployment and workers' compensation, leaves of absence, hours of work and recordkeeping. Except as would not be reasonably likely to result in a material liability to the Company or any of its Subsidiaries, with respect to employees of the Company and its Subsidiaries, each of the Company and its Subsidiaries, since January 1, 2018: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, demands, lawsuits, investigations, audits or administrative matters pending or, to the Company's Knowledge, threatened or reasonably anticipated against the Company or any of its Subsidiaries relating to any current or former employee, applicant for employment, consultant, employment agreement or Company Benefit Plan (other than routine claims for benefits).

(q) The Company is, and at all times since January 1, 2018 has been, in material compliance with the WARN Act, 29 U.S.C. § 2101 et seq., and any applicable state analogues relating to reductions in force, terminations, mass layoffs and plant closings (collectively, the "***WARN Act***").

(r) Except as would not be reasonably likely to result in a material liability to the Company or any of its Subsidiaries or any Company Benefit Plan, with respect to each individual who currently renders services to the Company or any of its Subsidiaries, the Company and each of its Subsidiaries has properly classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, the Company and each of its Subsidiaries has properly classified him or her as overtime eligible or overtime ineligible under all applicable Laws. Neither the Company nor any of its Subsidiaries has any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages.

(s) There is not and has not been since January 1, 2018, nor is there or has there been since January 1, 2018 any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to the Company's Knowledge, any union organizing activity, against the Company or any of its Subsidiaries. No event has occurred, and, to the Company's Knowledge, no condition or circumstance exists, that might directly or indirectly give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute.

2.19 **Environmental Matters.** The Company and each of its Subsidiaries are in compliance, and since January 1, 2019 have complied, with all applicable Environmental Laws, which compliance includes the possession by the Company of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either individually or in the aggregate, would not reasonably be expected to be material to the Company or its business. Neither the Company nor any of its Subsidiaries has received since January 1, 2019 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that the Company or any of its Subsidiaries is not in compliance with or has liability pursuant to any Environmental Law and, to the Company's Knowledge, there are no circumstances that would reasonably be expected to prevent or interfere with the Company's or any of its Subsidiaries' compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to the Company or its business. No current or (during the time a prior property was leased or controlled by the Company or any of its Subsidiaries) prior property leased or controlled by the Company or any of its Subsidiaries has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of the Company or any of its Subsidiaries pursuant to Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by Environmental Laws in connection with the execution and delivery of this Agreement or the consummation of the Contemplated Transactions. Prior to the date hereof, the Company has provided or otherwise made available to Parent true and correct copies of all material environmental reports, assessments, studies and audits in the possession or control of the Company or any of its Subsidiaries with respect to any property leased or controlled by the Company or any of its Subsidiaries or any business operated by them.

2.20 **Insurance**. The Company has delivered or made available to Parent accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of the Company and each of its Subsidiaries. Each of such insurance policies is in full force and effect and the Company and each of its Subsidiaries are in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2019, neither the Company nor any of its Subsidiaries has received any notice or other communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. The Company and each of its Subsidiaries have provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against the Company or any of its Subsidiaries for which the Company or such Subsidiary has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed the Company or any of its Subsidiaries of its intent to do so.

2.21 **No Financial Advisors**. Except as set forth in Section 2.21 of the Company Disclosure Schedule, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated

Transactions based upon arrangements made by or on behalf of the Company or any of its Subsidiaries.

2.22 **Transactions with Affiliates.**

(a) Section 2.22(a) of the Company Disclosure Schedule describes any material transactions or relationships, since January 1, 2019, between, on one hand, the Company or any of its Subsidiaries and, on the other hand, any (i) executive officer or director of the Company or, to the Company's Knowledge, any of its Subsidiaries or any of such executive officer's or director's immediate family members, (ii) owner of more than 5% of the voting power of the outstanding Company Capital Stock or (iii) to the Company's Knowledge, any "related person" (within the meaning of Item 404 of Regulation S-K as promulgated under the Securities Act) of any such executive officer, director or equityholder (other than the Company or its Subsidiaries) in the case of each of (i), (ii) or (iii) that is of the type that would be required to be disclosed under Item 404 of Regulation S-K as promulgated under the Securities Act (assuming the Company was subject to the public reporting requirements of the Exchange Act).

(b) Section 2.22(b) of the Company Disclosure Schedule lists each stockholders' agreement, voting agreement, registration rights agreement, co-sale agreement or other similar Contract (other than the Company Stockholder Support Agreements and the Company Lock-Up Agreements) between the Company and any holders of Company Capital Stock, including any such Contract granting any Person investor rights, rights of first refusal, rights of first offer, registration rights, director designation rights or similar rights (collectively, the "***Investor Agreements***").

2.23 **Anti-Bribery**. None of the Company or any of its Subsidiaries or any of their respective directors, officers, employees or, to the Company's Knowledge, agents or any other Person acting on their behalf has, directly or indirectly, made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of the Foreign Corrupt Practices Act of 1977, the UK Bribery Act of 2010 or any other anti-bribery or anti-corruption Law (collectively, the "***Anti-Bribery Laws***"). Neither the Company nor any of its Subsidiaries is or has been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

2.24 **Disclaimer of Other Representations or Warranties**. Except as previously set forth in this Section 2 or in any certificate delivered by the Company to Parent and/or Merger Sub pursuant to this Agreement, the Company makes no representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed.

Section 3. REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Subject to Section 10.13(h), except (a) as set forth in the disclosure schedule delivered by Parent to the Company (the "***Parent Disclosure Schedule***") or (b) as disclosed in the Parent SEC Documents filed with, or furnished to, the SEC prior to the date hereof and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system (but (i) without giving effect to any amendment thereof filed with, or furnished to, the SEC on or after the date hereof and (ii) excluding any disclosures contained under the heading "Risk Factors" and any disclosure of risks included in any "forward-looking statements" disclaimer or in any other section to the extent they are forward-looking statements or cautionary, predictive or forward-looking in nature), it being understood that any matter disclosed in the Parent SEC Documents (x) shall not be deemed disclosed for the purposes of Section 3.1, Section 3.2, Section 3.3, Section 3.4, Section 3.5 or Section 3.6; and (y) shall be deemed to be disclosed in a section of the Parent Disclosure Schedule only to the extent that it is reasonably

apparent from a reading of the applicable Parent SEC Document that it is applicable to such section of the Parent Disclosure Schedule, Parent and Merger Sub represent and warrant to the Company as follows:

3.1 **Due Organization; No Subsidiaries.**

(a) Each of Parent and Merger Sub is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware, and has all necessary corporate power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own or lease and use its property and assets in the manner in which its property and assets are currently owned or leased and used; and (iii) to perform its obligations under all Contracts by which it is bound, except where the failure to have such power or authority would not reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions. Since the date of its incorporation, Merger Sub has not engaged in any activities other than activities incident to its formation or in connection with or as contemplated by this Agreement.

(b) Parent is duly licensed and qualified to do business, and is in good standing (to the extent applicable in such jurisdiction), under the Laws of all jurisdictions where the nature of its business requires such licensing or qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Parent Material Adverse Effect.

(c) Other than Merger Sub, Parent does not have any Subsidiary.

(d) Parent is not and has not otherwise been, directly or indirectly, a party to, member of or participant in any partnership, joint venture or similar business entity. Parent has not agreed and is not obligated to make, and is not bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Parent has not, at any time, been a general partner of, and has not otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

3.2 **Organizational Documents.** Parent has made available to the Company accurate and complete copies of Parent's and Merger Sub's Organizational Documents in effect as of the date of this Agreement. Neither Parent nor Merger Sub is in material breach or violation of its respective Organizational Documents.

3.3 **Authority; Binding Nature of Agreement**. Each of Parent and Merger Sub has all necessary corporate power and authority to enter into this Agreement and, subject, with respect to Parent, to receipt of the Required Parent Stockholder Vote and, with respect to Merger Sub, the adoption of this Agreement by Parent in its capacity as sole stockholder of Merger Sub, to perform its obligations under this Agreement and to consummate the Contemplated Transactions. The Parent Board has unanimously: (a) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Parent and its stockholders; (b) approved and declared advisable this Agreement and the Contemplated Transactions, including the authorization and issuance of shares of Parent Common Stock to the stockholders of the Company pursuant to the terms of this Agreement, the change of control of Parent and other actions contemplated by this Agreement; and (c) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the stockholders of Parent vote to approve the Parent Stockholder Matters and the Other Parent Stockholder Matters. The Merger Sub Board (by unanimous written consent) has: (x) determined that the Contemplated Transactions are fair to, advisable and in the best interests of Merger Sub and its sole stockholder; (y) approved and declared advisable this Agreement and the Contemplated

Transactions; and (z) determined to recommend, upon the terms and subject to the conditions set forth in this Agreement, that the sole stockholder of Merger Sub vote to approve this Agreement and the Contemplated Transactions. This Agreement has been duly executed and delivered by Parent and Merger Sub and, assuming the due authorization, execution and delivery by the Company, constitutes the legal, valid and binding obligation of Parent and Merger Sub, enforceable against each of Parent and Merger Sub in accordance with its terms, subject to the Enforceability Exceptions. Prior to the execution of the Parent Stockholder Support Agreements, the Parent Board approved the Parent Stockholder Support Agreements and the transactions contemplated thereby.

3.4 **Vote Required**. The affirmative vote of a majority of the votes cast is the only vote of the holders of any class or series of Parent's capital stock necessary to approve the Parent Stockholder Matters (the "***Required Parent Stockholder Vote***").

3.5 **Non-Contravention; Consents**. Subject to obtaining the Required Parent Stockholder Vote and the filing of the Certificate of Merger required by the DGCL and subject to making all filings and notifications as may be required in connection with the transactions described herein under the HSR Act and any other Antitrust Laws and obtaining all consents, authorizations, clearances, approvals and waiting period expirations or terminations as may be required in connection with the transactions described herein under the HSR Act and other Antitrust Laws, neither (x) the execution, delivery or performance of this Agreement by Parent or Merger Sub, nor (y) the consummation of the Contemplated Transactions, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of any of the provisions of the Organizational Documents of Parent or Merger Sub;

(b) contravene, conflict with or result in a violation of, or give any Governmental Body the right to challenge the Contemplated Transactions or to exercise any remedy or obtain any relief under, any Law or any order, writ, injunction, judgment or decree to which Parent or Merger Sub, or any of the assets owned or used by Parent or Merger Sub, is subject, except as would not reasonably be expected to be material to Parent or its business;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Parent, except as would not reasonably be expected to be material to Parent or its business;

(d) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Parent Material Contract, or give any Person the right to: (i) declare a default or exercise any remedy under any Parent Material Contract; (ii) any material payment, rebate, chargeback, penalty or change in delivery schedule under any Parent Material Contract; (iii) accelerate the maturity or performance of any Parent Material Contract; or (iv) cancel, terminate or modify any term of any Parent Material Contract, except in the case of any non-material breach, default, penalty or modification; or

(e) result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by Parent (except for Permitted Encumbrances).

Except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware pursuant to the DGCL, and (ii) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities Laws, the HSR Act or other Antitrust Laws, Parent is not and will not be required to make any filing with or give any notice to, or to obtain any Consent from, any Governmental Body in connection with (x) the

execution, delivery or performance of this Agreement, or (y) the consummation of the Contemplated Transactions, which if individually or in the aggregate were not given or obtained, would reasonably be expected to prevent or materially delay the ability of Parent and Merger Sub to consummate the Contemplated Transactions. The Parent Board and the Merger Sub Board have taken and will take all actions necessary to ensure that the restrictions applicable to business combinations contained in Section 203 of the DGCL are, and will be, inapplicable to the execution, delivery and performance of this Agreement, the Parent Stockholder Support Agreements and the Parent Lock-up Agreements and to the consummation of the Contemplated Transactions. No other state takeover statute or similar Law applies or purports to apply to the Merger, this Agreement, the Parent Stockholder Support Agreements, the Parent Lock-up Agreements or any of the Contemplated Transactions.

3.6 **Capitalization.**

(a) The authorized capital stock of Parent as of the date of this Agreement consists of (i) 200,000,000 shares of Parent Common Stock, par value $0.0001 per share, of which 35,187,344 shares have been issued and are outstanding as of the close of business on the Reference Date, of which 16,175 shares are subject to Parent's right of repurchase, and (ii) 10,000,000 shares of preferred stock of Parent, par value $0.0001 per share, of which no shares have been issued and are outstanding as of the date of this Agreement. Parent does not hold any shares of its capital stock in its treasury.

(b) All of the outstanding shares of Parent Common Stock have been duly authorized and validly issued, and are fully paid and nonassessable. None of the outstanding shares of Parent Common Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Parent Common Stock is subject to any right of first refusal in favor of Parent. Except as contemplated herein and as set forth in Section 3.6(b)(i) of the Parent Disclosure Schedule, there is no Parent Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Parent Common Stock. Except as set forth in Section 3.6(b)(ii) of the Parent Disclosure Schedule, Parent is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Parent Common Stock or other securities.

(c) Except for the Parent Plans, Parent does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. As of the close of business on the Reference Date, Parent has (i) reserved 11,591,459 shares of Parent Common Stock for issuance under the Parent Equity Incentive Plans, of which 547,337 shares have been issued and are currently outstanding, of which 16,175 shares are subject to Parent's right of repurchase, 8,572,491 shares have been reserved for issuance upon exercise of Parent Options previously granted and currently outstanding under the Parent Equity Incentive Plans, 738,350 shares have been reserved for issuance upon the settlement of Parent RSUs granted under the Parent Equity Incentive Plans that are outstanding as of the close of business on the Reference Date, and 1,733,281 shares remain available for future issuance pursuant to the Parent Equity Incentive Plans; and (ii) 1,049,354 shares have been reserved and available for purchase under the Parent ESPP, 109,781 shares have been issued under the Parent ESPP and 939,573 shares remain available for future purchase under the Parent ESPP.

(d) Except for the Parent Plans, including the Parent Options, the Parent RSUs and purchase rights under the Parent ESPP, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of Parent or Merger Sub; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of

Parent or Merger Sub; or (iii) condition or circumstance that could be reasonably likely to give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other securities of Parent or Merger Sub. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Parent or Merger Sub.

(e) All outstanding shares of Parent Common Stock, Parent Options, Parent RSUs and other securities of Parent have been issued and granted in material compliance with (i) all applicable securities Laws and other applicable Laws, and (ii) all requirements set forth in applicable Contracts.

3.7 **SEC Filings; Financial Statements.**

(a) Other than such documents that can be obtained on the SEC's website at www.sec.gov, Parent has delivered or made available to the Company accurate and complete copies of all registration statements, proxy statements, Certifications (as defined below) and other statements, reports, schedules, forms and other documents filed by Parent with the SEC since December 2, 2020 (the "***Parent SEC Documents***"). All material statements, reports, schedules, forms and other documents required to have been filed by Parent or its officers with the SEC have been so filed on a timely basis. As of the time it was filed with the SEC (or, if amended or superseded by a filing prior to the date of this Agreement, then on the date of such filing), each of the Parent SEC Documents complied in all material respects with the applicable requirements of the Securities Act or the Exchange Act (as the case may be) and, as of the time they were filed, none of the Parent SEC Documents contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The certifications and statements required by (i) Rule 13a-14 under the Exchange Act and (ii) 18 U.S.C. §1350 (Section 906 of the Sarbanes-Oxley Act) relating to the Parent SEC Documents (collectively, the "***Certifications***") are accurate and complete and comply as to form and content with all applicable Laws. As used in this Section 3.7, the term "file" and variations thereof shall be broadly construed to include any manner in which a document or information is furnished, supplied or otherwise made available to the SEC.

(b) The financial statements (including any related notes) contained or incorporated by reference in the Parent SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP (except as may be indicated in the notes to such financial statements or, in the case of unaudited financial statements, except as permitted by the SEC on Form 10-Q under the Exchange Act, and except that the unaudited financial statements may not contain footnotes and are subject to normal and recurring year-end adjustments, none of which are material) applied on a consistent basis unless otherwise noted therein throughout the periods indicated; and (iii) fairly present, in all material respects, the financial position of Parent as of the respective dates thereof and the results of operations and cash flows of Parent for the periods covered thereby. Other than as expressly disclosed in the Parent SEC Documents filed prior to the date hereof, there has been no material change in Parent's accounting methods or principles that would be required to be disclosed in Parent's financial statements in accordance with GAAP.

(c) Since January 1, 2019 through the date of this Agreement, Parent has not received any comment letter from the SEC or the staff thereof or any correspondence from officials of Nasdaq or the staff thereof relating to the delisting or maintenance of listing of the Parent Common Stock on Nasdaq.

(d) Since January 1, 2019 through the date of this Agreement, there have been no formal internal investigations regarding financial reporting or accounting policies and practices

discussed with, reviewed by or initiated at the direction of the Chief Executive Officer, Chief Financial Officer or general counsel of Parent, the Parent Board or any committee thereof. Since January 1, 2019, neither Parent nor, to Parent's Knowledge, its independent auditors have identified (i) any significant deficiency or material weakness in the design or operation of the system of internal accounting controls utilized by Parent, (ii) any fraud, whether or not material, that involves Parent, Parent's management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by Parent or (iii) any claim or allegation regarding any of the foregoing.

(e) As of the date of this Agreement, Parent is in compliance in all material respects with the applicable current listing and governance rules and regulations of Nasdaq.

(f) Parent maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and to provide reasonable assurance (i) that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, (ii) that receipts and expenditures are made only in accordance with authorizations of management and the Parent Board and (iii) regarding prevention or timely detection of the unauthorized acquisition, use or disposition of Parent's assets that could have a material effect on Parent's financial statements. Parent has evaluated the effectiveness of Parent's internal control over financial reporting as of December 31, 2021, and, to the extent required by applicable Law, presented in any applicable Parent SEC Document that is a report on Form 10-K or Form 10-Q (or any amendment thereto) its conclusions about the effectiveness of the internal control over financial reporting as of the end of the period covered by such report or amendment based on such evaluation. Parent has disclosed, based on its most recent evaluation of internal control over financial reporting, to Parent's auditors and audit committee (and made available to the Company a summary of the significant aspects of such disclosure) (A) all significant deficiencies, if any, in the design or operation of internal control over financial reporting that are reasonably likely to adversely affect Parent's ability to record, process, summarize and report financial information and (B) any known fraud that involves management or other employees who have a significant role in Parent's internal control over financial reporting. Parent has not identified, based on its most recent evaluation of internal control over financial reporting, any material weaknesses in the design or operation of Parent's internal control over financial reporting.

(g) Parent maintains "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) that are reasonably designed to ensure that information required to be disclosed by Parent in the periodic reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods, and that all such information is accumulated and communicated to Parent's management as appropriate to allow timely decisions regarding required disclosure and to make the Certifications.

3.8 **Absence of Changes**. Except as set forth in Section 3.8 of the Parent Disclosure Schedule and reasonable and good faith actions or omissions taken to comply with applicable Law or guidance by a Governmental Body in connection with the COVID-19 pandemic, between the date of the Parent Balance Sheet and the date of this Agreement, Parent has conducted its business only in the Ordinary Course of Business (except for the execution and performance of this Agreement and the discussions, negotiations and transactions related thereto, including the Contemplated Transactions) and there has not been any (a) Parent Material Adverse Effect or (b) action, event or occurrence that would have required the consent of the Company pursuant to Section 4.1(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

3.9 **No Competitive Products**. Parent has no current products, or products in development, for the treatment of allergic reactions using epinephrine nasal spray.

3.10 **Absence of Undisclosed Liabilities.** As of the date hereof, Parent does not have any Liability, individually or in the aggregate, of a type required to be recorded or reflected on a balance sheet or disclosed in the footnotes thereto under GAAP except for: (a) Liabilities disclosed, reflected or reserved against in the Parent Balance Sheet; (b) Liabilities that have been incurred by Parent since the date of the Parent Balance Sheet in the Ordinary Course of Business; (c) Liabilities for performance of obligations of Parent under Parent Material Contracts which have not resulted from a breach of such Parent Material Contracts or violation of Law; (d) Liabilities incurred in connection with the Contemplated Transactions; (e) Liabilities which would not, individually or in the aggregate, reasonably be expected to be material to Parent; and (f) Liabilities described in Section 3.10 of the Parent Disclosure Schedule.

3.11 **Title to Assets**. Parent owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or tangible assets and equipment used or held for use in its business or operations or purported to be owned by it, including: (a) all tangible assets reflected on the Parent Balance Sheet; and (b) all other tangible assets reflected in the books and records of Parent as being owned by Parent. All of such assets are owned or, in the case of leased assets, leased by Parent free and clear of any Encumbrances, other than Permitted Encumbrances.

3.12 **Real Property; Leasehold**. Parent does not own any real property. Parent has made available to the Company (a) an accurate and complete list of all real properties with respect to which Parent directly or indirectly holds a valid leasehold interest as well as any other real estate that is in the possession of or leased by Parent, and (b) copies of all leases under which any such real property is possessed (the "***Parent Real Estate Leases***"), each of which is in full force and effect, with no existing material default thereunder. Parent's use and operation of each such leased property conforms to all applicable Laws in all material respects, and Parent has exclusive possession of each such leased property and has not granted any occupancy rights to tenants or licensees with respect to such leased property. In addition, each such leased property is free and clear of all Encumbrances other than Permitted Encumbrances.

3.13 **Intellectual Property.**

(a) Section 3.13(a) of the Parent Disclosure Schedule identifies (i) the name of the applicant/registrant, (ii) the jurisdiction of application/registration, (iii) the application, registration or grant number and (iv) any other co-owners, for each item of Registered IP owned in whole or in part by Parent ("***Parent Owned Registered IP***"). To Parent's Knowledge, each of the patents and patent applications included in the Parent Owned Registered IP properly identifies by name each and every inventor of the inventions claimed therein as determined in accordance with applicable Laws of the United States. Except as set forth in Section 3.13(a) of the Parent Disclosure Schedule and to Parent's Knowledge: (A) the Parent Owned Registered IP is valid, enforceable and subsisting, (B) none of the Parent Owned Registered IP has been misused, withdrawn, cancelled or abandoned, and (C) all application, registration, issuance, renewal and maintenance fees due for the Parent Owned Registered IP having a due date on or before the date hereof have been paid in full and are current, except where the failure to do so would not be reasonably expected to have a material and adverse effect on Parent. To Parent's Knowledge, with respect to each item of Parent Owned Registered IP and each patent application from which such Parent Owned Registered IP claims priority, all statements made and information presented to the applicable patent office by or on behalf of Parent or any inventor thereof, or their respective patent counsel, during the prosecution thereof are accurate and complete and comply with 37 CFR 1.56. As of the date of this Agreement, no interference, opposition, reissue, reexamination or other proceeding of any nature (other than initial examination proceedings) is pending or, to Parent's Knowledge, threatened in writing, in which the scope, validity, enforceability or ownership of any Parent Owned Registered IP is being or has been contested or

challenged, except as would not be reasonably expected to have, individually or in the aggregate, a material and adverse effect on Parent.

(b) Parent solely owns all right, title and interest in and to all material Parent IP free and clear of all Encumbrances other than Permitted Encumbrances. To Parent's Knowledge, each Parent Associate involved in the creation or development of any material Parent IP, pursuant to such Parent Associate's activities on behalf of Parent, has signed a valid, enforceable written agreement containing a present assignment of all such Parent Associate's rights in such material Parent IP to Parent (without further payment being owed to any such Parent Associate and without any restrictions or obligations on Parent's ownership or use thereof) and confidentiality provisions protecting the Parent IP, which, to Parent's Knowledge, has not been materially breached by such Parent Associate.

(c) To Parent's Knowledge, no funding, facilities or personnel of any Governmental Body or any university, college, research institute or other educational or academic institution has been used, in whole or in part, to create any Parent IP, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership or other rights (including any "march in" rights or a right to direct the location of manufacturing of products) to such Parent IP or the right to receive royalties or other consideration for the practice of such Parent IP, except as would not be reasonably expected to have, individually or in the aggregate, a material and adverse effect on Parent.

(d) Section 3.13(d) of the Parent Disclosure Schedule sets forth each license agreement pursuant to which Parent (i) is granted a license under any material Intellectual Property Right owned by any third party that is used by Parent in its business as currently conducted (each a "***Parent In-bound License***") or (ii) grants to any third party a license, option, covenant not to sue or other right under any material Parent IP or any material Intellectual Property Right licensed to Parent under a Parent In-bound License (each a "***Parent Out-bound License***") (*provided*, that, Parent In-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, commercially available Software-as-a-Service offerings, off-the-shelf software licenses or generally available patent license agreements entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of Parent; and Parent Out-bound Licenses shall not include material transfer agreements, clinical trial agreements, services agreements, non-disclosure agreements, or non-exclusive outbound licenses entered into in the Ordinary Course of Business on a non-exclusive basis and that do not grant any commercial rights to any products or services of Parent). Neither Parent nor, to Parent's Knowledge, any other party to any Parent In-bound License or Parent Out-bound License has breached or is in breach of any of its obligations under any Parent In-bound License or Parent Out-bound License.

(e) Except as set forth in Section 3.13(e) of the Parent Disclosure Schedule and to Parent's Knowledge, (i) the operation of the business of Parent as currently conducted does not infringe any valid and enforceable Registered IP or misappropriate or otherwise violate any other Intellectual Property Right owned by any other Person; and (ii) no other Person is infringing, misappropriating or otherwise violating any Parent IP or any material Intellectual Property Rights exclusively licensed to Parent ("***Parent In-Licensed IP***"), except as would not be reasonably expected to have, individually or in the aggregate, a material and adverse effect on Parent. As of the date of this Agreement, no Legal Proceeding is pending (or, to Parent's Knowledge, is threatened in writing) (A) against Parent alleging that the operation of the business of Parent infringes or constitutes the misappropriation or other violation of any Intellectual Property Rights of another Person or (B) by Parent alleging that another Person has infringed, misappropriated or otherwise violated any of Parent IP or any Parent In-Licensed IP. Since January 1, 2019, Parent has not received any written notice or other written communication alleging that the operation of the business of Parent infringes or

constitutes the misappropriation or other violation of any Intellectual Property Right of another Person, except as would not be reasonably expected to have, individually or in the aggregate, a material and adverse effect on Parent.

(f) None of the Parent IP or, to Parent's Knowledge, any Parent In-Licensed IP is subject to any pending or outstanding injunction, directive, order, judgment or other disposition of dispute that adversely and materially restricts the use, transfer, registration or licensing by Parent of any such Parent IP or Parent In-Licensed IP, or otherwise would reasonably be expected to adversely affect the validity, scope, use, registrability, or enforceability of any Parent IP or Parent In-Licensed IP.

(g) To Parent's Knowledge, Parent and the operation of Parent's business are in substantial compliance with all applicable Laws pertaining to data privacy and data security of Sensitive Data, except to the extent that such noncompliance has not and would not reasonably be expected to have a Parent Material Adverse Effect. To Parent's Knowledge, since January 1, 2019, there have been (i) no material losses or thefts of data or security breaches relating to Sensitive Data used in the business of Parent, (ii) no violations of any security policy of Parent regarding any such Sensitive Data, (iii) no unauthorized access or unauthorized use of any Sensitive Data used in the business of Parent and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of Parent or a contractor or agent acting on behalf of Parent, in each case of (i) through (iv), except as would not reasonably be expected to, individually or in the aggregate, have a Parent Material Adverse Effect.

(h) Parent is not now nor has it ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that would reasonably be expected to require or obligate Parent to grant or offer to any other Person any license or right to any Parent IP.

3.14 **Agreements, Contracts and Commitments.**

(a) Section 3.14 of the Parent Disclosure Schedule lists the following Parent Contracts in effect as of the date of this Agreement (other than any Parent Benefit Plan) (each, a "***Parent Material Contract***" and collectively, the "***Parent Material Contracts***"):

(i) a material contract as defined in Item 601(b)(10) of Regulation S-K as promulgated under the Securities Act;

(ii) each Contract relating to any agreement of indemnification or guaranty not entered into in the Ordinary Course of Business;

(iii) each Contract containing (A) any covenant limiting the freedom of Parent to engage in any line of business or compete with any Person, (B) any "most-favored nations" pricing provisions or marketing or distribution rights related to any products or territory, (C) any exclusivity provision, (D) any agreement to purchase minimum quantity of goods or services, or (E) any material non-solicitation provisions applicable to Parent;

(iv) each Contract relating to capital expenditures and requiring payments after the date of this Agreement in excess of $200,000 pursuant to its express terms and not cancelable without penalty;

(v) each Contract relating to the disposition or acquisition of material assets or any ownership interest in any Entity;

(vi) each Contract relating to any mortgages, indentures, loans, notes or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit or creating any material Encumbrances with respect to any assets of Parent or any loans or debt obligations with officers or directors of Parent;

(vii) each Contract requiring payment by or to Parent after the date of this Agreement in excess of $200,000 pursuant to its express terms relating to: (A) any distribution agreement (identifying any that contain exclusivity provisions); (B) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Parent; (C) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Parent has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Parent has continuing obligations to develop any Intellectual Property Rights that will not be owned, in whole or in part, by Parent; or (D) any Contract to license any third party to manufacture or produce any product, service or technology of Parent or any Contract to sell, distribute or commercialize any products or service of Parent, in each case, except for Contracts entered into in the Ordinary Course of Business;

(viii) each Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to Parent in connection with the Contemplated Transactions;

(ix) each Parent Real Estate Lease;

(x) each Contract with any Governmental Body;

(xi) each Parent Out-bound License and Parent In-bound License;

(xii) each Contract containing any royalty, dividend or similar arrangement based on the revenues or profits of Parent; or

(xiii) any other Contract that is not terminable at will (with no penalty or payment) by Parent and (A) which involves payment or receipt by Parent after the date of this Agreement under any such agreement, contract or commitment of more than $200,000 in the aggregate, or obligations after the date of this Agreement in excess of $500,000 in the aggregate, or (B) that is material to the business or operations of Parent.

(b) Parent has delivered or made available to the Company accurate and complete copies of all Parent Material Contracts, including all amendments thereto. There are no Parent Material Contracts that are not in written form. As of the date of this Agreement, neither Parent nor, to Parent's Knowledge, any other party to a Parent Material Contract, has breached, violated or defaulted under, or received notice that it breached, violated or defaulted under, any of the terms or conditions of, or Laws applicable to, any Parent Material Contract in such manner as would permit any other party to cancel or terminate any such Parent Material Contract, or would permit any other party to seek damages or pursue other legal remedies which would reasonably be expected to be material to Parent or its business or operations. As to Parent, as of the date of this Agreement, each Parent Material Contract is valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions. No Person is renegotiating, or has a right pursuant to the terms of any Parent Material Contract to change, any material amount paid or payable to Parent under any Parent Material Contract or any other material term or provision of any Parent Material Contract.

3.15 **Compliance; Permits; Restrictions.**

(a) Parent is, and since January 1, 2019 has been, in compliance in all material respects with all applicable Laws, including the FDCA, the FDA regulations adopted thereunder, the Public Health Service Act and any other similar Law administered or promulgated by the FDA or other Drug Regulatory Agency, except for any noncompliance, either individually or in the aggregate, which would not be material to Parent. No investigation, claim, suit, proceeding, audit or other action by any Governmental Body is pending or, to Parent's Knowledge, threatened against Parent or any of Parent's officers, directors, managing employees, agents or representatives, in their capacity as such. There is

no agreement, judgment, injunction, order or decree binding upon Parent which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of Parent or any of Parent's officers, directors, managing employees, agents or representatives, in their capacity as such, any acquisition of material property by Parent or the conduct of business by Parent as currently conducted, (ii) is reasonably likely to have an adverse effect on Parent's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) is reasonably likely to have the effect of preventing, delaying, making illegal or otherwise interfering with the Contemplated Transactions. Notwithstanding the foregoing, for all purposes of this Agreement, Parent does not make any representation or warranty (pursuant to this Section 3.15 or elsewhere) regarding the effect of any applicable Antitrust Laws on Parent's ability to execute, deliver or perform its obligations under this Agreement or to consummate the Contemplated Transactions as a result of any enactment, promulgation, application or threatened or actual judicial or administrative investigation or litigation under, or enforcement of, any Antitrust Laws with respect to the consummation of the Contemplated Transactions.

(b) Parent holds all required Governmental Authorizations which are material to the operation of the business of Parent as currently conducted (the "***Parent Permits***"). Section 3.15(b) of the Parent Disclosure Schedule identifies each Parent Permit. Parent holds all right, title and interest in and to all Parent Permits free and clear of any Encumbrance. Parent is in material compliance with the terms of the Parent Permits. No Legal Proceeding is pending or, to Parent's Knowledge, threatened, which seeks to revoke, limit, suspend, or materially modify any Parent Permit.

(c) There are no proceedings pending or, to Parent's Knowledge, threatened with respect to an alleged material violation by Parent or any of Parent's officers, directors, managing employees, agents or representatives, in their capacity as such, of the FDCA, FDA regulations adopted thereunder, the Public Health Service Act or any other similar Law administered or promulgated by any Drug Regulatory Agency. Parent is not currently conducting or addressing, and to Parent's Knowledge there is no basis to expect that it will be required to conduct or address, any corrective actions, including, without limitation, product recalls or clinical holds.

(d) All clinical, pre-clinical and other studies and tests conducted by or on behalf of, or sponsored by, Parent, or in which Parent or its respective current products or product candidates have participated, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and in compliance in all material respects with the applicable regulations of any applicable Drug Regulatory Agency and other applicable Law, including 21 C.F.R. Parts 50, 54, 56, 58 and 312. Since January 1, 2019, Parent has not received any notices, correspondence, or other communications from any Drug Regulatory Agency requiring, or, to Parent's Knowledge, threatening to initiate, the termination or suspension of any clinical studies conducted by or on behalf of, or sponsored by, Parent or in which Parent or its current products or product candidates have participated. To Parent's Knowledge, any third party that is a contractor for Parent is in material compliance with all Governmental Authorizations from the FDA or comparable Governmental Body insofar as they pertain to the manufacture, development, testing, and/or distribution of the products or product candidates of Parent.

(e) Parent has not received any Form FDA-483, notice of adverse finding, FDA warning letters, notice of violation or "untitled letters," or notice of FDA action for import detentions or refusals to allow entry into the United States from the FDA or other Governmental Body alleging or asserting noncompliance with any applicable Law or Governmental Authorization. Parent is not subject to any obligation arising under an FDA inspection, FDA warning letter, FDA notice of violation letter or other enforcement notice, response or commitment made to or with the FDA or any comparable Governmental Body.

(f) Parent is not the subject of any pending or, to Parent's Knowledge, threatened investigation in respect of its business or products by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To Parent's Knowledge, Parent has not committed any acts, made any statement, or has not failed to make any statement, in each case in respect of its business or products that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. Parent or any of its officers, employees or agents has not been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion (i) under 21 U.S.C. Section 335a or (ii) any similar applicable Law. No debarment or exclusionary claims, actions, proceedings or investigations in respect of their business or products are pending or, to Parent's Knowledge, threatened against Parent or any of its officers, employees or agents.

(g) Parent has complied with all Laws relating to patient, medical or individual health information, including the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations promulgated thereunder, all as amended from time to time (collectively, "***HIPAA***"), including the standards for the privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and E, the standards for the protection of Electronic Protected Health Information set forth at 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subpart A and Subpart C, the standards for transactions and code sets used in electronic transactions at 45 C.F.R. Part 160, Subpart A and Part 162, and the standards for Breach Notification for Unsecured Protected Health Information at 45 C.F.R. Part 164, Subpart D, all as amended from time to time. Parent has entered into, where required, and is in compliance in all material respects with the terms of all Business Associate agreements ("***Business Associate Agreements***") to which Parent is a party or otherwise bound. Parent has created and maintained written policies and procedures to protect the privacy of all protected health information, provide training to all employees and agents as required under HIPAA, and has implemented security procedures, including physical, technical and administrative safeguards, to protect all personal information and Protected Health Information stored or transmitted in electronic form. Parent has not received written notice from the Office for Civil Rights for the U.S. Department of Health and Human Services or any other Governmental Body of any allegation regarding its failure to comply with HIPAA or any other state law or regulation applicable to the protection of individually identifiable health information or personally identifiable information. No successful "Security Incident," "Breach of Unsecured Protected Health Information" or breach of personally identifiable information under applicable state or federal laws have occurred with respect to information maintained or transmitted to Parent or an agent or third party subject to a Business Associate Agreement with Parent. Parent is currently submitting, receiving and handling or is capable of submitting receiving and handling transactions in accordance with the Standard Transaction Rule. All capitalized terms in this Section 3.15(g) not otherwise defined in this Agreement shall have the meanings set forth under HIPAA.

3.16 **Legal Proceedings; Orders.**

(a) As of the date of this Agreement, except as set forth in Section 3.16(a) of the Parent Disclosure Schedule, there is no pending Legal Proceeding and, to Parent's Knowledge, no Person has threatened in writing to commence any Legal Proceeding: (i) that involves (A) Parent, (B) any Parent Associate (in his or her capacity as such) or (C) any of the material assets owned or used by Parent; or (ii) that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the Contemplated Transactions.

(b) Since January 1, 2019, no Legal Proceeding has been pending against Parent that resulted in material liability to Parent.

(c) There is no order, writ, injunction, judgment or decree to which Parent, or any of the material assets owned or used by Parent, is subject. To Parent's Knowledge, no officer or employee of Parent is subject to any order, writ, injunction, judgment or decree that prohibits such officer or employee from engaging in or continuing any conduct, activity or practice relating to the business of Parent or to any material assets owned or used by Parent.

3.17 **Tax Matters.**

(a) Parent has timely filed all income Tax Returns and other material Tax Returns that they were required to file under applicable Law. All such Tax Returns are correct and complete in all material respects and have been prepared in compliance with all applicable Law. No written claim has ever been made by any Governmental Body in any jurisdiction where Parent does not file a particular Tax Return or pay a particular Tax that Parent is subject to taxation by that jurisdiction.

(b) All material amounts of income and other Taxes due and owing by Parent on or before the date hereof (whether or not shown on any Tax Return) have been fully paid. The unpaid Taxes of Parent did not, as of the date of the Parent Balance Sheet, materially exceed the reserve for Tax liability (excluding any reserve for deferred Taxes established to reflect timing differences between book and Tax items) set forth on the face of the Parent Balance Sheet. Since the date of the Parent Balance Sheet, Parent has not incurred any material Liability for Taxes outside the Ordinary Course of Business.

(c) All material amounts of Taxes that Parent is or was required by Law to withhold or collect on behalf of its employees, independent contractors, stockholders, lenders, customers or other third parties have been duly and timely withheld or collected and have been timely paid to the proper Governmental Body or other Person or properly set aside in accounts for this purpose.

(d) There are no Encumbrances for material Taxes (other than Taxes not yet due and payable) upon any of the assets of Parent.

(e) No deficiencies for income or other material Taxes with respect to Parent have been claimed, proposed or assessed by any Governmental Body in writing. There are no pending or ongoing audits, assessments or other actions for or relating to any liability in respect of a material amount of Taxes of Parent and Parent has not received written notice threatening any such audit, assessment or other action. Neither Parent nor any of its predecessors has waived any statute of limitations in respect of any income or other material Taxes or agreed to any extension of time with respect to any income or other material Tax assessment or deficiency.

(f) Parent has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(g) Parent is not a party to any Tax allocation agreement, Tax sharing agreement, Tax indemnity agreement, or similar agreement or arrangement, other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes.

(h) Parent will not be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any Tax period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting for Tax purposes made on or prior to the Closing Date; (ii) use of an improper method of accounting for a Tax period ending on or prior to the Closing Date; (iii) "closing agreement" as described in Section 7121 of the Code (or any similar

provision of state, local or foreign Law) executed on or prior to the Closing Date; (iv) intercompany transaction or excess loss account described in Treasury Regulations under Section 1502 of the Code (or any similar provision of state, local or foreign Law) entered into on or prior to the Closing Date; (v) installment sale or open transaction disposition made on or prior to the Closing Date; (vi) prepaid amount received or deferred revenue accrued on or prior to the Closing Date; (vii) application of Section 367(d) of the Code to any transfer of intangible property on or prior to the Closing Date; (viii) application of Sections 951 or 951A of the Code (or any similar provision of state, local or foreign Law) to any income received or accrued on or prior to the Closing Date; or (ix) election under Section 108(i) of the Code (or any similar provision of state, local or foreign Law) made on or prior to the Closing Date. Parent has not made any election under Section 965(h) of the Code.

(i) Parent has never been (i) a member of a consolidated, combined or unitary Tax group (other than such a group the common parent of which is Parent) or (ii) a party to any joint venture, partnership, or other arrangement that is treated as a partnership for U.S. federal income Tax purposes. Parent has no Liability for any material Taxes of any Person (other than Parent and Merger Sub) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Law), or as a transferee or successor.

(j) Parent (i) is not a "controlled foreign corporation" as defined in Section 957 of the Code; (ii) is not a "passive foreign investment company" within the meaning of Section 1297 of the Code; or (iii) has never had a permanent establishment (within the meaning of an applicable Tax treaty) or otherwise had an office or fixed place of business in a country other than the country in which it is organized.

(k) Parent has not participated in or been a party to a transaction that, as of the date of this Agreement, constitutes a "listed transaction" that is required to be reported to the IRS pursuant to Section 6011 of the Code and applicable Treasury Regulations thereunder.

(l) Parent has not taken any action or knows of any fact that would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(m) Parent has not availed itself of any Tax relief pursuant to any Pandemic Response Laws that could reasonably be expected to materially impact the Tax payment and/or Tax reporting obligations of Parent and its Affiliates (including the Company and its Subsidiaries) after the Closing Date.

For purposes of this Section 3.17, each reference to Parent shall be deemed to include any Person that was liquidated into, merged with, or is otherwise a predecessor to, Parent.

3.18 **Employee and Labor Matters; Benefit Plans.**

(a) Section 3.18(a) of the Parent Disclosure Schedule is a list of all material Parent Benefit Plans, including, without limitation, each Parent Benefit Plan that provides for retirement, change in control, stay or retention deferred compensation, incentive compensation, severance or retiree medical or life insurance benefits. "***Parent Benefit Plan***" means each (i) "employee benefit plan" as defined in Section 3(3) of ERISA and (ii) other pension, retirement, deferred compensation, excess benefit, profit sharing, bonus, incentive, equity or equity-based, phantom equity, employment (other than at-will employment offer letters on Parent's standard form that may be terminated without notice and with no penalty to Parent and other than individual Parent Options, Parent RSUs or other compensatory equity award agreements made pursuant to Parent's standard forms, in which case only representative standard forms of such agreements shall be scheduled), consulting, severance, change-of-control, retention, health, life, disability, group insurance, paid-time off, holiday, welfare and

fringe benefit plan, program, agreement, contract, or arrangement (whether written or unwritten, qualified or nonqualified, funded or unfunded and including any that have been frozen or terminated), in any case, maintained, contributed to, or required to be contributed to, by Parent or Parent ERISA Affiliates for the benefit of any current or former employee, director, officer or independent contractor of Parent or under which Parent has any actual or contingent liability (including, without limitation, as to the result of it being treated as a single employer under Sections 414(b) or 414(c) of the Code with any other person).

(b) As applicable with respect to each material Parent Benefit Plan, Parent has made available to the Company, true and complete copies of (i) each material Parent Benefit Plan, including all amendments thereto, and in the case of an unwritten material Parent Benefit Plan, a written description thereof, (ii) all current trust documents, investment management contracts, custodial agreements, administrative services agreements and insurance and annuity contracts relating thereto, (iii) the current summary plan description and each summary of material modifications thereto, (iv) the most recently filed annual reports with any Governmental Body (*e.g.*, Form 5500 and all schedules thereto), (v) the most recent IRS determination, opinion or advisory letter, (vi) the most recent summary annual reports, nondiscrimination testing reports, actuarial reports, financial statements and trustee reports, and (vii) all records, notices and filings concerning IRS or United States Department of Labor or other Governmental Body examinations, audits or investigations, voluntary compliance programs or policies, or "prohibited transactions" within the meaning of Section 406 of ERISA or Section 4975 of the Code.

(c) Each Parent Benefit Plan has been maintained, operated and administered in compliance in all material respects with its terms and any related documents or agreements and the applicable provisions of ERISA, the Code and all other applicable Laws.

(d) The Parent Benefit Plans which are "employee pension benefit plans" within the meaning of Section 3(2) of ERISA and which are intended to meet the qualification requirements of Section 401(a) of the Code have received determination or opinion letters from the IRS on which they may currently rely to the effect that such plans are qualified under Section 401(a) of the Code and the related trusts are exempt from federal income Taxes under Section 501(a) of the Code, respectively, and, to Parent's Knowledge, nothing has occurred that would reasonably be expected to materially adversely affect the qualification of such Parent Benefit Plan or the tax exempt status of the related trust.

(e) Neither Parent nor any Parent ERISA Affiliate maintains, contributes to, is required to contribute to, or has any actual or contingent liability with respect to, (i) any "employee pension benefit plan" (within the meaning of Section 3(2) of ERISA) that is subject to Title IV or Section 302 of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" (within the meaning of Section 3(37) of ERISA), (iii) any "multiple employer plan" (within the meaning of Section 413 of the Code) or (iv) any "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA).

(f) There are no pending audits or investigations by any Governmental Body involving any Parent Benefit Plan, and no pending or, to Parent's Knowledge, threatened claims (except for individual claims for benefits payable in the normal operation of the Parent Benefit Plans), suits or proceedings involving any Parent Benefit Plan, any fiduciary thereof or service provider thereto, in any case except as would not be reasonably expected to result in material liability to Parent. All contributions and premium payments required to have been made under any of the Parent Benefit Plans or by applicable Law (without regard to any waivers granted under Section 412 of the Code), have been timely made and neither Parent nor any Parent ERISA Affiliate has any liability for any unpaid contributions with respect to any Parent Benefit Plan.

(g) Neither Parent or any Parent ERISA Affiliates, nor, to Parent's Knowledge, any fiduciary, trustee or administrator of any Parent Benefit Plan, has engaged in, or in connection with the Contemplated Transactions will engage in, any transaction with respect to any Parent Benefit Plan which would subject any such Parent Benefit Plan, Parent or Parent ERISA Affiliates to a material Tax, material penalty or material liability for a "prohibited transaction" under Section 406 of ERISA or Section 4975 of the Code.

(h) No Parent Benefit Plan provides death, medical, dental, vision, life insurance or other welfare benefits beyond termination of service or retirement, other than coverage mandated by Law and neither Parent nor any Parent ERISA Affiliates has made a written or oral representation promising the same.

(i) Except as set forth in Section 3.18(i) of the Parent Disclosure Schedule, neither the execution of this Agreement, nor the consummation of the Contemplated Transactions will either alone or in connection with any other event(s) (i) result in any payment becoming due to any current or former employee, director, officer, independent contractor or other service provider of Parent, (ii) increase any amount of compensation or benefits otherwise payable to any current or former employee, director, officer, independent contractor or other service provider of Parent, (iii) result in the acceleration of the time of payment, funding or vesting of any benefits under any Parent Benefit Plan, (iv) require any contribution or payment to fund any obligation under any Parent Benefit Plan or (v) limit the right to merge, amend or terminate any Parent Benefit Plan.

(j) Except as set forth in Section 3.18(j) of the Parent Disclosure Schedule, neither the execution of this Agreement, nor the consummation of the Contemplated Transactions (either alone or when combined with the occurrence of any other event, including without limitation, a termination of employment) will result in the receipt or retention by any person who is a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to Parent of any payment or benefit that is or could be characterized as a "parachute payment" (within the meaning of Section 280G of the Code), determined without regard to the application of Section 280G(b)(5) of the Code.

(k) Each Parent arrangement providing for deferred compensation that constitutes a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code and the regulations promulgated thereunder) is, and has been, established, administered and maintained in compliance with the requirements of Section 409A of the Code and the regulations promulgated thereunder in all material respects.

(l) No Person has any "gross up" agreements with Parent or other assurance of reimbursement by Parent for any Taxes imposed under Section 409A or Section 4999 of the Code.

(m) Parent does not have any Parent Benefit Plan that is maintained for service providers located outside of the United States.

(n) There has been no amendment to, announcement by Parent or any Parent ERISA Affiliate relating to, or change in employee participation or coverage under, any Parent Benefit Plan or collective bargaining agreement that would increase the annual expense of maintaining such plan above the level of the expense incurred for the most recently completed fiscal year (other than on a de minimis basis) with respect to any director, officer, employee, independent contractor or consultant, as applicable. Neither Parent nor any Parent ERISA Affiliate has any commitment or obligation or has made any representations to any director, officer, employee, independent contractor or consultant, whether or not legally binding, to adopt, amend, modify or terminate any Parent Benefit Plan or any collective bargaining agreement.

(o) Parent is not a party to or bound by, and does not have a duty to bargain under, any collective bargaining agreement or other Contract with a labor union or labor organization representing any of its employees, and there is no labor union or labor organization representing or, to Parent's Knowledge, purporting to represent or seeking to represent any employees of Parent, including through the filing of a petition for representation election.

(p) Except as set forth in Section 3.18(p) of the Parent Disclosure Schedule, Parent is, and since January 1, 2018 has been, in material compliance with all applicable Laws respecting labor, employment, employment practices, and terms and conditions of employment, including without limitation worker classification, discrimination, harassment and retaliation, equal employment opportunities, fair employment practices, meal and rest periods, immigration, employee safety and health, wages (including overtime wages, timely payment of wages, and legally compliant wage statements), unemployment and workers' compensation, leaves of absence, hours of work and recordkeeping. Except as would not be reasonably likely to result in a material liability to Parent or as otherwise set forth on Section 3.18(p) of the Parent Disclosure Schedule, with respect to employees of Parent, Parent, since January 1, 2018: (i) has withheld and reported all amounts required by Law or by agreement to be withheld and reported with respect to wages, salaries and other payments, benefits, or compensation to employees, (ii) is not liable for any arrears of wages (including overtime wages), severance pay or any Taxes or any penalty for failure to comply with any of the foregoing, and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body, with respect to unemployment compensation benefits, disability, social security or other benefits or obligations for employees (other than routine payments to be made in the Ordinary Course of Business). There are no actions, suits, claims, charges, demands, lawsuits, investigations, audits or administrative matters pending or, to Parent's Knowledge, threatened or reasonably anticipated against Parent relating to any current or former employee, applicant for employment, consultant, employment agreement or Parent Benefit Plan (other than routine claims for benefits).

(q) Parent is, and at all times since January 1, 2018 has been, in material compliance with the WARN Act.

(r) Except as would not be reasonably likely to result in a material liability to Parent or any Parent Benefit Plan, with respect to each individual who currently renders services to Parent, Parent has properly classified each such individual as an employee, independent contractor, or otherwise under all applicable Laws and, for each individual classified as an employee, Parent has properly classified him or her as overtime eligible or overtime ineligible under all applicable Laws. Parent does not have any material liability with respect to any misclassification of: (a) any Person as an independent contractor rather than as an employee, (b) any employee leased from another employer, or (c) any employee currently or formerly classified as exempt from overtime wages.

(s) There is not and has not been since January 1, 2019, nor is there or has there been since January 1, 2019 any threat of, any strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or, to Parent's Knowledge, any union organizing activity, against Parent. No event has occurred, and, to Parent's Knowledge, no condition or circumstance exists, that might directly or indirectly be likely to give rise to or provide a basis for the commencement of any such strike, slowdown, work stoppage, lockout, union election petition, demand for recognition, or any similar activity or dispute, or to Parent's Knowledge, any union organizing activity.

3.19 **Environmental Matters.** Parent is and since January 1, 2019 has complied with all applicable Environmental Laws, which compliance includes the possession by Parent of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof, except for any failure to be in such compliance that, either

individually or in the aggregate, would not reasonably be expected to be material to Parent or its business. Parent has not received since January 1, 2019 (or prior to that time, which is pending and unresolved), any written notice or other communication (in writing or otherwise), whether from a Governmental Body or other Person, that alleges that Parent is not in compliance with or has liability pursuant to any Environmental Law and, to Parent's Knowledge, there are no circumstances that would reasonably be expected to prevent or interfere with Parent's compliance in any material respects with any Environmental Law, except where such failure to comply would not reasonably be expected to be material to Parent or its business. No current or (during the time a prior property was leased or controlled by Parent) prior property leased or controlled by Parent has had a release of or exposure to Hazardous Materials in material violation of or as would reasonably be expected to result in any material liability of Parent pursuant to Environmental Law. No consent, approval or Governmental Authorization of or registration or filing with any Governmental Body is required by Environmental Laws in connection with the execution and delivery of this Agreement or the consummation of the Contemplated Transactions. Prior to the date hereof, Parent has provided or otherwise made available to the Company true and correct copies of all material environmental reports, assessments, studies and audits in the possession or control of Parent with respect to any property leased or controlled by Parent or any business operated by it.

3.20 **Transactions with Affiliates**. Except as set forth in the Parent SEC Documents filed prior to the date of this Agreement, as contemplated by this Agreement or as otherwise set forth on Section 3.20 of the Parent Disclosure Schedule, since the date of Parent's proxy statement filed in 2022 with the SEC, no event has occurred that would be required to be reported by Parent pursuant to Item 404 of Regulation S-K as promulgated under the Securities Act.

3.21 **Insurance**. Parent has delivered or made available to the Company accurate and complete copies of all material insurance policies and all material self-insurance programs and arrangements relating to the business, assets, liabilities and operations of Parent. Each of such insurance policies is in full force and effect and Parent is in compliance in all material respects with the terms thereof. Other than customary end of policy notifications from insurance carriers, since January 1, 2019, Parent has not received any notice or other communication regarding any actual or possible: (i) cancellation or invalidation of any insurance policy; or (ii) refusal or denial of any coverage, reservation of rights or rejection of any material claim under any insurance policy. Parent has provided timely written notice to the appropriate insurance carrier(s) of each Legal Proceeding that is currently pending against Parent for which Parent has insurance coverage, and no such carrier has issued a denial of coverage or a reservation of rights with respect to any such Legal Proceeding, or informed Parent of its intent to do so.

3.22 **No Financial Advisors**. Other than SVB Securities LLC, no broker, finder or investment banker is entitled to any brokerage fee, finder's fee, opinion fee, success fee, transaction fee or other fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Parent.

3.23 **Anti-Bribery**. Neither Parent nor any of its directors, officers, employees or, to Parent's Knowledge, agents or any other Person acting on its behalf has directly or indirectly made any bribes, rebates, payoffs, influence payments, kickbacks, illegal payments, illegal political contributions, or other payments, in the form of cash, gifts, or otherwise, or taken any other action, in violation of Anti-Bribery Laws. Parent is not or has not been the subject of any investigation or inquiry by any Governmental Body with respect to potential violations of Anti-Bribery Laws.

3.24 **Valid Issuance**. The Parent Common Stock to be issued in the Merger will, when issued in accordance with the provisions of this Agreement, be validly issued, fully paid and nonassessable.

3.25 **Opinion of Financial Advisor**. The Parent Board has received an opinion of SVB Securities LLC to the effect that, as of July 20, 2022 and subject to the assumptions, qualifications, limitations and other matters set forth therein, the Exchange Ratio is fair, from a financial point of view, to Parent. It is agreed and understood that such opinion is for the benefit of the Parent Board and may not be relied upon by the Company.

3.26 **Disclaimer of Other Representations or Warranties**. Except as previously set forth in this Section 3 or in any certificate delivered by Parent or Merger Sub to the Company pursuant to this Agreement, neither Parent nor Merger Sub makes any representation or warranty, express or implied, at law or in equity, with respect to it or any of its assets, liabilities or operations, and any such other representations or warranties are hereby expressly disclaimed.

Section 4. CERTAIN COVENANTS OF THE PARTIES

4.1 **Operation of Parent's Business.**

(a) Except (i) as set forth in Section 4.1(a) of the Parent Disclosure Schedule, (ii) as expressly permitted by or required in accordance this Agreement, including in connection with the Asset Dispositions, (iii) as required by applicable Law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary, (A) to protect the health and safety of Parent's employees, (B) to respond to third party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable Law, directive or guideline from any Governmental Body arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as may be consented to in writing by the Company (which consent shall not be unreasonably withheld, delayed or conditioned), during the period commencing on the date of this Agreement and continuing until the earlier to occur of the termination of this Agreement pursuant to Section 9 and the Effective Time (the "***Pre-Closing Period***"): Parent shall use commercially reasonable efforts to conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Parent Material Contracts.

(b) Except (i) as expressly permitted by this Agreement, (ii) as set forth in Section 4.1(b) of the Parent Disclosure Schedule, (iii) as required by applicable Law, (iv) in connection with the Asset Dispositions, a Permitted Dividend or the winding down of Parent's prior research and development activities (including the termination of ongoing contractual obligations related to Parent's current products or product candidates), or (v) with the prior written consent of the Company (which consent shall not be unreasonably withheld, delayed or conditioned), at all times during the Pre-Closing Period, Parent shall not, nor shall it cause or permit Merger Sub to, do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire, directly or indirectly, any shares of its capital stock or other securities (except repurchases from terminated employees, directors or consultants of Parent or in connection with the payment of the exercise price and/or withholding Taxes incurred upon the exercise, settlement or vesting of any award or purchase rights granted under the Parent Plans in accordance with the terms of such award in effect on the date of this Agreement); *provided, however*, that to the extent that Parent Net Cash is greater than $255,000,000, Parent shall be permitted to declare any such excess amount as a dividend (a "***Permitted Dividend***");

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of Parent (except for shares of outstanding Parent Common Stock issued upon the valid exercise of Parent Options or upon settlement of purchase rights under the Parent ESPP or Parent RSUs); (B) any option, warrant or right to acquire any capital stock or any other security, other than (i) stock options or restricted

stock unit awards granted to employees and service providers or (ii) offerings providing eligible employees with purchase rights under the Parent ESPP, in either case, in the Ordinary Course of Business which are included in the calculation of the Parent Outstanding Shares; or (C) any instrument convertible into or exchangeable for any capital stock or other security of Parent;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of its Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(v) (A) lend money to any Person (except for the advancement of expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others or (D) other than the incurrence or payment of any Transaction Expenses, make any capital expenditure in excess of $50,000;

(vi) forgive any loans to any Person, including its employees, officers, directors or Affiliates;

(vii) other than as required by applicable Law, the terms of any Parent Benefit Plan as in effect on the date of this Agreement or as disclosed in Section 4.1(b)(vii) of the Parent Disclosure Schedule: (A) adopt, terminate, establish or enter into any Parent Benefit Plan; (B) cause or permit any Parent Benefit Plan to be amended in any material respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business consistent with past practice; (D) increase the severance or change of control benefits offered to any current or new employees, directors or consultants or (E) hire any (x) officer or (y) employee whose annual base salary is or is expected to be more than $250,000 per year;

(viii) recognize any labor union or labor organization, except as otherwise required by applicable Law and after prior written consent of the Company (which consent shall not be unreasonably withheld, delayed or conditioned);

(ix) enter into any material transaction other than in the Ordinary Course of Business;

(x) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its assets or properties, or grant any Encumbrance with respect to such assets or properties, except in the Ordinary Course of Business;

(xi) either solely or in collaboration with any third party, directly or indirectly, commence, enter, join, revive, solicit, or otherwise get engaged in, any clinical trial other than the clinical trials existing on or prior to the date of this Agreement and disclosed by Parent in Section 4.1(b)(xi) of the Parent Disclosure Schedule;

(xii) sell, assign, transfer, license, sublicense or otherwise dispose of any material Parent IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business);

(xiii) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing,

indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven (7) months), or adopt or change any material accounting method in respect of Taxes;

(xiv) enter into, materially amend or terminate any Parent Material Contract;

(xv) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xvi) initiate or settle any Legal Proceeding;

(xvii) enter into or amend a Contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions; or

(xviii) agree, resolve or commit to do any of the foregoing.

(c) Nothing contained in this Agreement shall give the Company, directly or indirectly, the right to control or direct the operations of Parent prior to the Effective Time. Prior to the Effective Time, Parent shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations. Notwithstanding anything to the contrary set forth in this Agreement, no consent of the Company shall be required with respect to any matter set forth in this Section 4.1 or elsewhere in this Agreement to the extent that the requirement of such consent could violate any applicable Laws.

4.2 **Operation of the Company's Business.**

(a) Except (i) as set forth in Section 4.2(a) of the Company Disclosure Schedule, (ii) as expressly permitted by or required in accordance this Agreement, (iii) as required by applicable Law, (iv) in connection with the COVID-19 pandemic, to the extent reasonably necessary, (A) to protect the health and safety of the Company's or any of its Subsidiaries' employees, (B) to respond to third party supply or service disruptions caused by the COVID-19 pandemic or (C) as required by any applicable Law, directive or guideline from any Governmental Body arising out of, or otherwise related to, the COVID-19 pandemic (including any response to COVID-19), or (v) as may be consented to in writing by Parent (which consent shall not be unreasonably withheld, delayed or conditioned), during the Pre-Closing Period: each of the Company and its Subsidiaries shall conduct its business and operations in the Ordinary Course of Business and in compliance in all material respects with all applicable Laws and the requirements of all Contracts that constitute Company Material Contracts.

(b) Except (i) as expressly permitted by this Agreement, (ii) as set forth in Section 4.2(b) of the Company Disclosure Schedule, (iii) as required by applicable Law or (iv) with the prior written consent of Parent (which consent shall not be unreasonably withheld, delayed or conditioned), at all times during the Pre-Closing Period, the Company shall not, nor shall it cause or permit any of its Subsidiaries to, do any of the following:

(i) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of its capital stock or repurchase, redeem or otherwise reacquire, directly or indirectly, any shares of its capital stock or other securities (except in connection with the payment of the exercise price and/or withholding Taxes incurred upon the exercise, settlement or vesting of any award granted under the Company Plan in accordance with the terms of such award in effect on the date of this Agreement);

(ii) sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: (A) any capital stock or other security of the Company or any of its Subsidiaries (except for shares of outstanding Company Common Stock issued upon the valid exercise of Company Options); (B) any option, warrant or right to acquire any capital stock or any other security, other than option grants or restricted stock unit awards granted to employees and service providers in the Ordinary Course of Business which are included in the calculation of the Company Outstanding Shares; or (C) any instrument convertible into or exchangeable for any capital stock or other security of the Company or any of its Subsidiaries;

(iii) except as required to give effect to anything in contemplation of the Closing, amend any of its or its Subsidiaries' Organizational Documents, or effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except, for the avoidance of doubt, the Contemplated Transactions;

(iv) form any Subsidiary or acquire any equity interest or other interest in any other Entity or enter into a joint venture with any other Entity;

(v) (A) lend money to any Person (except for the advancement of expenses to employees, directors and consultants in the Ordinary Course of Business), (B) incur or guarantee any indebtedness for borrowed money, (C) guarantee any debt securities of others, or (D) other than the incurrence or payment of any Transaction Expenses, make any capital expenditure in excess of the budgeted capital expenditure amounts set forth in the Company operating budget delivered to Parent concurrently with the execution of this Agreement (the "***Company Budget***");

(vi) other than as required by applicable Law or the terms of any Company Benefit Plan as in effect on the date of this Agreement: (A) adopt, terminate, establish or enter into any Company Benefit Plan; (B) cause or permit any Company Benefit Plan to be amended in any material respect; (C) pay any bonus or make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions, benefits or other compensation or remuneration payable to, any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the Ordinary Course of Business consistent with past practice and which do not exceed, in the aggregate, the amounts specifically budgeted therefore in the Company Budget; (D) increase the severance or change of control benefits offered to any current or new employees, directors or consultants; (E) hire any (x) officer or (y) employee whose annual base salary is or is expected to be more than $250,000 per year or (F) terminate or give notice of termination to any officer other than for cause;

(vii) recognize any labor union or labor organization, except as otherwise required by applicable Law and after prior written consent of Parent (which consent shall not be unreasonably withheld, delayed or conditioned);

(viii) enter into any material transaction other than in the Ordinary Course of Business;

(ix) acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its assets or properties, or grant any Encumbrance with respect to such assets or properties, except in the Ordinary Course of Business;

(x) sell, assign, transfer, license, sublicense or otherwise dispose of any Company IP (other than pursuant to non-exclusive licenses in the Ordinary Course of Business);

(xi) make, change or revoke any material Tax election, fail to pay any income or other material Tax as such Tax becomes due and payable, file any amendment making any material change to any Tax Return, settle or compromise any income or other material Tax liability or submit any voluntary disclosure application, enter into any Tax allocation, sharing,

indemnification or other similar agreement or arrangement (other than customary commercial contracts entered into in the Ordinary Course of Business the principal subject matter of which is not Taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material Taxes (other than pursuant to an extension of time to file any Tax Return granted in the Ordinary Course of Business of not more than seven (7) months), or adopt or change any material accounting method in respect of Taxes;

(xii) enter into, materially amend or terminate any Company Material Contract;

(xiii) other than as required by Law or GAAP, take any action to change accounting policies or procedures;

(xiv) initiate or settle any Legal Proceeding

(xv) enter into or amend a Contract that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation of the Contemplated Transactions; or

(xvi) agree, resolve or commit to do any of the foregoing.

(c) Nothing contained in this Agreement shall give Parent, directly or indirectly, the right to control or direct the operations of the Company prior to the Effective Time. Prior to the Effective Time, the Company shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over its business operations. Notwithstanding anything to the contrary set forth in this Agreement, no consent of Parent shall be required with respect to any matter set forth in this Section 4.2 or elsewhere in this Agreement to the extent that the requirement of such consent could violate any applicable Laws.

4.3 **Access and Investigation**. Subject to the terms of the Confidentiality Agreement, which the Parties agree will continue in full force following the date of this Agreement, during the Pre-Closing Period, upon reasonable notice, Parent, on the one hand, and the Company, on the other hand, shall and shall use commercially reasonable efforts to cause such Party's Representatives to: (a) provide the other Party and such other Party's Representatives with reasonable access during normal business hours to such Party's Representatives, personnel, property and assets and to all existing books, records, Tax Returns, work papers and other documents and information relating to such Party and its Subsidiaries; (b) provide the other Party and such other Party's Representatives with such copies of the existing books, records, Tax Returns, work papers, product data, and other documents and information relating to such Party and its Subsidiaries, and with such additional financial, operating and other data and information regarding such Party and its Subsidiaries as the other Party may reasonably request; (c) permit the other Party's officers and other employees to meet, upon reasonable notice and during normal business hours, with the chief financial officer and other officers and managers of such Party responsible for such Party's financial statements and the internal controls of such Party to discuss such matters as the other Party may deem necessary or appropriate and; (d) make available to the other Party copies of unaudited financial statements, material operating and financial reports prepared for senior management or the board of directors of such Party, and any material notice, report or other document filed with or sent to or received from any Governmental Body in connection with the Contemplated Transactions; *provided*, that the Notification and Report Form and documentary attachments thereto made under the HSR Act need not be provided to the other Party; *provided*, *further*, that if a Governmental Body commences an investigation of the Contemplated Transactions under the HSR Act, any submission by a Party to such Governmental Body to respond to any requests by such Governmental Body for information or documents will be shared with the other Party, but may be restricted to the other Party's outside counsel. Any investigation conducted by either Parent or the Company pursuant to this Section 4.3 shall be conducted in such manner as not to interfere unreasonably with the conduct of the business of the other Party.

Notwithstanding the foregoing, any Party may restrict the foregoing access to the extent that such Party has a reasonable good faith belief that any Law applicable to such Party requires such Party to restrict or prohibit access to any such properties or information or as may be necessary to preserve the attorney-client privilege under any circumstances in which such privilege may be jeopardized by such disclosure or access.

4.4 **Parent Non-Solicitation.**

(a) Parent agrees that, during the Pre-Closing Period, it shall not, and shall not authorize any of its Representatives to, directly or indirectly, other than relating to communicating, discussing, negotiating or consummating the Asset Dispositions: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding Parent to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions (other than to inform any Person of the existence of the provisions in this Section 4.4) or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal (subject to Section 5.3); (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any Acquisition Transaction (other than a confidentiality agreement permitted under this Section 4.4(a)); or (vi) publicly propose to do any of the foregoing; *provided*, *however*, that, notwithstanding anything contained in this Section 4.4 and subject to compliance with this Section 4.4, prior to obtaining the Required Parent Stockholder Vote, Parent may furnish non-public information regarding Parent to, and enter into discussions or negotiations with, any Person in response to an unsolicited *bona fide* Acquisition Proposal by such Person, which the Parent Board determines in good faith, after consultation with Parent's outside financial advisors and outside legal counsel, constitutes, or could be reasonably likely to result in, a Superior Offer (and is not withdrawn) if: (A) neither Parent nor any of its Representatives shall have breached this Section 4.4 in any material respect, (B) the Parent Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action could be reasonably likely to be inconsistent with the fiduciary duties of the Parent Board under applicable Law; (C) Parent receives from such Person an executed confidentiality agreement containing provisions, in the aggregate, at least as favorable to Parent as those contained in the Confidentiality Agreement; and (D) substantially contemporaneously with furnishing any such non-public information to such Person, Parent furnishes such non-public information to the Company (to the extent such information has not been previously furnished by Parent to the Company). Without limiting the generality of the foregoing, Parent acknowledges and agrees that, in the event any Representative of Parent (whether or not such Representative is purporting to act on behalf of Parent) takes any action that, if taken by Parent, would constitute a breach of this Section 4.4, the taking of such action by such Representative shall be deemed to constitute a breach of this Section 4.4 by Parent for purposes of this Agreement.

(b) If Parent or any Representative of Parent receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then Parent shall promptly (and in no event later than one (1) Business Day after Parent becomes aware of such Acquisition Proposal or Acquisition Inquiry) advise the Company orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry, and the material terms thereof) and provide to the Company a copy of any written Acquisition Proposal or Acquisition Inquiry. Parent shall keep the Company reasonably informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and any material modification or proposed material modification thereto.

(c) Parent shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal

or Acquisition Inquiry (other than any Asset Disposition) that has not already been terminated as of the date of this Agreement and request the destruction or return of any non-public information of Parent provided to such Person as soon as practicable after the date of this Agreement.

4.5 **Company Non-Solicitation.**

(a) The Company agrees that, during the Pre-Closing Period, neither it nor any of its Subsidiaries shall, nor shall it or any of its Subsidiaries authorize any of their respective Representatives to, directly or indirectly: (i) solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry or take any action that could reasonably be expected to lead to an Acquisition Proposal or Acquisition Inquiry; (ii) furnish any non-public information regarding the Company or any of its Subsidiaries to any Person in connection with or in response to an Acquisition Proposal or Acquisition Inquiry; (iii) engage in discussions (other than to inform any Person of the existence of the provisions in this Section 4.5) or negotiations with any Person with respect to any Acquisition Proposal or Acquisition Inquiry; (iv) approve, endorse or recommend any Acquisition Proposal; (v) execute or enter into any letter of intent or any Contract contemplating or otherwise relating to any Acquisition Transaction; or (vi) publicly propose to do any of the foregoing. Without limiting the generality of the foregoing, the Company acknowledges and agrees that, in the event any Representative of the Company or any of its Subsidiaries (whether or not such Representative is purporting to act on behalf of the Company or any of its Subsidiaries) takes any action that, if taken by the Company, would constitute a breach of this Section 4.5, the taking of such action by such Representative shall be deemed to constitute a breach of this Section 4.5 by the Company for purposes of this Agreement.

(b) If the Company, any of its Subsidiaries or any of their respective Representatives receives an Acquisition Proposal or Acquisition Inquiry at any time during the Pre-Closing Period, then the Company shall promptly (and in no event later than one (1) Business Day after the Company becomes aware of such Acquisition Proposal or Acquisition Inquiry) advise Parent orally and in writing of such Acquisition Proposal or Acquisition Inquiry (including the identity of the Person making or submitting such Acquisition Proposal or Acquisition Inquiry, and the material terms thereof). The Company shall keep Parent reasonably informed with respect to the status and material terms of any such Acquisition Proposal or Acquisition Inquiry and any material modification or proposed material modification thereto.

(c) The Company shall immediately cease and cause to be terminated any existing discussions, negotiations and communications with any Person that relate to any Acquisition Proposal or Acquisition Inquiry that has not already been terminated as of the date of this Agreement and request the destruction or return of any non-public information of the Company or any of its Subsidiaries provided to such Person as soon as practicable after the date of this Agreement.

4.6 **Notification of Certain Matters.**

(a) During the Pre-Closing Period the Company shall promptly (and in no event later than one (1) Business Day after the Company becomes aware of same) notify Parent (and, if in writing, furnish copies of any relevant documents) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting the Company or its Subsidiaries is commenced, or, to the Company's Knowledge, threatened against the Company or its Subsidiaries or, to the Company's Knowledge, any director or officer of the Company or its Subsidiaries; (iii) the Company becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; (iv) any communication is received from the FDA or comparable Government Body concerning the Company business; or (v) the

failure of the Company to comply with any covenant or obligation of the Company; in the case of (iii) and (v) that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in Sections 6 or 7, as applicable, impossible or materially less likely. No notification given to Parent pursuant to this Section 4.6(a) shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of the Company or any of its Subsidiaries contained in this Agreement or the Company Disclosure Schedule for purposes of Sections 6 and 7, as applicable.

(b) During the Pre-Closing Period Parent shall promptly (and in no event later than one (1) Business Day after the Parent becomes aware of same) notify the Company (and, if in writing, furnish copies of any relevant documents) if any of the following occurs: (i) any notice or other communication is received from any Person alleging that the Consent of such Person is or may be required in connection with any of the Contemplated Transactions; (ii) any Legal Proceeding against or involving or otherwise affecting Parent is commenced, or, to Parent's Knowledge, threatened against Parent or, to Parent's Knowledge, any director or officer of Parent; (iii) Parent becomes aware of any inaccuracy in any representation or warranty made by it in this Agreement; or (iv) the failure of Parent to comply with any covenant or obligation of Parent or Merger Sub; in the case of (iii) and (iv) that could reasonably be expected to make the timely satisfaction of any of the conditions set forth in Sections 6 or 8, as applicable, impossible or materially less likely. No notification given to the Company pursuant to this Section 4.6(b) shall change, limit or otherwise affect any of the representations, warranties, covenants or obligations of Parent contained in this Agreement or the Parent Disclosure Schedule for purposes of Sections 6 and 8, as applicable.

4.7 **Potentially Transferable Assets.** Parent shall be entitled, but under no obligation, to separate into a new company or sell, transfer, assign or otherwise divest the Potentially Transferable Assets to a third party in one or a series of transactions prior to, concurrently with, or immediately following the Closing (each an "***Asset Disposition***" and collectively, the "***Asset Dispositions***"); *provided*, *however*, that Parent shall notify the Company at least five (5) Business Days prior to entering into any agreement with respect to any Asset Disposition and provide copies of all written agreements or documents with respect to such sale and provide the Company with an opportunity to provide comments to such documents, *provided, however,* that the inclusion or exclusion of such Company comments will be at the sole discretion of Parent after having considered such comments in good faith and engaging in good faith discussions with the Company regarding the same; and *provided further, however*, that any such Asset Disposition that would create any material post-disposition Liabilities for Parent following the Closing shall require, to the extent consistent with applicable Laws, the written consent of the Company, not to be unreasonably withheld, delayed or conditioned. Each Party acknowledges that Parent may not be successful in completing, or may determine not to proceed, with any Asset Dispositions. For clarity, if the Asset Dispositions are not completed prior to, concurrently with, or immediately following the Closing, the Potentially Transferable Assets shall be retained by Parent and the value of such Potentially Transferable Assets shall have no impact on the calculation of the Exchange Ratio.

4.8 **Termination of Employees of Parent.** Effective as of the Effective Time, Parent and Merger Sub shall terminate all of their respective employees other than those who will continue as employees of Parent or the Surviving Corporation following the Closing (the "***Retained Employees***"). At least ten (10) Business Days prior to the Closing, the Company shall deliver a list to Parent setting forth the names of any such Retained Employees.

Section 5. ADDITIONAL AGREEMENTS OF THE PARTIES

5.1 **Proxy Statement.**

(a) As promptly as practicable after the date of this Agreement, the Parties shall prepare, and Parent shall cause to be filed with the SEC, the Proxy Statement. Parent covenants and

agrees that the Proxy Statement will not, at the time the Proxy Statement or any amendment or supplement thereto is filed with the SEC or is first mailed to Parent's stockholders, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company covenants and agrees that the information provided by or on behalf of the Company to Parent for inclusion in the Proxy Statement (including the Company Audited Financial Statements or the Company Interim Financial Statements, as the case may be) will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make such information not misleading. Notwithstanding the foregoing, Parent makes no covenant, representation or warranty with respect to statements made in the Proxy Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, based on information provided by or on behalf of the Company or any of its Representatives for inclusion therein, and the Company makes no covenant, representation or warranty with respect to statements made in the Proxy Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, other than with respect to the information provided by or on behalf of the Company or any of its Representatives for inclusion therein. The Company and its legal counsel shall be given reasonable opportunity to review and comment on the Proxy Statement, including all amendments and supplements thereto, prior to the filing thereof with the SEC, and on the response to any comments of the SEC on the Proxy Statement, prior to the filing or submission thereof with or to the SEC. Parent shall use commercially reasonable efforts to cause the Proxy Statement to comply with the applicable rules and regulations promulgated by the SEC and to respond promptly to any comments of the SEC or its staff. Parent shall use commercially reasonable efforts to cause the Proxy Statement to be mailed to Parent's stockholders as promptly as practicable after the resolution of SEC staff comments and the filing of the Definitive Proxy Statement. Each Party shall promptly furnish to the other Party all information concerning such Party and such Party's Affiliates and such Party's stockholders that may be required or reasonably requested in connection with any action contemplated by this Section 5.1. If Parent, Merger Sub or the Company become aware of any event or information that, pursuant to the Exchange Act, should be disclosed in an amendment or supplement to the Proxy Statement, then such Party, as the case may be, shall promptly inform the other Parties thereof and shall cooperate with such other Parties in filing such amendment or supplement with the SEC and, if appropriate, in mailing such amendment or supplement to Parent's stockholders. No filing of, or amendment or supplement to, the Proxy Statement will be made by Parent, in each case, without the prior written consent of the Company, which shall not be unreasonably withheld, conditioned or delayed. The Company and Parent shall each use commercially reasonable efforts to cause the Proxy Statement to comply with applicable federal and state securities laws requirements.

(b) The Parties shall reasonably cooperate with each other and provide, and require their respective Representatives to provide, the other Party and its Representatives, with all true, correct and complete information regarding such Party or its Subsidiaries that is required by Law to be included in the Proxy Statement or reasonably requested by the other Party to be included in the Proxy Statement.

(c) Following the final determination of Parent Net Cash at the Anticipated Closing Date in accordance with Section 1.6 (either as a result of the mutual agreement of the parties or the determination of the Accounting Firm), Parent and the Company shall mutually agree on the form and substance of a press release setting forth the anticipated Exchange Ratio as of the Anticipated Closing Date, which the Parties shall cause to be publicly disclosed (and which Parent shall file on Form 8-K with the SEC) as early as practicable prior to the Parent Stockholders' Meeting (and in no event shall this delay or cause the postponement of such meeting under any applicable Law).

5.2 **Company Information Statement; Stockholder Written Consent.**

(a) As promptly as reasonably practicable after the date of this Agreement, and in any event no later than one (1) Business Day after the date of this Agreement, the Company shall obtain Company Stockholder Written Consents sufficient for the Required Company Stockholder Vote in lieu of a meeting pursuant to Section 228 of the DGCL, for purposes of (i) adopting and approving this Agreement and the Contemplated Transactions, (ii) electing an automatic conversion of each share of Company Preferred Stock into shares of Company Common Stock immediately prior to the Effective Time in accordance with the relevant provisions of the Company's Organizational Documents (the "***Preferred Stock Conversion***"), (iii) approving the termination of the Investor Agreements, (iv) acknowledging that the approval given thereby is irrevocable and that such stockholder is aware of its rights to demand appraisal for its shares of Company Capital Stock pursuant to Section 262 of the DGCL and Chapter 13 of California Law, a true and correct copy of which will be attached thereto, and that such stockholder has received and read a copy of Section 262 of the DGCL and Chapter 13 of California Law, and (v) acknowledging that by its approval of the Merger it is not entitled to appraisal rights with respect to its shares of Company Capital Stock in connection with the Merger and thereby waives any rights to receive payment of the fair value of its shares of Company Capital Stock under the DGCL or California Law (collectively, the "***Company Stockholder Matters***"). Under no circumstances shall the Company assert that any other approval or consent is necessary by its stockholders to approve this Agreement and the Contemplated Transactions. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this Section 5.2(a) shall be subject to Parent's advance review and reasonable approval.

(b) As promptly as reasonably practicable after the date of this Agreement, and in any event no later than three (3) Business Days after the date of this Agreement or such date as the Parties mutually agree, the Company shall prepare, with the cooperation of Parent, and cause to be mailed, distributed or otherwise made available to its stockholders that did not execute Company Stockholder Written Consents approving the Company Stockholder Matters in accordance Section 5.2(a), with an information statement that meets the requirements of Rule 502(b) of Regulation D (the "***Information Statement***"). The Parties shall reasonably cooperate with each other and provide, and require their respective Representatives to provide the other Party and its Representatives with, all true, correct and complete information regarding such Party or its Subsidiaries that is required by Law to be included in the Information Statement or reasonably requested by the other Party to be included in the Information Statement. Promptly following receipt of the Required Company Stockholder Vote, the Company shall prepare and mail a notice (the "***Stockholder Notice***") to every stockholder of the Company that did not execute the Company Stockholder Written Consent. The Stockholder Notice shall (i) be a statement to the effect that the Company Board determined that the Merger is advisable in accordance with Section 251(b) of the DGCL and in the best interests of the stockholders of the Company and approved and adopted this Agreement, the Merger and the other Contemplated Transactions, (ii) provide the stockholders of the Company to whom it is sent with notice of the actions taken in the Company Stockholder Written Consent, including the adoption and approval of this Agreement, the Merger and the other Contemplated Transactions in accordance with Section 228(e) of the DGCL and the Organizational Documents of the Company and (iii) include a description of the appraisal rights of the Company's stockholders available under the DGCL and California Law, along with such other information as is required thereunder and pursuant to applicable Law. All materials (including any amendments thereto) submitted to the stockholders of the Company in accordance with this Section 5.2(b) shall be subject to Parent's advance review and reasonable approval.

(c) The Company covenants and agrees that the Information Statement, including any pro forma financial statements included therein (and the letter to stockholders and form of Company Stockholder Written Consent included therewith), will not, at the time that the Information Statement or any amendment or supplement thereto is first mailed, distributed or otherwise made available to its

stockholders that did not execute the written consent approving the Company Stockholder Matters in accordance Section 5.2(a), at the time of receipt of the Required Company Stockholder Vote and at the Effective Time, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. Notwithstanding the foregoing, the Company makes no covenant, representation or warranty with respect to statements made in the Information Statement (and the letter to the stockholders and form of Company Stockholder Written Consent included therewith), if any, based on information furnished in writing by Parent specifically for inclusion therein. Each of the Parties shall use commercially reasonable efforts to cause the Information Statement to comply with the applicable rules and regulations promulgated by the SEC and applicable federal and state securities laws requirements in all material respects.

(d) The Company agrees that: (i) the Company Board shall recommend that the Company's stockholders vote to approve the Company Stockholder Matters and shall use reasonable best efforts to solicit such approval from each of the Company Signatories within the time set forth in Section 5.2(a) (the recommendation of the Company Board that the Company's stockholders vote to adopt and approve the Company Stockholder Matters being referred to as the "***Company Board Recommendation***"); and (ii) the Company Board Recommendation shall not be withdrawn or modified (and the Company Board shall not publicly propose to withdraw or modify the Company Board Recommendation) in a manner adverse to Parent, and no resolution by the Company Board or any committee thereof to withdraw or modify the Company Board Recommendation in a manner adverse to Parent or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any Acquisition Proposal shall be adopted or proposed (the actions set forth in the foregoing clause (ii), collectively, a "***Company Board Adverse Recommendation Change***").

(e) The Company's obligation to solicit the consent of its stockholders to sign the Company Stockholder Written Consent in accordance with Section 5.2(a) and Section 5.2(d) shall not be limited or otherwise affected by the commencement, disclosure, announcement or submission of any Superior Offer or other Acquisition Proposal.

5.3 **Parent Stockholders' Meeting.**

(a) Promptly as reasonably practicable after the resolution of SEC staff comments and the filing of the Definitive Proxy Statement, Parent shall take all action necessary under applicable Law to call, give notice of and hold a meeting of the holders of Parent Common Stock for the purpose of seeking approval of (i) the issuance of Parent Common Stock or other securities of Parent that represent (or are convertible into) more than twenty percent (20%) of the shares of Parent Common Stock outstanding immediately prior to the Merger to the holders of Company Capital Stock, Company Options and Company Warrants in connection with the Contemplated Transactions and the change of control of Parent resulting from the Contemplated Transactions, in each case pursuant to the Nasdaq rules; (ii) in accordance with Section 14A of the Exchange Act and the applicable SEC rules issued thereunder, seeking advisory approval of a proposal to Parent's stockholders for a non-binding, advisory vote to approve certain compensation that may become payable to Parent's named executive officers in connection with the completion of the Merger, if applicable; and (iii) any other proposals the Parties deem necessary or desirable to consummate the Contemplated Transactions (the matters contemplated by this Section 5.3(a)(i) are collectively referred to as the "***Parent Stockholder Matters***," and the matters contemplated by this Section 5.3(a)(ii) and (iii) are collectively referred to herein as, the "***Other Parent Stockholder Matters***," and such meeting, the "***Parent Stockholders' Meeting***").

(b) The Parent Stockholders' Meeting shall be held as promptly as practicable after the filing of the Definitive Proxy Statement with the SEC. Parent shall take reasonable measures to ensure that all proxies solicited in connection with the Parent Stockholders' Meeting are solicited in compliance

with all applicable Laws. Notwithstanding anything to the contrary contained herein, if on the date of the Parent Stockholders' Meeting, or a date preceding the date on which the Parent Stockholders' Meeting is scheduled, Parent reasonably believes that (i) it will not receive proxies sufficient to obtain the Required Parent Stockholder Vote, whether or not a quorum would be present, or (ii) it will not have sufficient shares of Parent Common Stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Parent Stockholders' Meeting, Parent may make one or more successive postponements or adjournments of the Parent Stockholders' Meeting as long as the date of the Parent Stockholders' Meeting is not postponed or adjourned more than an aggregate of sixty (60) calendar days in connection with any postponements or adjournments.

(c) Parent agrees that, subject to Section 5.3(d): (i) the Parent Board shall recommend that the holders of Parent Common Stock vote to approve the Parent Stockholder Matters and the Other Parent Stockholder Matters, (ii) the Proxy Statement shall include a statement to the effect that the Parent Board recommends that Parent's stockholders vote to approve the Parent Stockholder Matters and the Other Parent Stockholder Matters (the recommendation of the Parent Board with respect to the Parent Stockholder Matters being referred to as the "***Parent Board Recommendation***"); and (iii) the Parent Board Recommendation shall not be withheld, amended, withdrawn or modified (and the Parent Board shall not publicly propose to withhold, amend, withdraw or modify the Parent Board Recommendation) in a manner adverse to the Company (the actions set forth in the foregoing clause (iii), collectively, a "***Parent Board Adverse Recommendation Change***").

(d) Notwithstanding anything to the contrary contained in this Agreement, if at any time prior to the approval of the Parent Stockholder Matters at the Parent Stockholders' Meeting by the Required Parent Stockholder Vote:

(i) if Parent has received a written Acquisition Proposal (which Acquisition Proposal did not arise out of a material breach of Section 4.4) from any Person that has not been withdrawn and after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer, (x) the Parent Board may make a Parent Board Adverse Recommendation Change or (y) Parent may terminate this Agreement pursuant to Section 9.1(j) to enter into a Permitted Alternative Agreement with respect to such Superior Offer, if and only if all of the following apply: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel, that the failure to do so would be reasonably likely to be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; (B) Parent shall have given the Company prior written notice of its intention to consider making a Parent Board Adverse Recommendation Change or terminate this Agreement pursuant to Section 9.1(j) at least three (3) Business Days prior to making any such Parent Board Adverse Recommendation Change or termination (a "***Determination Notice***") (which notice shall not constitute a Parent Board Adverse Recommendation Change); and (C) (1) Parent shall have provided to the Company a summary of the material terms and conditions of the Acquisition Proposal in accordance with Section 4.4(b), (2) Parent shall have given the Company the three (3) Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal and shall have made its Representatives reasonably available to negotiate in good faith with the Company (to the extent the Company desires to negotiate) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that such Acquisition Proposal is a Superior Offer and that the failure to make the Parent Board Adverse Recommendation Change or terminate this Agreement pursuant to Section 9.1(j) would be reasonably likely to be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law. For the avoidance of doubt, the provisions of this Section 5.3(d)(i) shall also apply to any material change

to the facts and circumstances relating to such Acquisition Proposal and require a new Determination Notice, except that the references to three (3) Business Days shall be deemed to be two (2) Business Days.

(ii) other than in connection with an Acquisition Proposal, the Parent Board may make a Parent Board Adverse Recommendation Change in response to a Parent Change in Circumstance, if and only if: (A) the Parent Board determines in good faith, after consultation with Parent's outside legal counsel, that the failure to do so would be reasonably likely to be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law; (B) Parent shall have given the Company a Determination Notice at least three (3) Business Days prior to making any such Parent Board Adverse Recommendation Change; and (C) (1) Parent shall have specified the Parent Change in Circumstance in reasonable detail, (2) Parent shall have given the Company the three (3) Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make another proposal, and shall have made its Representatives reasonably available to negotiate in good faith with the Company (to the extent the Company desires to do so) with respect to such proposed revisions or other proposal, if any, and (3) after considering the results of any such negotiations and giving effect to the proposals made by the Company, if any, after consultation with outside legal counsel, the Parent Board shall have determined, in good faith, that the failure to make the Parent Board Adverse Recommendation Change in response to such Parent Change in Circumstance would be reasonably likely to be inconsistent with the fiduciary duties of the Parent Board to Parent's stockholders under applicable Law. For the avoidance of doubt, the provisions of this Section 5.3(d)(ii) shall also apply to any material change to the facts and circumstances relating to such Parent Change in Circumstance and require a new Determination Notice, except that the references to three (3) Business Days shall be deemed to be two (2) Business Days.

(e) Nothing contained in this Agreement shall prohibit Parent or the Parent Board from (i) complying with Rules 14d-9 and 14e-2(a) promulgated under the Exchange Act, (ii) issuing a "stop, look and listen" communication or similar communication of the type contemplated by Section 14d-9(f) under the Exchange Act or (iii) otherwise making any disclosure to Parent's stockholders; *provided however*, that in the case of the foregoing clause (iii) the Parent Board determines in good faith, after consultation with its outside legal counsel, that failure to make such disclosure could be reasonably likely to be inconsistent with applicable Law, including its fiduciary duties under applicable Law.

5.4 **Regulatory Approvals.**

(a) Each Party shall, and shall cause its ultimate parent entity (as such term is defined in the HSR Act) to, use reasonable best efforts to file or otherwise submit, as soon as practicable after the date of this Agreement, all applications, notices, reports, filings and other documents reasonably required to be filed by such Party or its ultimate parent entity with or otherwise submitted by such Party or its ultimate parent entity to any Governmental Body with respect to the Contemplated Transactions, and shall file no later than ten (10) Business Days thereafter the Notification and Report Forms required by the HSR Act. Each Party shall (i) promptly supply the other with any information which may be required in order to effectuate such filings, (ii) submit promptly any additional information which may be reasonably requested by any such Governmental Body, and (iii) coordinate with the other Party in making any such filings or information submissions pursuant to and in connection with the foregoing that may be necessary, proper, or advisable in order to consummate and make effective the Contemplated Transactions.

(b) Without limiting the generality of anything contained in this Section 5.4, in connection with its efforts to obtain all requisite approvals and authorizations, and the expiration or termination of all applicable waiting periods for the Contemplated Transactions under any Antitrust

Law, each Party hereto shall use its reasonable best efforts to (i) cooperate with the other with respect to any investigation or other inquiry; (ii) promptly provide to the other a copy of all communications received by such Party from, or given by such Party to, any Governmental Body, in each case regarding the Contemplated Transactions; and (iii) to the extent not prohibited under applicable Antitrust Law, permit the other to review in advance any communication given by it to any Governmental Body concerning the Contemplated Transactions, consider in good faith the views of the other in connection with any proposed written communications by such Party to any Governmental Body concerning the Contemplated Transactions, and consult with each other in advance of any meeting or telephone or video conference with, any Governmental Body, and give the other or its outside counsel the opportunity to attend and participate in such meetings and conferences unless prohibited by the applicable Governmental Body; *provided*, that materials required to be provided pursuant to this Section 5.4(b) may be restricted to outside counsel and redacted to (A) remove references concerning the valuation of either Party, (B) comply with contractual arrangements, and (C) preserve attorney-client privilege. Neither Party shall commit to or agree with any Governmental Body to stay, toll or extend any applicable waiting period under applicable Antitrust Law, or pull and refile under the HSR Act, without the prior written consent of the other. Parent and the Company shall each pay one-half of the filing fee under the HSR Act relating to the HSR filing required for the Merger; *provided, however,* that each Party shall bear its own legal fees.

(c) Except as required by this Agreement, prior to Closing, neither the Company nor Parent shall, and shall cause its Affiliates not to, acquire or agree to acquire by merging or consolidating with, or by purchasing a substantial portion of the assets of or equity in, or by any other manner, any Person or portion thereof, or otherwise acquire or agree to acquire any assets, if the entering into of an agreement relating to or the consummation of such acquisition, merger or consolidation would reasonably be expected to (i) impose any delay in the obtaining of, or significantly increase the risk of not obtaining, any authorizations, consents, orders, declarations or approvals of any Governmental Body necessary to consummate the Contemplated Transactions or the expiration or termination of any applicable waiting period, or (ii) increase the risk of any Governmental Body entering an order prohibiting the consummation of the Contemplated Transactions.

5.5 **Company Options and Company Warrants.**

(a) At the Effective Time, each Company Option that is outstanding and unexercised immediately prior to the Effective Time under the Company Plan, whether or not vested, shall be converted into and become an option to purchase Parent Common Stock, and Parent shall assume the Company Plan and each such Company Option in accordance with the terms (as in effect as of the date of this Agreement) of the Company Plan and the terms of the stock option agreement by which such Company Option is evidenced (but with changes to such documents as Parent and the Company mutually agree are appropriate to reflect the substitution of the Company Options by Parent to purchase shares of Parent Common Stock). All rights with respect to Company Common Stock under Company Options assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time: (i) each Company Option assumed by Parent may be exercised solely for shares of Parent Common Stock; (ii) the number of shares of Parent Common Stock subject to each Company Option assumed by Parent shall be determined by multiplying (A) the number of shares of Company Common Stock that were subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Parent Common Stock; (iii) the per share exercise price for the Parent Common Stock issuable upon exercise of each Company Option assumed by Parent shall be determined by dividing (A) the per share exercise price of Company Common Stock subject to such Company Option, as in effect immediately prior to the Effective Time, by (B) the Exchange Ratio, and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any Company Option assumed by Parent shall

continue in full force and effect and the term, exercisability, vesting schedule and other provisions of such Company Option shall otherwise remain unchanged; *provided, however*, that: (A) Parent may amend the terms of the Company Options and the Company Plan to reflect Parent's substitution of the Company Options with options to purchase Parent Common Stock (such as by making any change in control or similar definition relate to Parent and having any provision that provides for the adjustment of Company Options upon the occurrence of certain corporate events relate to corporate events that relate to Parent and/or Parent Common Stock); and (B) the Parent Board or a committee thereof shall succeed to the authority and responsibility of the Company Board or any committee thereof with respect to each Company Option assumed by Parent. Each Company Option so assumed by Parent is intended to qualify following the Effective Time as an incentive stock option as defined in Section 422 of the Code to the extent permitted under Section 422 of the Code and to the extent such Company Option qualified as an incentive stock option prior to the Effective Time, and, further, the assumption of such Company Option pursuant to this Section 5.5(a) shall be effected in a manner that satisfies the requirements of Sections 409A and 424(a) of the Code and the Treasury Regulations promulgated thereunder, and this Section 5.5(a) will be construed consistent with this intent.

(b) Parent shall file with the SEC, promptly, but no later than thirty (30) calendar days after the Effective Time, a registration statement on Form S-8 (or any successor form), if available for use by Parent, relating to the shares of Parent Common Stock that are either (i) issuable with respect to Company Options assumed by Parent in accordance with Section 5.5(a) or (ii) reserved for future grants under the Company Plan.

(c) At the Effective Time, each Company Warrant that is outstanding and unexercised as of immediately prior to the Effective Time, if any, and after giving effect to the Preferred Stock Conversion, shall be converted into and become a warrant to purchase Parent Common Stock and Parent shall assume each such Company Warrant in accordance with its terms. All rights with respect to Company Capital Stock under Company Warrants assumed by Parent shall thereupon be converted into rights with respect to Parent Common Stock. Accordingly, from and after the Effective Time: (i) each Company Warrant assumed by Parent may be exercised solely for shares of Parent Common Stock; (ii) the number of shares of Parent Common Stock subject to each Company Warrant assumed by Parent shall be determined by multiplying (A) the number of shares of Company Common Stock, or the number of shares of Company Preferred Stock issuable upon exercise of the Company Warrant, as applicable, that were subject to such Company Warrant immediately prior to the Effective Time by (B) the Exchange Ratio and rounding the resulting number up to the nearest whole number of shares of Parent Common Stock; (iii) the per share exercise price for the Parent Common Stock issuable upon exercise of each Company Warrant assumed by Parent shall be determined by dividing the per share exercise price of Company Capital Stock subject to such Company Warrant, as in effect immediately prior to the Effective Time, by the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on any Company Warrant assumed by Parent shall continue in full force and effect and the term and other provisions of such Company Warrant shall otherwise remain unchanged.

(d) Prior to the Effective Time, the Company shall take all actions that may be necessary (under the Company Plan, the Company Warrants and otherwise) to effectuate the provisions of this Section 5.5 and to ensure that, from and after the Effective Time, holders of Company Options and Company Warrants have no rights with respect thereto other than those specifically provided in this Section 5.5.

5.6 **Employee Benefits.**

(a) For purposes of vesting, eligibility to participate, and level of benefits under the benefit plans, programs, contracts or arrangements of Parent or any of its Subsidiaries (including,

following the Effective Time, the Surviving Corporation) providing benefits to any Continuing Employee after the Closing (the "***Post-Closing Plans***"), each employee who continues to be employed by Parent, the Surviving Corporation or any of their respective Subsidiaries immediately following the Closing ("***Continuing Employees***") shall be credited with his or her years of service with Parent, the Company or any of their respective Subsidiaries, as applicable, and their respective predecessors; *provided*, *however*, that the foregoing shall not apply to the extent that its application would result in a duplication of benefits. In addition, and without limiting the generality of the foregoing, for purposes of each Post-Closing Plan providing medical, dental, pharmaceutical and/or vision benefits to a Continuing Employee, the Surviving Corporation shall cause all pre-existing condition exclusions and actively-at-work requirements of such Post-Closing Plan to be waived for such Continuing Employee and his or her covered dependents to the extent such conditions would have been waived or satisfied under the employee benefit plan whose coverage is being replaced under the Post-Closing Plan, and the Surviving Corporation shall use commercially reasonable efforts to cause any eligible expenses incurred by a Continuing Employee and his or her covered dependents during the portion of such plan year in which coverage is replaced with coverage under a Post-Closing Plan to be taken into account under such Post-Closing Plan with respect to the plan year in which participation in such Post-Closing Plan begins for purposes of satisfying all deductible, coinsurance and maximum out-of-pocket requirements applicable to such Continuing Employee and his or her covered dependents for such plan year as if such amounts had been paid in accordance with such Post-Closing Plan.

(b) Parent shall provide, or shall cause the Surviving Corporation or any of their respective Subsidiaries to provide, severance payments and benefits to each Continuing Employee who was an employee of Parent or any of its Subsidiaries prior to the Closing that are no less favorable than the severance payments and benefits listed on Section 5.6(b) of the Parent Disclosure Schedule.

(c) The provisions of this Section 5.6 are for the sole benefit of Parent and the Company and no provision of this Agreement shall (i) create any third-party beneficiary or other rights in any Person, including rights in respect of any benefits that may be provided, directly or indirectly, under any Company Benefit Plan, Parent Benefit Plan or Post-Closing Plan or rights to continued employment or service with the Company or Parent (or any Subsidiary thereof), (ii) be construed as an amendment, waiver or creation of or limitation on the ability to terminate any Company Benefit Plan, Parent Benefit Plan or Post-Closing Plan, or (iii) limit the ability of Parent to terminate the employment of any Continuing Employee.

(d) During the Pre-Closing Period, Parent shall use commercially reasonable efforts to make the Parent Associates set forth on Section 5.6(d) of the Parent Disclosure Schedule available to the Company at the Company's reasonable request, for purposes of informational interviews and discussions regarding their employment following the Closing.

5.7 **Indemnification of Officers and Directors.**

(a) From the Effective Time through the sixth (6^{th}) anniversary of the date on which the Effective Time occurs, each of Parent and the Surviving Corporation, jointly and severally, shall indemnify and hold harmless each person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Effective Time, a director, officer, fiduciary or agent of Parent or the Company and their respective Subsidiaries, respectively (the "***D&O Indemnified Parties***"), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the D&O Indemnified Party is or was a director, officer, fiduciary or agent of Parent or of the Company, whether asserted or claimed prior to, at or after the Effective Time, in each case, to the fullest extent permitted under applicable Law. Each D&O Indemnified Party will be entitled

to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from each of Parent and the Surviving Corporation, jointly and severally, upon receipt by Parent or the Surviving Corporation from the D&O Indemnified Party of a request therefor; *provided* that any such person to whom expenses are advanced provides an undertaking to Parent, to the extent then required by the DGCL, to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

(b) The provisions of the Organizational Documents of Parent with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Parent that are set forth in the Organizational Documents of Parent as of the date of this Agreement shall not be amended, modified or repealed for a period of six (6) years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were officers or directors of Parent. The Organizational Documents of the Surviving Corporation shall contain, and Parent shall cause the Organizational Documents of the Surviving Corporation to so contain, provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers as those set forth in the Organizational Documents of Parent as of the date of this Agreement.

(c) From and after the Effective Time, (i) the Surviving Corporation shall fulfill and honor in all respects the obligations of the Company to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under the Company's Organizational Documents and pursuant to any indemnification agreements between the Company and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time and (ii) Parent shall fulfill and honor in all respects the obligations of Parent to its D&O Indemnified Parties as of immediately prior to the Closing pursuant to any indemnification provisions under Parent's Organizational Documents and pursuant to any indemnification agreements between Parent and such D&O Indemnified Parties, with respect to claims arising out of matters occurring at or prior to the Effective Time.

(d) From and after the Effective Time, Parent shall maintain directors' and officers' liability insurance policies, with an effective date as of the Closing Date, on commercially available terms and conditions and with coverage limits customary for U.S. public companies similarly situated to Parent. In addition, Parent shall purchase, prior to the Effective Time, a six (6)-year prepaid "tail policy" (the "***D&O Tail Policy***") for the non-cancellable extension of the directors' and officers' liability coverage of Parent's existing directors' and officers' insurance policies for a claims reporting or discovery period of at least six (6) years from and after the Effective Time with respect to any claim related to any period of time at or prior to the Effective Time. During the term of the D&O Tail Policy, Parent shall not take any action following the Effective Time to cause the D&O Tail Policy to be cancelled or any provision therein to be amended or waived in any manner that would adversely affect in any material respect the rights of their former and current officers and directors.

(e) From and after the Effective Time, Parent shall pay all expenses, including reasonable attorneys' fees, that are incurred by the persons referred to in this Section 5.7 in connection with their successful enforcement of the rights provided to such persons in this Section 5.7.

(f) All rights to exculpation, indemnification and advancement of expenses for acts or omissions occurring at or prior to the Effective Time, whether asserted or claimed prior to, at or after the Closing, now existing in favor of the current or former directors, officers or employees, as the case may be, of Parent or the Company as provided in their respective Organizational Documents or in any agreement shall survive the Merger and shall continue in full force and effect. The provisions of this Section 5.7 are intended to be in addition to the rights otherwise available to the current and former officers and directors of Parent and the Company by Law, charter, statute, bylaw or agreement, and

shall operate for the benefit of, and shall be enforceable by, each of the D&O Indemnified Parties, their heirs and their representatives.

(g) From and after the Effective Time, in the event Parent or the Surviving Corporation or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in each such case, proper provision shall be made so that the successors and assigns of Parent or the Surviving Corporation, as the case may be, shall succeed to the obligations set forth in this Section 5.7. Parent shall cause the Surviving Corporation to perform all of the obligations of the Surviving Corporation under this Section 5.7. The obligations set forth in this Section 5.7 shall not be terminated, amended or otherwise modified in any manner that adversely affects any D&O Indemnified Party, or any person who is a beneficiary under the policies referred to in this Section 5.7 and their heirs and representatives, without the prior written consent of such affected D&O Indemnified Party or other person

5.8 **Additional Agreements**. The Parties shall (a) use commercially reasonable efforts to cause to be taken all actions necessary to consummate the Contemplated Transactions and (b) reasonably cooperate with the other Parties and provide the other Parties with such assistance as may be reasonably requested for the purpose of facilitating the performance by each Party of its respective obligations under this Agreement and to enable the Surviving Corporation to continue to meet its obligations under this Agreement following the Closing. Without limiting the generality of the foregoing, each Party to this Agreement: (i) shall make all filings and other submissions (if any) and give all notices (if any) required to be made and given by such Party in connection with the Contemplated Transactions; (ii) shall use reasonable best efforts to obtain each Consent (if any) reasonably required to be obtained (pursuant to any applicable Law or Contract, or otherwise) by such Party in connection with the Contemplated Transactions or for such Contract (with respect to Contracts set forth in Section 5.8 of the Company Disclosure Schedule or Section 5.8 of the Parent Disclosure Schedule, as applicable) to remain in full force and effect; (iii) shall use commercially reasonable efforts to lift any injunction prohibiting, or any other legal bar to, the Contemplated Transactions; and (iv) shall use commercially reasonable efforts to satisfy the conditions precedent to the consummation of this Agreement.

5.9 **Public Announcement**. The initial press release relating to this Agreement shall be a joint press release issued by the Company and Parent and thereafter Parent and the Company shall consult with each other before issuing any further press release(s) or otherwise making any public statement or making any announcement to Parent Associates or Company Associates (to the extent not previously issued or made in accordance with this Agreement) with respect to the Contemplated Transactions and shall not issue any such press release, public statement or announcement to Parent Associates or Company Associates without the other Party's written consent (which shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing: (a) each Party may, without such consultation or consent, make any public statement in response to questions from the press, analysts, investors or those attending industry conferences, make internal announcements to employees and make disclosures in Parent SEC Documents, so long as such statements are consistent with public disclosures or public statements made jointly by the Parties (or individually, if approved by the other Party); (b) a Party may, without the prior consent of the other Party hereto but subject to giving advance notice to the other Party, issue any such press release or make any such public announcement or statement as may be required by any applicable Law; and (c) Parent need not consult with the Company in connection with such portion of any press release, public statement or filing to be issued or made pursuant to Section 5.3(e) or with respect to any Acquisition Proposal or Parent Board Adverse Recommendation Change.

5.10 **Listing**. Parent shall use its commercially reasonable efforts, (a) to maintain its existing listing on Nasdaq until the Effective Time and to obtain approval of the listing of the combined corporation on Nasdaq; (b) to the extent required by the rules and regulations of Nasdaq, to prepare and submit to Nasdaq a notification form for the listing of the shares of Parent Common Stock to be issued in connection with the Contemplated Transactions, and to cause such shares to be approved for listing (subject to official notice of issuance); and (c) to the extent required by Nasdaq Marketplace Rule 5110, to file an initial listing application for the Parent Common Stock on Nasdaq (the "***Nasdaq Listing Application***") and to cause such Nasdaq Listing Application to be conditionally approved prior to the Effective Time. Each Party will reasonably promptly inform the other Party of all verbal or written communications between Nasdaq and such Party or its representatives. The Parties will use commercially reasonable efforts to coordinate with respect to compliance with Nasdaq rules and regulations. The Company agrees to pay all Nasdaq fees associated with the Nasdaq Listing Application. The Company will cooperate with Parent as reasonably requested by Parent with respect to the Nasdaq Listing Application and promptly furnish to Parent all information concerning the Company and its stockholders that may be required or reasonably requested in connection with any action contemplated by this Section 5.10.

5.11 **Tax Matters.**

(a) For United States federal income Tax purposes, (i) the Parties intend that the Merger qualify as a "reorganization" within the meaning of Section 368(a) of the Code, and (ii) this Agreement is intended to be, and is hereby adopted as, a "plan of reorganization" for purposes of Sections 354 and 361 of the Code and Treasury Regulations Sections 1.368-2(g) and 1.368-3(a), to which Parent, Merger Sub and the Company are parties under Section 368(b) of the Code.

(b) The Parties shall use their respective reasonable best efforts to cause the Merger to qualify, and will not knowingly take any action (or knowingly fail to take any action) or knowingly cause any action to be taken (or omission to occur) which action (or omission) would reasonably be expected to prevent the Merger from qualifying, for the Intended Tax Treatment. Neither Party shall take any Tax reporting position inconsistent with the Intended Tax Treatment for United States federal income Tax purposes unless otherwise required by a change in applicable Law after the date of this Agreement or a "determination" within the meaning of Section 1313(a) of the Code. Notwithstanding the foregoing, none of Parent, Merger Sub, or the Company makes any representations or warranties to any securityholder of Parent or the Company regarding the Tax treatment of the Merger, or any of the Tax consequences to any securityholder of Parent or the Company of this Agreement, the Merger or any of the Contemplated Transactions.

5.12 **Legends**. Parent shall be entitled to place appropriate legends on the book entries and/or certificates evidencing any shares of Parent Common Stock to be received in the Merger by the equity holders of the Company who may be considered "affiliates" of Parent for purposes of Rules 144 and 145 promulgated under the Securities Act reflecting the restrictions set forth in Rules 144 and 145 and to issue appropriate stop transfer instructions to the transfer agent for Parent Common Stock.

5.13 **Directors and Officers**. The Parties shall use reasonable best efforts and take all necessary action so that immediately after the Effective Time, (a) the Parent Board is comprised of ten (10) members, with three (3) such members designated by Parent and seven (7) such members designated by the Company, (b) the Persons listed in **Exhibit E** under the heading "Officers" are elected or appointed, as applicable, to the positions of officers of Parent, as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law. If any Person listed in **Exhibit E** is unable or unwilling to serve as an officer of Parent, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor. The Persons listed in **Exhibit E** under the heading "Board Designees – Parent" shall be

Parent's designees pursuant to clause (a) of this Section 5.13 (which list may be changed by Parent at any time prior to the Closing by written notice to the Company to include different board designees who are reasonably acceptable to the Company) (the "***Parent Designees***"). The Persons listed in **Exhibit E** under the heading "Board Designees – Company" shall be the Company's designees pursuant to clause (a) of this Section 5.13 (which list may be changed by the Company at any time prior to the Closing by written notice to Parent to include different board designees who are reasonably acceptable to Parent).

5.14 **Termination of Certain Agreements and Rights**. The Company shall cause the Investor Agreements to be terminated immediately prior to the Effective Time, without any liability being imposed on the part of Parent or the Surviving Corporation.

5.15 **Section 16 Matters**. Prior to the Effective Time, Parent and the Company shall take all such steps as may be required (to the extent permitted under applicable Laws) to cause any acquisitions of Parent Common Stock, restricted stock awards to acquire Parent Common Stock and any options to purchase Parent Common Stock in connection with the Contemplated Transactions, by each individual who is reasonably expected to become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent, to be exempt under Rule 16b-3 promulgated under the Exchange Act. Promptly following the date of this Agreement and at least thirty (30) calendar days prior to the Closing Date, the Company shall furnish the following information to Parent for each individual who, immediately after the Effective Time, will become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Parent: (a) the number of shares of Company Capital Stock owned by such individual and expected to be exchanged for shares of Parent Common Stock pursuant to the Merger, and (b) the number of other derivative securities (if any) with respect to Company Capital Stock owned by such individual and expected to be converted into shares of Parent Common Stock, restricted stock awards to acquire Parent Common Stock or derivative securities with respect to Parent Common Stock in connection with the Merger.

5.16 **Cooperation**. Each Party shall cooperate reasonably with the other Party and shall provide the other Party with such assistance as may be reasonably requested for the purpose of facilitating the performance by each Party of its respective obligations under this Agreement and to enable the combined entity to continue to meet its obligations following the Effective Time.

5.17 **Allocation Certificates**.

(a) The Company will prepare and deliver to Parent at least ten (10) Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of the Company in a form reasonably acceptable to Parent setting forth (as of immediately prior to the Effective Time) (i) each holder of Company Capital Stock, Company Options and Company Warrants, (ii) such holder's name and address; (iii) the number and type of Company Capital Stock held and/or underlying the Company Options and Company Warrants as of the immediately prior to the Effective Time for each such holder; and (iv) the number of shares of Parent Common Stock to be issued to such holder, or to underlie any Parent Option or Company Warrant to be issued to such holder, pursuant to this Agreement in respect of the Company Capital Stock, Company Options or Company Warrants held by such holder as of immediately prior to the Effective Time (the "***Allocation Certificate***").

(b) Parent will prepare and deliver to the Company at least ten (10) Business Days prior to the Closing Date a certificate signed by the Chief Financial Officer of Parent in a form reasonably acceptable to the Company, setting forth, as of immediately prior to the Effective Time (i) each record holder of Parent Common Stock, Parent Options or Parent RSUs, (ii) such record holder's name and address, (iii) the number of shares of Parent Common Stock held and/or underlying the Parent Options or Parent RSUs as of the Effective Time for such holder (the "***Parent Outstanding Shares Certificate***").

5.18 **Company Financial Statements**. As promptly as reasonably practicable following the date of this Agreement, the Company will furnish to Parent (i) audited consolidated financial statements for the fiscal years ended 2021, 2020 and 2019 for inclusion in the Proxy Statement (the "***Company Audited Financial Statements***") and (ii) unaudited interim consolidated financial statements for each interim period completed prior to Closing that would be required to be included in the Proxy Statement or any periodic report due prior to the Closing if the Company were subject to the periodic reporting requirements under the Securities Act or the Exchange Act (the "***Company Interim Financial Statements***"). Each of the Company Audited Financial Statements and the Company Interim Financial Statements will be suitable for inclusion in the Proxy Statement and prepared in accordance with GAAP as applied on a consistent basis during the periods involved (except in each case as described in the notes thereto) and on that basis will present fairly, in all material respects, the consolidated financial position and the results of operations, changes in stockholders' equity, and cash flows of the Company and its consolidated Subsidiaries as of the dates of and for the periods referred to in the Company Audited Financial Statements or the Company Interim Financial Statements, as the case may be.

5.19 **Takeover Statutes**. If any Takeover Statute is or may become applicable to the Contemplated Transactions, each of the Company, the Company Board, Parent and the Parent Board, as applicable, shall grant such approvals and take such actions as are necessary so that the Contemplated Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise act to eliminate or minimize the effects of such Takeover Statute on the Contemplated Transactions.

5.20 **Stockholder Litigation**. Parent shall conduct and control the settlement and defense of any stockholder litigation against Parent or any of its directors; *provided* that prior to the Closing no such settlement shall be agreed to without the prior written consent of the Company, which consent shall not be unreasonably withheld, conditioned or delayed; and *provided further* that any settlement or other resolution of any stockholder litigation commenced prior to Closing and agreed to by Parent after the Closing shall be approved in advance by at least a majority of the Parent Designees for so long as any Parent Designees are still members of the Parent Board, which approval shall not be unreasonably withheld, conditioned or delayed. Without limiting the foregoing, prior to the Closing, Parent shall give the Company the opportunity to consult with Parent in connection with the defense and settlement of any such stockholder litigation, and Parent shall keep the Company reasonably apprised of any material developments in connection with any such stockholder litigation.

Section 6. CONDITIONS PRECEDENT TO OBLIGATIONS OF EACH PARTY

The obligations of each Party to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing are subject to the satisfaction or, to the extent permitted by applicable Law, the written waiver by each of the Parties, at or prior to the Closing, of each of the following conditions:

6.1 **No Restraints**. No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Contemplated Transactions shall have been issued by any court of competent jurisdiction or other Governmental Body of competent jurisdiction and remain in effect and there shall not be any Law which has the effect of making the consummation of the Contemplated Transactions illegal.

6.2 **Stockholder Approval**. (a) Parent shall have obtained the Required Parent Stockholder Vote and (b) the Company shall have obtained the Required Company Stockholder Vote.

6.3 **Listing**. (a) The existing shares of Parent Common Stock shall have been continually listed on Nasdaq as of and from the date of this Agreement through the Closing Date and (b) the

shares of Parent Common Stock to be issued in the Merger pursuant to this Agreement shall have been approved for listing (subject to official notice of issuance) on Nasdaq as of the Closing.

6.4 **Government Approvals**. The waiting period applicable to the consummation of the Contemplated Transactions under the HSR Act, and any extensions thereof, shall have expired or been terminated.

6.5 **Net Cash Determination**. Parent Net Cash shall have been finally determined in accordance with Section 1.6.

Section 7. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATIONS OF PARENT AND MERGER SUB

The obligations of Parent and Merger Sub to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing are subject to the satisfaction or the written waiver by Parent, at or prior to the Closing, of each of the following conditions:

7.1 **Accuracy of Representations**. The Company Fundamental Representations shall have been true and correct in all material respects as of the date of this Agreement and shall be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct in all material respects as of such date). The representations and warranties of the Company contained in this Agreement (other than the Company Fundamental Representations) shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have a Company Material Adverse Effect (without giving effect to any references therein to any Company Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Company Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

7.2 **Performance of Covenants**. The Company shall have performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it under this Agreement at or prior to the Effective Time.

7.3 **Documents**. Parent shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the Chief Executive Officer or Chief Financial Officer of the Company certifying (i) that the conditions set forth in Sections 7.1, 7.2, 7.5 and 7.6 have been duly satisfied and (ii) that the information set forth in the Allocation Certificate delivered by the Company in accordance with Section 5.17 is true and accurate in all respects as of the Closing Date; and

(b) the Allocation Certificate.

7.4 **FIRPTA Certificate**. Parent shall have received (i) an original signed statement from the Company that the Company is not, and has not been at any time during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code, a “United States real property holding corporation,” as defined in Section 897(c)(2) of the Code, conforming to the requirements of Treasury Regulations

Section 1.1445-2(c)(3) and 1.897-2(h), and (ii) an original signed notice to be delivered to the IRS in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2), together with written authorization for Parent to deliver such notice to the IRS on behalf of the Company following the Closing, each dated as of the Closing Date, duly executed by an authorized officer of the Company, and in form and substance reasonably acceptable to Parent.

7.5 **No Company Material Adverse Effect**. Since the date of this Agreement, there shall not have occurred any Company Material Adverse Effect that is continuing.

7.6 **Termination of Investor Agreements**. The Investor Agreements shall have been terminated (or will be terminated as of the Closing).

7.7 **Accredited Investors**. The number of stockholders of the Company who have not executed an Investor Questionnaire certifying that such stockholder of the Company is an "accredited investor" pursuant to Regulation D under the Securities Act, is less than ten (10) stockholders, and any such stockholder either alone or with such stockholder's purchaser representative(s) has such knowledge and experience in financial and business matters that such stockholder is capable of evaluating the merits and risks of the Merger.

7.8 **Company Stockholder Written Consent**. The Company Stockholder Written Consent executed by each Company Signatory shall be in full force and effect.

7.9 **Dissenting Shares**. No stockholders of the Company shall have exercised statutory appraisal rights pursuant to Section 262 of the DGCL or Chapter 13 of California Law with respect to their shares of Company Capital Stock.

7.10 **Company New Drug Application**. The Company shall have provided Parent with FDA confirmation of submission for a New Drug Application for Company's *neffy*™ (epinephrine nasal spray) 2 mg.

7.11 **Company Lock-Up Agreements**. Parent shall have received the Company Lock-Up Agreements duly executed by each of the Company Lock-Up Signatories and each executive officer and director of the Company who is elected or appointed, as applicable, as an executive officer and director of Parent as of immediately following the Closing, each of which shall be in full force and effect.

Section 8. ADDITIONAL CONDITIONS PRECEDENT TO OBLIGATION OF THE COMPANY

The obligations of the Company to effect the Merger and otherwise consummate the Contemplated Transactions to be consummated at the Closing are subject to the satisfaction or the written waiver by the Company, at or prior to the Closing, of each of the following conditions:

8.1 **Accuracy of Representations**. The Parent Fundamental Representations shall have been true and correct in all material respects as of the date of this Agreement and shall be true and correct in all material respects on and as of the Closing Date with the same force and effect as if made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct in all material respects as of such date). The representations and warranties of Parent and Merger Sub contained in this Agreement (other than the Parent Fundamental Representations) shall have been true and correct as of the date of this Agreement and shall be true and correct on and as of the Closing Date with the same force and effect as if made on the Closing Date except (a) in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have a Parent

Material Adverse Effect (without giving effect to any references therein to any Parent Material Adverse Effect or other materiality qualifications), or (b) for those representations and warranties which address matters only as of a particular date (which representations shall have been true and correct, subject to the qualifications as set forth in the preceding clause (a), as of such particular date) (it being understood that, for purposes of determining the accuracy of such representations and warranties, any update of or modification to the Parent Disclosure Schedule made or purported to have been made after the date of this Agreement shall be disregarded).

8.2 **Performance of Covenants**. Parent and Merger Sub shall have performed or complied with in all material respects all of their agreements and covenants required to be performed or complied with by each of them under this Agreement at or prior to the Effective Time.

8.3 **Documents**. The Company shall have received the following documents, each of which shall be in full force and effect:

(a) a certificate executed by the Chief Executive Officer or Chief Financial Officer of Parent certifying that the conditions set forth in Sections 8.1, 8.2, and 8.4 have been duly satisfied;

(b) the Parent Outstanding Shares Certificate;

(c) a written resignation, in a form reasonably satisfactory to the Company, dated as of the Closing Date and effective as of the Closing, executed by each of the directors of Parent who are not to continue as directors of Parent after the Closing pursuant to Section 5.13 hereof; and

(d) the Parent Closing Financial Certificate, a draft of which shall have been provided at least five (5) Business Days prior to the Closing, which certificate shall be accompanied by such supporting documentation, information and calculations as are reasonably requested by the Company to verify and determine the information contained therein.

8.4 **No Parent Material Adverse Effect**. Since the date of this Agreement, there shall not have occurred any Parent Material Adverse Effect that is continuing.

8.5 **Parent Net Cash**. Parent Net Cash, as finally determined pursuant to Section 1.6, shall not be less than $210,000,000 nor greater than $255,000,000; *provided, however,* that if Parent Net Cash is greater than $255,000,000, Parent may declare a Permitted Dividend in the amount of such excess to satisfy such condition.

8.6 **Parent Lock-Up Agreements**. The Company shall have received the Parent Lock-Up Agreements duly executed by each of the Parent Lock-Up Signatories, each of which shall be in full force and effect.

Section 9. TERMINATION

9.1 **Termination**. This Agreement may be terminated prior to the Effective Time (whether before or after approval of the Company Stockholder Matters by the Company's stockholders and whether before or after approval of the Parent Stockholder Matters by Parent's stockholders, unless otherwise specified below):

(a) by mutual written consent of Parent and the Company;

(b) by either Parent or the Company if the Contemplated Transactions shall not have been consummated by January 21, 2023 (subject to possible extension as provided in this Section 9.1(b), the "***End Date***"); *provided*, *however*, that the right to terminate this Agreement under

this Section 9.1(b) shall not be available to the Company, on the one hand, or to Parent, on the other hand, if such Party's action or failure to act has been a principal cause of the failure of the Contemplated Transactions to occur on or before the End Date and such action or failure to act constitutes a breach of this Agreement; *provided*, *further*, *however*, that, in the event that a request for additional information has been made by any Governmental Body (including via a comment letter or other communication from the SEC) which request has not been satisfied by the End Date, then either Parent or the Company shall be entitled to extend the End Date for an additional sixty (60) calendar days by written notice to the other Party;

(c) by either Parent or the Company if a court of competent jurisdiction or other Governmental Body shall have issued a final and nonappealable order, decree or ruling, or shall have taken any other action, having the effect of permanently restraining, enjoining or otherwise prohibiting the Contemplated Transactions;

(d) by Parent if the Company Stockholder Written Consent executed by each Company Signatory shall not have been obtained within one (1) Business Day of the date of this Agreement; *provided*, *however*, that once the Company Stockholder Written Consent has been obtained, Parent may not terminate this Agreement pursuant to this Section 9.1(d);

(e) by either Parent or the Company if (i) the Parent Stockholders' Meeting (including any adjournments and postponements thereof) shall have been held and completed and Parent's stockholders shall have taken a final vote on the Parent Stockholder Matters and (ii) the Parent Stockholder Matters shall not have been approved at the Parent Stockholders' Meeting (or at any adjournment or postponement thereof) by the Required Parent Stockholder Vote;

(f) by the Company (at any time prior to the approval of the Parent Stockholder Matters by the Required Parent Stockholder Vote) if a Parent Triggering Event shall have occurred;

(g) by Parent (at any time prior to the Required Company Stockholder Vote being obtained) if a Company Triggering Event shall have occurred;

(h) by the Company, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by Parent or Merger Sub or if any representation or warranty of Parent or Merger Sub shall have become inaccurate, in either case, such that the conditions set forth in Section 8.1 or Section 8.2 would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that the Company is not then in material breach of any representation, warranty, covenant or agreement under this Agreement; *provided*, *further*, that if such inaccuracy in Parent's or Merger Sub's representations and warranties or breach by Parent or Merger Sub is curable by the End Date by Parent or Merger Sub, then this Agreement shall not terminate pursuant to this Section 9.1(h) as a result of such particular breach or inaccuracy until the earlier of (i) the End Date and (ii) the expiration of a thirty (30) calendar day period commencing upon delivery of written notice from the Company to Parent or Merger Sub of such breach or inaccuracy and its intention to terminate pursuant to this Section 9.1(h) (it being understood that this Agreement shall not terminate pursuant to this Section 9.1(h) as a result of such particular breach or inaccuracy if such breach by Parent or Merger Sub is cured prior to such termination becoming effective);

(i) by Parent, upon a breach of any representation, warranty, covenant or agreement set forth in this Agreement by the Company or if any representation or warranty of the Company shall have become inaccurate, in either case, such that the conditions set forth in Section 7.1 or Section 7.2 would not be satisfied as of the time of such breach or as of the time such representation or warranty shall have become inaccurate; *provided* that Parent is not then in material breach of any

representation, warranty, covenant or agreement under this Agreement; *provided*, *further*, that if such inaccuracy in the Company's representations and warranties or breach by the Company is curable by the End Date by the Company then this Agreement shall not terminate pursuant to this Section 9.1(i) as a result of such particular breach or inaccuracy until the earlier of (i) the End Date and (ii) the expiration of a thirty (30) calendar day period commencing upon delivery of written notice from Parent to the Company of such breach or inaccuracy and its intention to terminate pursuant to this Section 9.1(i) (it being understood that this Agreement shall not terminate pursuant to this Section 9.1(i) as a result of such particular breach or inaccuracy if such breach by the Company is cured prior to such termination becoming effective); or

(j) by Parent, at any time, if (i) Parent has received a Superior Offer, (ii) Parent has complied with its obligations under Section 5.3(d) in order to accept such Superior Offer, (iii) Parent concurrently terminates this Agreement and enters into a Permitted Alternative Agreement with respect to such Superior Offer and (iv) within two (2) Business Days of such termination, Parent pays to the Company the amount contemplated by Section 9.3(b).

The Party desiring to terminate this Agreement pursuant to Section 9.1, shall give the other Party written notice of such termination, specifying the provisions hereof pursuant to which such termination is made and the basis therefor described in reasonable detail.

9.2 **Effect of Termination**. In the event of the termination of this Agreement as provided in Section 9.1, this Agreement shall be of no further force or effect; *provided*, *however*, that (a) this Section 9.2, Section 5.9, Section 9.3, Section 10 and the definitions of the defined terms in such Sections (including the definitions of such defined terms on **Exhibit A**) shall survive the termination of this Agreement and shall remain in full force and effect, and (b) the termination of this Agreement and the provisions of Section 9.3 shall not relieve any Party of any liability for fraud or for any willful and material breach of any representation, warranty, covenant, obligation or other provision contained in this Agreement.

9.3 **Expenses; Termination Fees.**

(a) Except as set forth in this Section 9.3, Section 1.6(e), Section 5.4(b), and Section 5.10, the Transaction Expenses shall be paid by the Party incurring such expenses, whether or not the Merger is consummated; *provided* that Parent and the Company shall each pay one-half of the fees and expenses incurred in relation to the printing and filing with the SEC of the Proxy Statement and any amendments and supplements thereto and paid to a financial printer or the SEC. It is understood and agreed that all fees and expenses incurred or to be incurred by or payable by each Party in connection with the Contemplated Transactions and preparing, negotiating and entering into this Agreement and the performance of its obligations under this Agreement shall be paid by such Party in cash at or prior to the Closing.

(b) If:

(i) (A) this Agreement is terminated pursuant to Section 9.1(b), Section 9.1(e) or Section 9.1(h), (B) an Acquisition Proposal with respect to Parent shall have been publicly announced or disclosed to Parent or the Parent Board after the date of this Agreement but prior to the termination of this Agreement (which shall not have been withdrawn), and (C) within twelve (12) months after the date of such termination, Parent consummates a Subsequent Transaction in respect of the Acquisition Proposal referred to in clause (B);

(ii) this Agreement is terminated by the Company pursuant to Section 9.1(f) (or, at the time this Agreement is terminated, the Company had the right to terminate this Agreement pursuant to Section 9.1(f)); or

(iii) this Agreement is terminated by Parent pursuant to Section 9.1(j);

then in the case of a termination pursuant to Section 9.3(b)(i) or Section 9.3(b)(ii), Parent shall pay to the Company an amount equal to $6,000,000, and in the case of a termination pursuant to Section 9.3(b)(iii), Parent shall pay to the Company an amount equal to $10,000,000 (each, the "***Company Termination Fee***"), within three (3) Business Days of consummation of such Subsequent Transaction or termination of this Agreement, as applicable.

(c) If:

(i) (A) this Agreement is terminated pursuant to Section 9.1(b), Section 9.1(e), or Section 9.1(i), (B) an Acquisition Proposal with respect to the Company shall have been publicly announced or disclosed or otherwise communicated to the Company or the Company Board after the date of this Agreement but prior to the termination of this Agreement (which shall not have been withdrawn), and (C) within twelve (12) months after the date of such termination, the Company consummates a Subsequent Transaction in respect of the Acquisition Proposal referred to in clause (B); or

(ii) this Agreement is terminated by Parent pursuant to Section 9.1(g) (or, at the time this Agreement is terminated, the Parent had the right to terminate this Agreement pursuant to Section 9.1(g);

then the Company shall pay to Parent an amount equal to $6,000,000 (the "***Parent Termination Fee***") within three (3) Business Days of consummation of such Subsequent Transaction or termination of this Agreement, as applicable.

(d) If this Agreement is terminated by either Parent or the Company pursuant to Section 9.1(e), then Parent shall reimburse the Company for all reasonable out-of-pocket fees and expenses incurred by the Company in connection with this Agreement and the Contemplated Transactions, up to a maximum of $1,500,000, by wire transfer of same-day funds within three (3) Business Days following the date on which the Company submits to Parent true and correct copies of reasonable documentation supporting such expenses.

(e) Any Company Termination Fee or Parent Termination Fee due under this Section 9.3 shall be paid by wire transfer of same day funds. If a Party fails to pay when due any amount payable by it under this Section 9.3, then such Party shall (i) reimburse the other Party for reasonable costs and expenses (including reasonable fees and disbursements of counsel) incurred by it in connection with the collection of such overdue amount and the enforcement by such Party of its rights under this Section 9.3 and (ii) pay to the other Party interest on such overdue amount (for the period commencing as of the date such overdue amount was originally required to be paid and ending on the date such overdue amount is actually paid to the Company in full) at a rate per annum equal to the "prime rate" (as published in *The Wall Street Journal* or any successor thereto) in effect on the date such overdue amount was originally required to be paid.

(f) The Parties agree that, (i) subject to Section 9.2, payment of the Company Termination Fee shall, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of the Company following the termination of this Agreement, it being understood that in no event shall Parent be required to pay the Company Termination Fee on more than one occasion and (ii) following payment of the Company Termination Fee (x) Parent shall have no further liability to the Company in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by Parent giving rise to such termination, or the failure of the Contemplated Transactions to be consummated, (y) neither the Company nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against Parent or Merger Sub or seek to obtain any recovery, judgment or damages of any kind against such Parties (or any partner, member, stockholder, director, officer, employee, Subsidiary,

Affiliate, agent or other Representative of such Parties) in connection with or arising out of this Agreement or the termination thereof, any breach by any such Parties giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (z) the Company and its Affiliates shall be precluded from any other remedy against Parent, Merger Sub and their respective Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; *provided*, *however*, that nothing in this Section 9.3(f) shall limit the rights of Parent and Merger Sub under Section 10.11.

(g) The Parties agree that, (i) subject to Section 9.2, payment of the Parent Termination Fee shall, in the circumstances in which it is owed in accordance with the terms of this Agreement, constitute the sole and exclusive remedy of Parent following the termination of this Agreement, it being understood that in no event shall the Company be required to pay the Parent Termination Fee on more than one occasion and (ii) following payment of the Parent Termination Fee (x) the Company shall have no further liability to Parent in connection with or arising out of this Agreement or the termination thereof, any breach of this Agreement by the Company giving rise to such termination, or the failure of the Contemplated Transactions to be consummated, (y) neither Parent nor any of its Affiliates shall be entitled to bring or maintain any other claim, action or proceeding against the Company or seek to obtain any recovery, judgment or damages of any kind against such Parties (or any partner, member, stockholder, director, officer, employee, Subsidiary, Affiliate, agent or other Representative of such Parties) in connection with or arising out of this Agreement or the termination thereof, any breach by any such Parties giving rise to such termination or the failure of the Contemplated Transactions to be consummated and (z) Parent and its Affiliates shall be precluded from any other remedy against the Company and its Affiliates, at law or in equity or otherwise, in connection with or arising out of this Agreement or the termination thereof, any breach by such Party giving rise to such termination or the failure of the Contemplated Transactions to be consummated; *provided*, *however*, that nothing in this Section 9.3(g) shall limit the rights of the Company under Section 10.11.

(h) Each of the Parties acknowledges that (i) the agreements contained in this Section 9.3 are an integral part of the Contemplated Transactions, (ii) without these agreements, the Parties would not enter into this Agreement and (iii) any amount payable pursuant to this Section 9.3 is not a penalty, but rather is liquidated damages in a reasonable amount that will compensate the applicable Party in the circumstances in which such amount is payable.

Section 10. MISCELLANEOUS PROVISIONS

10.1 **Non-Survival of Representations and Warranties**. The representations and warranties and covenants of the Company, Parent and Merger Sub contained in this Agreement or any certificate or instrument delivered pursuant to this Agreement shall terminate at the Effective Time; *provided* that the covenants that by their terms survive the Effective Time and this Section 10 shall survive the Effective Time.

10.2 **Amendment**. This Agreement may be amended with the approval of the Company, Merger Sub and Parent at any time (whether before or after obtaining the Required Company Stockholder Vote or before or after obtaining the Required Parent Stockholder Vote); *provided*, *however*, that after any such approval of this Agreement by a Party's stockholders, no amendment shall be made which by Law requires further approval of such stockholders without the further approval of such stockholders. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Company, Merger Sub and Parent.

10.3 **Waiver.**

(a) No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

10.4 **Entire Agreement; Counterparts; Exchanges by Electronic Transmission**. This Agreement, the Company Disclosure Schedule, the Parent Disclosure Schedule and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; *provided*, *however*, that the Confidentiality Agreement shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

10.5 **Applicable Law; Jurisdiction**. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws. In any action or proceeding between any of the Parties arising out of or relating to this Agreement or any of the Contemplated Transactions, each of the Parties: (a) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware or, to the extent that neither of the foregoing courts has jurisdiction, the Superior Court of the State of Delaware; (b) agrees that all claims in respect of such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 10.5; (c) waives any objection to laying venue in any such action or proceeding in such courts; (d) waives any objection that such courts are an inconvenient forum or do not have jurisdiction over any Party; (e) agrees that service of process upon such Party in any such action or proceeding shall be effective if notice is given in accordance with Section 10.8 of this Agreement; and (f) irrevocably and unconditionally waives the right to trial by jury.

10.6 **Attorneys' Fees**. In any action at law or suit in equity to enforce this Agreement or the rights of any of the Parties, the prevailing Party in such action or suit (as determined by a court of competent jurisdiction) shall be entitled to recover its reasonable out-of-pocket attorneys' fees and all other reasonable costs and expenses incurred in such action or suit.

10.7 **Assignability**. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and permitted assigns; *provided*, *however*, that neither this Agreement nor any of a Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect.

10.8 **Notices**. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, (b) upon delivery in the case of delivery by hand, or (c) on the date delivered in the place of delivery if sent by email (with a written or electronic confirmation of delivery) prior to 5:00 p.m. San Diego time, otherwise on the next succeeding Business Day, in each case to the intended recipient as set forth below:

if to Parent or Merger Sub:

Silverback Therapeutics, Inc.
500 Fairview Ave N, Suite 600
Seattle, Washington 98109
Attention: General Counsel
Email: [***]

with a copy to (which shall not constitute notice):

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Rama Padmanabhan, Ken Rollins
Email: rama@cooley.com, krollins@cooley.com

if to the Company:

ARS Pharmaceuticals, Inc.
11682 El Camino Real Suite 120
San Diego, CA 92130
Attention: Legal Department
Email: [***]

with a copy to (which shall not constitute notice):

Inceptiv Law, Inc.
Attention: Ethan Christensen
12463 Rancho Bernardo Rd #281
San Diego, CA 92128
Email: ethan@inceptiv.law

10.9 **Cooperation**. **Each Party agrees to cooperate fully with the other Party and to execute and deliver such further documents, certificates, agreements and instruments and to take such other actions as may be reasonably requested by the other Party to evidence or reflect the Contemplated Transactions and to carry out the intent and purposes of this Agreement.**

10.10 **Severability**. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such

invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

10.11 **Other Remedies; Specific Performance**. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. The Parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that any Party does not perform the provisions of this Agreement (including failing to take such actions as are required of it hereunder to consummate this Agreement) in accordance with its specified terms or otherwise breaches such provisions. Accordingly, the Parties acknowledge and agree that the Parties shall be entitled to an injunction, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, in addition to any other remedy to which they are entitled at law or in equity. Each of the Parties agrees that it will not oppose the granting of an injunction, specific performance or other equitable relief on the basis that any other Party has an adequate remedy at law or that any award of specific performance is not an appropriate remedy for any reason at law or in equity. Any Party seeking an injunction or injunctions to prevent breaches of this Agreement shall not be required to provide any bond or other security in connection with any such order or injunction.

10.12 **No Third Party Beneficiaries**. Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person (other than the Parties and the D&O Indemnified Parties to the extent of their respective rights pursuant to Section 5.7) any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.13 **Construction.**

(a) References to “cash,” “dollars” or “$” are to U.S. dollars.

(b) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(c) The Parties have participated jointly in the negotiating and drafting of this Agreement and agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

(d) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

(e) Except as otherwise indicated, all references in this Agreement to “Sections,” “Exhibits” and “Schedules” are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement, respectively.

(f) Any reference to legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations, and statutory instruments issued or related to such legislations.

(g) The bold-faced headings and table of contents contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

(h) The Parties agree that each of the Company Disclosure Schedule and the Parent Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement. The disclosures in any section or subsection of the Company Disclosure Schedule or the Parent Disclosure Schedule shall qualify other sections and subsections in this Agreement to the extent it is readily apparent on its face from a reading of the disclosure that such disclosure is applicable to such other sections and subsections.

(i) Each of "delivered" or "made available" means, with respect to any documentation, that prior to 11:59 p.m. (San Diego time) on the date that is two (2) calendar days prior to the date of this Agreement (i) a copy of such material has been posted to and made available by a Party to the other Party and its Representatives in the electronic data room maintained by such disclosing Party or (ii) such material is disclosed in the Parent SEC Documents filed with the SEC prior to the date hereof and publicly made available on the SEC's Electronic Data Gathering Analysis and Retrieval system.

(j) Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a Saturday, Sunday, or any date on which banks in San Diego, California are authorized or obligated by Law to be closed, the Party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day which is a regular Business Day.

(*Remainder of page intentionally left blank*)

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

SILVERBACK THERAPEUTICS, INC.

By: /s/ Laura Shawver, Ph.D.
Name: Laura Shawver, Ph.D.
Title: Chief Executive Officer

SABRE MERGER SUB, INC.

By: /s/ Jonathan Piazza
Name: Jonathan Piazza
Title: Chief Financial Officer and Treasurer

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal, M.S., MBA
Name: Richard Lowenthal, M.S., MBA
Title: Chief Executive Officer

[Signature Page to Agreement and Plan of Merger and Reorganization]

EXHIBIT A

CERTAIN DEFINITIONS

For purposes of this Agreement (including this **Exhibit A**):

"***Acquisition Inquiry***" means, with respect to a Party, an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by the Company, on the one hand, or Parent, on the other hand, to the other Party) that would reasonably be expected to lead to an Acquisition Proposal.

"***Acquisition Proposal***" means, with respect to a Party, any offer or proposal, whether written or oral (other than an offer or proposal made or submitted by or on behalf of the Company or any of its Affiliates, on the one hand, or by or on behalf of Parent or any of its Affiliates, on the other hand, to the other Party) contemplating or otherwise relating to or that would reasonably be interpreted to lead to any Acquisition Transaction with such Party, other than the Asset Dispositions.

"***Acquisition Transaction***" means any transaction or series of related transactions (other than the Asset Dispositions) involving:

(i) any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction: (i) in which a Party is a constituent entity; (ii) in which a Person or "group" (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of a Party or any of its Subsidiaries; or (iii) in which a Party or any of its Subsidiaries issues securities representing more than 20% of the outstanding securities of any class of voting securities of such Party or any of its Subsidiaries; or

(ii) any sale, lease, exchange, transfer, license, acquisition or disposition of any business or businesses or assets that constitute or account for 20% or more of the consolidated book value or the fair market value of the assets of a Party and its Subsidiaries, taken as a whole.

"***Affiliate***" of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"***Agreement***" means the Agreement and Plan of Merger and Reorganization to which this **Exhibit A** is attached, as it may be amended from time to time.

"***Antitrust Law***" means any antitrust, competition or trade regulation Law that is designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening competition through merger or acquisition, including the HSR Act, the Clayton Act, the Federal Trade Commission Act, the Sherman Act and similar domestic, foreign and multilateral competition laws.

"***Business Day***" means any day other than a Saturday, Sunday or other day on which banks in San Diego, California are authorized or obligated by Law to be closed.

"***California Law***" means the California Corporations Code, as amended.

"***Code***" means the Internal Revenue Code of 1986, as amended.

"***Company Affiliate***" means any Person that is (or at any relevant time was) under common control with the Company within the meaning of Sections 414(b) or 414(c) of the Code, and the regulations issued thereunder.

"***Company Associate***" means any current or former employee, independent contractor, officer or director of the Company or any of its Subsidiaries.

"***Company Board***" means the board of directors of the Company.

"***Company Capital Stock***" means the Company Common Stock and the Company Preferred Stock.

"***Company Common Stock***" means the Common Stock, $0.01 par value per share, of the Company.

"***Company Contract***" means any Contract: (a) to which the Company or any of its Subsidiaries is a Party; (b) by which the Company or any of its Subsidiaries or any Company IP or any other asset of the Company or its Subsidiaries is or may become bound or under which the Company or any of its Subsidiaries has, or may become subject to, any obligation; or (c) under which the Company or any of its Subsidiaries has or may acquire any right or interest.

"***Company ERISA Affiliate***" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with the Company or any of its Subsidiaries as a single employer within the meaning of Sections 414(b) or 414(c) of the Code.

"***Company Fundamental Representations***" means the representations and warranties of the Company set forth in Sections 2.1 (Due Organization; Subsidiaries.), 2.3 (Authority; Binding Nature of Agreement), 2.4 (Vote Required), 2.6(a) and (c) (Capitalization) and 2.21 (No Financial Advisors).

"***Company IP***" means all Intellectual Property Rights that are owned or co-owned or purported to be owned or co-owned by the Company or its Subsidiaries.

"***Company Material Adverse Effect***" means any Effect that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of the Company or its Subsidiaries, taken as a whole; *provided*, *however*, that Effects resulting from the following shall not be taken into account in determining whether there has been a Company Material Adverse Effect: (a) general business or economic conditions generally affecting the industry in which the Company and its Subsidiaries operate, (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions, (c) changes in financial, banking or securities markets, (d) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (e) resulting from the announcement of this Agreement or the pendency of the Contemplated Transactions, or (f) resulting from the taking of any action required to be taken by this Agreement, except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting the Company and its Subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which the Company and its Subsidiaries operate.

"***Company Options***" means options or other rights to purchase shares of Company Capital Stock issued by the Company.

"***Company Plan***" means the Company's 2018 Equity Incentive Plan, as amended.

"***Company Preferred Stock***" means the Preferred Stock, $0.01 par value per share, of the Company.

"***Company Triggering Event***" shall be deemed to have occurred if: (a) the Company shall have made a Company Board Adverse Recommendation Change; (b) the Company Board or any committee thereof shall have publicly approved, endorsed or recommended any Acquisition Proposal; or (c) the Company shall have entered into any letter of intent or similar document relating to any Acquisition Proposal in violation of the terms of the Agreement.

"***Company Unaudited Interim Balance Sheet***" means the unaudited consolidated balance sheet of the Company and its consolidated Subsidiaries for the period ended March 31, 2022 provided to Parent prior to the date of this Agreement.

"***Company Warrant***" means the warrants to purchase capital stock of the Company listed on **Exhibit D**.

"***Company's Knowledge***" means the actual knowledge of Richard Lowenthal, Kathleen Scott, Sarina Tanimoto, Justin Chakma, or Eric Karas and such knowledge as such Persons would reasonably be expected to have obtained in the course of their performance of their duties to the Company or any of its Subsidiaries (after due inquiry); *provided* that with respect to any matters relating to Intellectual Property Rights, such knowledge or reasonable expectation to have knowledge does not require any such individual to conduct or have conducted or obtain or have obtained any freedom to operate opinions or similar opinions of counsel or any Intellectual Property Rights clearance searches.

"***Confidentiality Agreement***" means the Mutual Confidential Disclosure Agreement, dated as of May 9, 2022, by and between the Company and Parent.

"***Consent***" means any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

"***Contemplated Transactions***" means the Merger and the other transactions and actions contemplated by this Agreement, including the Asset Dispositions.

"***Contract***" means, with respect to any Person, any agreement, contract, subcontract, lease (whether for real or personal property), mortgage, license, sublicense or other legally binding commitment or undertaking of any nature to which such Person is a party or by which such Person or any of its assets are bound or affected under applicable Law.

"***COVID-19***" means the novel coronavirus (SARS-CoV-2) and related variants thereof.

"***Definitive Proxy Statement***" means the definitive proxy statement to be sent to Parent's stockholders in connection with the Parent Stockholders' Meeting and filed with the SEC on Schedule 14A.

"***DGCL***" means the General Corporation Law of the State of Delaware.

"***Effect***" means any effect, change, event, circumstance or development.

"***Encumbrance***" means any lien, pledge, hypothecation, charge, mortgage, security interest, lease, license, option, easement, reservation, servitude, adverse title, claim, infringement,

interference, option, right of first refusal, preemptive right, community property interest or restriction or encumbrance of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

"*Enforceability Exceptions*" means the (a) Laws of general application relating to bankruptcy, insolvency and the relief of debtors; and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

"***Entity***" means any corporation (including any non-profit corporation), partnership (including any general partnership, limited partnership or limited liability partnership), joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity, and each of its successors.

"***Environmental Law***" means any federal, state, local or foreign Law relating to pollution or protection of human health or the environment (including ambient air, surface water, ground water, land surface or subsurface strata), including any Law or regulation relating to emissions, discharges, releases or threatened releases of Hazardous Materials, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials.

"***ERISA***" means the Employee Retirement Income Security Act of 1974, as amended.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Exchange Ratio***" means, subject to Section 1.5(g), the following ratio (rounded to four decimal places): the quotient obtained by dividing (a) (i) the Company Valuation divided by (ii) the Company Outstanding Shares; by (b) (i) the Parent Valuation divided by (ii) the Parent Outstanding Shares, in which:

- "***Company Valuation***" means $435,000,000.
- "***Company Outstanding Shares***" means the total number of shares of Company Capital Stock outstanding immediately prior to the Effective Time after giving effect to the Preferred Stock Conversion, expressed on a fully-diluted and as-converted to Company Common Stock basis and using the treasury stock method, but assuming, without limitation or duplication, (i) the exercise of all Company Options and Company Warrants, in each case outstanding as of immediately prior to the Effective Time, and (ii) the issuance of shares of Company Capital Stock in respect of all other outstanding options, restricted stock awards, warrants or rights to receive such shares, whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger (but excluding any shares of Company Capital Stock reserved for issuance other than with respect to outstanding Company Warrants or Company Options under the Company Plan as of immediately prior to the Effective Time).
- "***Parent Equity Value***" means $255,000,000.
- "***Parent Outstanding Shares***" means, subject to Section 1.5(g) and the immediately following sentence, the total number of shares of Parent Common Stock outstanding immediately prior to the Effective Time expressed on a fully-diluted basis and using the treasury stock method, but assuming, without limitation or duplication, the issuance of shares of Parent Common Stock in respect of all Parent Options, Parent RSUs, and other outstanding options, warrants or rights to receive such shares, in each case,

outstanding as of immediately prior to the Effective Time (assuming cashless exercise using the Parent Closing Price), whether conditional or unconditional and including any outstanding options, warrants or rights triggered by or associated with the consummation of the Merger, (but excluding any shares of Parent Common Stock reserved for issuance other than with respect to outstanding Parent Options and Parent RSUs as of immediately prior to the Effective Time and as set forth above). No out-of-the-money Parent Options shall be included in the total number of shares of Parent Common Stock outstanding for purposes of determining the Parent Outstanding Shares.

- "***Parent Valuation***" means (i) if Parent Net Cash is greater than $240,000,000, the sum of (x) the Parent Equity Value *plus* (y) the amount by which, up to $15,000,000, Parent Net Cash exceeds $240,000,000, (ii) if Parent Net Cash is equal to $240,000,000, the Parent Equity Value, or (iii) if Parent Net Cash is less than $240,000,000, the sum of (x) the Parent Equity Value, *minus* (y) the amount by which $240,000,000 exceeds Parent Net Cash.

"***GAAP***" means generally accepted accounting principles and practices in effect from time to time within the United States applied consistently throughout the period involved.

"***Governmental Authorization***" means any: (a) permit, license, certificate, franchise, permission, variance, exception, order, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Law; or (b) right under any Contract with any Governmental Body.

"***Governmental Body***" means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, bureau, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any taxing authority); or (d) self-regulatory organization (including Nasdaq).

"***Hazardous Materials***" means any pollutant, chemical, substance and any toxic, infectious, carcinogenic, reactive, corrosive, ignitable or flammable chemical, or chemical compound, or hazardous substance, material or waste, whether solid, liquid or gas, that is subject to regulation, control or remediation under any Environmental Law, including without limitation, crude oil or any fraction thereof, and petroleum products or by-products.

"***HSR Act***" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

"***Intellectual Property Rights***" means and includes all past, present, and future rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, software, databases, and mask works; (b) trademarks, service marks, trade dress, logos, trade names and other source identifiers, domain names and URLs and similar rights and any goodwill associated therewith; (c) rights associated with trade secrets, know how, inventions, invention disclosures, methods, processes, protocols, specifications, techniques and other forms of technology; (d) patents and industrial property rights; and (e) other similar proprietary rights in intellectual property of every kind and nature; (f) rights of privacy and publicity; and (g) all registrations, renewals, extensions, statutory invention registrations, provisionals, continuations, continuations-in-part, divisions, or reissues of, and applications for, any of the rights referred to in clauses "(a)" through "(f)" above (whether or not in tangible form and including all tangible embodiments of any of the foregoing, such as samples,

studies and summaries), along with all rights to prosecute and perfect the same through administrative prosecution, registration, recordation or other administrative proceeding, and all causes of action and rights to sue or seek other remedies arising from or relating to the foregoing.

"***IRS***" means the United States Internal Revenue Service.

"***Law***" means any federal, state, national, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of Nasdaq or the Financial Industry Regulatory Authority).

"***Legal Proceeding***" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Body or any arbitrator or arbitration panel.

"***Merger Sub Board***" means the board of directors of Merger Sub.

"***Nasdaq***" means the Nasdaq Stock Market, including the Nasdaq Global Market or such other Nasdaq market on which shares of Parent Common Stock are then listed.

"***Ordinary Course of Business***" means, in the case of each of the Company and Parent, such actions taken in the ordinary course of its normal operations and consistent with its past practices and the Ordinary Course of Business of Parent shall also include actions required to effect the Asset Dispositions or effect the winding down of Parent's prior research and development activities (including the termination of ongoing contractual obligations relating to Parent current products or product candidates).

"***Organizational Documents***" means, with respect to any Person (other than an individual), (a) the certificate or articles of association or incorporation or organization or limited partnership or limited liability company, and any joint venture, limited liability company, operating or partnership agreement and other similar documents adopted or filed in connection with the creation, formation or organization of such Person and (b) all bylaws, regulations and similar documents or agreements relating to the organization or governance of such Person, in each case, as amended or supplemented.

"***Pandemic Response Laws***" means the Coronavirus Aid, Relief, and Economic Security Act, the Families First Coronavirus Response Act, the COVID-related Tax Relief Act of 2020, the Presidential Memorandum on Deferring Payroll Tax Obligations in Light of the Ongoing COVID-19 Disaster (as issued on August 8, 2020 and including any administrative or other guidance published with respect thereto by any Taxing authority (including IRS Notice 2020-65)), and any other similar or additional U.S. federal, state, or local or non-U.S. Law, or administrative guidance intended to benefit taxpayers in response to the COVID-19 pandemic and associated economic downturn.

"***Parent Affiliate***" means any Person that is (or at any relevant time was) under common control with Parent within the meaning of Sections 414(b) or 414(c) of the Code, and the regulations issued thereunder.

"***Parent Associate***" means any current or former employee, independent contractor, officer or director of Parent.

"***Parent Balance Sheet***" means the unaudited balance sheet of Parent as of March 31, 2022 included in Parent's Report on Form 10-Q for the quarterly period ended March 31, 2022, as filed with the SEC.

"***Parent Board***" means the board of directors of Parent.

"***Parent Change in Circumstance***" means a change in circumstances (other than an Acquisition Proposal) that affects the business, assets or operations of Parent that occurs or arises after the date of this Agreement that was neither known to Parent or the Parent Board nor reasonably foreseeable on, or prior to, the date of this Agreement.

"***Parent Closing Financial Certificate***" means a certificate executed by the Chief Financial Officer of Parent, on behalf of Parent and not in his or her personal capacity, certifying Parent Net Cash as of the Anticipated Closing Date.

"***Parent Closing Price***" means the volume weighted average closing trading price of a share of Parent Common Stock on Nasdaq for the five (5) consecutive trading days ending five (5) trading days immediately prior to the date upon which the Merger becomes effective.

"***Parent Common Stock***" means the Common Stock, $0.0001 par value per share, of Parent.

"***Parent Contract***" means any Contract: (a) to which Parent is a party; (b) by which Parent or any Parent IP or any other asset of Parent is or may become bound or under which Parent has, or may become subject to, any obligation; or (c) under which Parent has or may acquire any right or interest.

"***Parent Equity Incentive Plans***" means (a) Parent's 2016 Equity Incentive Plan, as amended, and (b) Parent's 2020 Equity Incentive Plan, as amended.

"***Parent ERISA Affiliate***" means any corporation or trade or business (whether or not incorporated) which is (or at any relevant time was) treated with Parent or any of its Subsidiaries as a single employer within the meaning of Sections 414(b) or 414(c) of the Code.

"***Parent ESPP***" means Parent's 2020 Employee Stock Purchase Plan.

"***Parent Fundamental Representations***" means the representations and warranties of Parent and Merger Sub set forth in Sections 3.1(a) (Due Organization; Subsidiaries), 3.3 (Authority; Binding Nature of Agreement), 3.4 (Vote Required), 3.6(a) and (c) (Capitalization) and 3.22 (No Financial Advisors).

"***Parent IP***" means all Intellectual Property Rights that are owned or purported to be owned by Parent or its Subsidiaries.

"***Parent Material Adverse Effect***" means any Effect that, considered together with all other Effects, has or would reasonably be expected to have a material adverse effect on the business, condition (financial or otherwise), assets, liabilities or results of operations of Parent; *provided*, *however*, that Effects resulting from the following shall not be taken into account in determining whether there has been a Parent Material Adverse Effect: (a) general business or economic conditions generally affecting the industry in which Parent operates, (b) acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions, (c) changes in financial,

banking or securities markets, (d) any change in the stock price or trading volume of Parent Common Stock (it being understood, however, that any Effect causing or contributing to any change in stock price or trading volume of Parent Common Stock may be taken into account in determining whether a Parent Material Adverse Effect has occurred, unless such Effects are otherwise excepted from this definition), (e) the failure of Parent to meet internal or analysts' expectations or projections or the results of operations of Parent; (f) any change in, or any compliance with or action taken for the purpose of complying with, any Law or GAAP (or interpretations of any Law or GAAP), (g) resulting from the announcement of this Agreement or the pendency of the Contemplated Transactions, (h) the Asset Dispositions, (i) any reduction in the amount of Parent's cash and cash equivalents as a result of expenditures made by Parent related to wind-down activities of Parent associated with the termination of its research and development activities (including the termination of ongoing contractual obligations relating to Parent current products or product candidates), or (j) resulting from the taking of any action required to be taken by this Agreement, except in each case with respect to clauses (a) through (c), to the extent disproportionately affecting Parent relative to other similarly situated companies in the industries in which Parent operates.

"***Parent Net Cash***" means, without duplication, (a) the sum of Parent's cash and cash equivalents, marketable securities, accounts, interest and other receivables, deposits and short and long term investments, in each case as of the Anticipated Closing Date, determined in a manner consistent with the manner in which such items were historically determined and in accordance with the financial statements (including any related notes) contained or incorporated by reference in the Parent Balance Sheet, *minus* (b) the sum of Parent's short and long term liabilities accrued at Closing, in each case as of the Anticipated Closing Date and determined in a manner consistent with the manner in which such items were historically determined and in accordance with the financial statements (including any related notes) contained or incorporated by reference in the Parent Balance Sheet (including the Transaction Expenses payable by Parent to the extent unpaid as of the Closing but excluding any lease liabilities to the extent that they are contractually mitigated through a commercially reasonable sub-leasing arrangement), *minus* (c) the cash cost of any unpaid change of control payments or severance, termination or similar payments pursuant to a Contract that are or become due to any current or former employee, director or independent contractor of Parent in connection with the Closing, *minus* (d) to the extent unpaid at Closing, the cost of the D&O Tail Policy purchased pursuant to Section 5.7(d), *plus* (e) prepaid expenses and receivables that will be utilized by Parent and/or Surviving Corporation on and following the Closing, *plus* (f) expenses paid, or liabilities incurred, prior to Closing, that will be covered by Parent's D&O insurance in excess of the deductible, and *plus* (g) any net cash proceeds due to Parent substantially concurrently with the Closing from any Asset Dispositions or, as mutually agreed in good faith, otherwise in connection with any Asset Disposition.

"***Parent Options***" means options or other rights to purchase shares of Parent Common Stock issued by Parent.

"***Parent Plans***" means, (a) the Parent Equity Incentive Plans and (b) the Parent ESPP.

"***Parent RSUs***" means any restricted stock unit award granted pursuant to the Parent Plans or otherwise.

"***Parent Triggering Event***" shall be deemed to have occurred if: (a) Parent shall have failed to include in the Proxy Statement the Parent Board Recommendation or shall have made a Parent Board Adverse Recommendation Change; (b) the Parent Board or any committee thereof shall have publicly approved, endorsed or recommended any Acquisition Proposal; or (c) Parent shall have entered into any letter of intent or similar document relating to any Acquisition Proposal (other than a confidentiality agreement permitted pursuant to Section 4.4) in violation of the terms of this Agreement.

"***Parent's Knowledge***" means the actual knowledge of Laura Shawver, Ph.D., Valerie Odegard, Ph.D., Jonathan Piazza and Jeffrey Pepe, Ph.D., and such knowledge as such Persons would reasonably be expected to have obtained in the course of their performance of their duties to Parent (after due inquiry); *provided* that with respect to any matters relating to Intellectual Property Rights, such knowledge or reasonable expectation to have knowledge does not require any such individual to conduct or have conducted or obtain or have obtained any freedom to operate opinions or similar opinions of counsel or any Intellectual Property Rights clearance searches.

"***Party***" or "***Parties***" means the Company, Merger Sub and Parent.

"***Permitted Alternative Agreement***" means a definitive agreement that contemplates or otherwise relates to an Acquisition Transaction that constitutes a Superior Offer.

"***Permitted Encumbrance***" means: (a) any liens for current Taxes not yet due and payable or for Taxes that are being contested in good faith and for which adequate reserves have been made on the Company Unaudited Interim Balance Sheet or the Parent Balance Sheet, as applicable; (b) minor liens that have arisen in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the assets or properties subject thereto or materially impair the operations of the Company or any of its Subsidiaries or Parent, as applicable; (c) statutory liens to secure obligations to landlords, lessors or renters under leases or rental agreements; (d) deposits or pledges made in connection with, or to secure payment of, workers' compensation, unemployment insurance or similar programs mandated by Law; (e) non-exclusive licenses of Intellectual Property Rights granted by the Company or any of its Subsidiaries or Parent, as applicable, in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the Intellectual Property Rights subject thereto; and (f) statutory liens in favor of carriers, warehousemen, mechanics and materialmen, to secure claims for labor, materials or supplies.

"***Person***" means any individual, Entity or Governmental Body.

"***Potentially Transferable Assets***" means the tangible and intangible assets used in or related to any Parent program, including, but not limited to, SBT6050, SBT6290, SBT8230, TLR8 linker payloads and Parent's discovery programs, including linker technology, payload technology, antibody technology, cytotoxic ADCs and glucocorticoid receptor agonist program.

"***Proxy Statement***" means the proxy statement to be sent to Parent's stockholders in connection with the Parent Stockholders' Meeting.

"***Reference Date***" means July 18, 2022.

"***Registered IP***" means all Intellectual Property Rights that are registered or issued under the authority of any Governmental Body, including all patents, registered copyrights, registered mask works, and registered trademarks, service marks and trade dress and registered domain names.

"***Representatives***" means directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors and representatives.

"***Sarbanes-Oxley Act***" means the Sarbanes-Oxley Act of 2002.

"***SEC***" means the United States Securities and Exchange Commission.

"***Securities Act***" means the Securities Act of 1933, as amended.

"***Subsequent Transaction***" means any Acquisition Transaction (with all references to 20% in the definition of Acquisition Transaction being treated as references to 100% for these purposes).

"***Subsidiary***" means an Entity of a Person that such Person directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities or other interests in such Entity that is sufficient to enable such Person to elect at least a majority of the members of such Entity's board of directors or other governing body, or (b) at least 50% of the outstanding equity, voting, beneficial or financial interests in such Entity.

"***Superior Offer***" means an unsolicited bona fide written Acquisition Proposal (with all references to 20% in the definition of Acquisition Transaction being treated as references to greater than 50% for these purposes) that: (a) was not obtained or made as a result of a breach of (or in violation of) this Agreement; and (b) is on terms and conditions that the Parent Board determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation thereof), as well as any written offer by the other Party to this Agreement to amend the terms of this Agreement, and following consultation with its outside legal counsel and outside financial advisors, if any, are more favorable, from a financial point of view, to Parent's stockholders than the terms of the Contemplated Transactions.

"***Takeover Statute***" means any "fair price," "moratorium," "control share acquisition" or other similar anti-takeover Law.

"***Tax***" means any federal, state, local, foreign or other tax, including any income, capital gain, gross receipts, capital stock, profits, transfer, estimated, registration, stamp, premium, escheat, unclaimed property, customs duty, ad valorem, occupancy, occupation, alternative, add-on, windfall profits, value added, severance, property, business, production, sales, use, license, excise, franchise, employment, payroll, social security, disability, unemployment, workers' compensation, national health insurance, withholding or other taxes, duties, or fees, assessments or governmental charges in the nature of a tax, surtaxes or deficiencies thereof of any kind whatsoever, however denominated, and including any fine, penalty, addition to tax or interest imposed by a Governmental Body with respect thereto.

"***Tax Return***" means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document, and any amendment or supplement to any of the foregoing, filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax.

"***Transaction Expenses***" means, with respect to each Party, all fees and expenses incurred by such Party at or prior to the Effective Time in connection with the Contemplated Transactions and this Agreement, including (a) any fees and expenses of legal counsel and accountants, the maximum amount of fees and expenses payable to financial advisors, investment bankers, brokers, consultants, and other advisors of such Party; (b) fees paid to the SEC in connection with filing the Proxy Statement, and any amendments and supplements thereto, with the SEC; (c) any fees and expenses in connection with the printing, mailing and distribution of the Proxy Statement and any amendments and supplements thereto; (d) any fees and expenses payable to Nasdaq; (e) only with respect to Parent, any bonus, severance, change-in-control payments or similar payment obligations (including payments with "single-trigger" provisions triggered at and as of the Closing) that become due or payable to any director, officer, employee or consultant of Parent in connection with the consummation of the Contemplated Transactions and (f) only with respect to Parent, the cost of the D&O Tail Policy purchased pursuant to Section 5.7(d).

"***Treasury Regulations***" means the United States Treasury regulations promulgated under the Code.

FIRST AMENDMENT TO THE

AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

This First Amendment (this "***Amendment***") to the Agreement and Plan of Merger and Reorganization (the "***Merger Agreement***"), dated as of July 21, 2022, by and among **SILVERBACK THERAPEUTICS, INC.**, a Delaware corporation ("***Parent***"), **SABRE MERGER SUB, INC.** a Delaware corporation and wholly owned subsidiary of Parent ("***Merger Sub***"), and **ARS PHARMACEUTICALS, INC.**, a Delaware corporation (the "***Company***"), is made and entered into as of August 11, 2022. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Merger Agreement (as defined below).

RECITALS

WHEREAS, on July 21, 2022, Parent, Merger Sub and the Company entered into the Merger Agreement; and

WHEREAS, in accordance with and as permitted by Section 10.2 of the Merger Agreement, the parties hereto desire to amend the Merger Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

1. **Amendment to the Merger Agreement**. The parties agree that Section 5.13 of the Merger Agreement is hereby amended and restated in its entirety as follows:

> "**Directors and Officers**. The Parties shall use reasonable best efforts and take all necessary action so that immediately after the Effective Time, (a) the Parent Board is comprised of eleven (11) members, with three (3) such members designated by Parent and eight (8) such members designated by the Company, (b) the Persons listed in Exhibit E under the heading "Officers" are elected or appointed, as applicable, to the positions of officers of Parent, as set forth therein, to serve in such positions effective as of the Effective Time until successors are duly appointed and qualified in accordance with applicable Law. If any Person listed in Exhibit E is unable or unwilling to serve as an officer of Parent, as set forth therein, as of the Effective Time, the Parties shall mutually agree upon a successor. The Persons listed in Exhibit E under the heading "Board Designees – Parent" shall be Parent's designees pursuant to clause (a) of this Section 5.13 (which list may be changed by Parent at any time prior to the Closing by written notice to the Company to include different board designees who are reasonably acceptable to the Company) (the "***Parent Designees***"). The Persons listed in Exhibit E under the heading "Board Designees – Company" shall be the Company's designees pursuant to clause (a) of this Section 5.13 (which list may be changed by the Company at any time prior to the Closing by written notice to Parent to include different board designees who are reasonably acceptable to Parent)."

2. **Amendment to Exhibit E of the Merger Agreement**. The parties agree that Exhibit E of the Merger Agreement is hereby deleted and replaced in its entirety with **Exhibit E** attached hereto.

3. **Miscellaneous**.

a. Effect of Amendment. Pursuant to Section 10.2 of the Merger Agreement, the Merger Agreement may not be amended except by an instrument in writing signed on behalf of each of the Company, Merger Sub and Parent. The Merger Agreement is amended by this Amendment only as specifically provided herein, and the Merger Agreement, as so amended, shall continue in full force and effect. Each reference in the Merger Agreement to "this Agreement", "herein," "hereof," "hereunder" or words of similar import shall hereafter be deemed to refer to the Merger Agreement as amended hereby (except that references in the Merger Agreement to the "date hereof" or "date of this Agreement" or words of similar import shall continue to mean July 21, 2022). References to the Merger Agreement in this Amendment and in any ancillary agreements or documents delivered in connection with the Merger Agreement or contemplated thereby, shall refer to the Merger Agreement as amended hereby.

b. Authorization and Validity. Each party to this Amendment hereby represents and warrants to the other parties hereto that: (a) such party has the requisite power and authority to execute and deliver this Amendment, to perform their obligations hereunder and to consummate the transactions contemplated hereby, (b) the execution and delivery of this Amendment has been duly and validly authorized by all necessary action of such party, and (c) this Amendment will be duly executed and delivered by such party and, assuming due execution and delivery by each of the other parties hereto, constitutes the legal, valid and binding obligation of such party, enforceable against such party in accordance with its terms, except as enforcement may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity (regardless of whether considered in a proceeding in equity or at law).

c. Counterparts; Exchanges by Electronic Transmission. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

d. Applicable Law; Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of laws.

e. Miscellaneous. Sections 10.2, 10.4, 10.5 and 10.7 through 10.13 of the Merger Agreement shall apply *mutatis mutandis* to this Amendment.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to the Agreement and Plan of Merger and Reorganization to be executed as of the date first written above.

SILVERBACK THERAPEUTICS, INC.

By: /s/ Laura Shawver, Ph.D.
Name: Laura Shawver, Ph.D.
Title: Chief Executive Officer

SABRE MERGER SUB, INC.

By: /s/ Jonathan Piazza
Name: Jonathan Piazza
Title: Chief Financial Officer and Treasurer

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal, M.S., MSEL
Name: Richard Lowenthal, M.S., MSEL
Title: Chief Executive Officer

[*Signature Page to First Amendment to the Merger Agreement*]

ANNEX B

OPINION OF SVB SECURITIES LLC

July 20, 2022

The Board of Directors
Silverback Therapeutics, Inc.
500 Fairview Ave N, Suite 600
Seattle, WA98109

Ladies and Gentlemen:

You have requested our opinion as to the fairness, from a financial point of view, to Silverback Therapeutics, Inc. ("Parent"), of the Exchange Ratio (as defined below) proposed to be paid by Parent pursuant to the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement") to be entered into by and among Parent, Sabre Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"), and ARS Pharmaceuticals, Inc., a Delaware corporation (the "Company"). The Merger Agreement provides for the acquisition by Parent of the Company through the merger of Merger Sub with and into the Company (the "Merger"), with the Company continuing as the surviving entity of the Merger and as a wholly owned subsidiary of Parent. At the effective time of the Merger (the "Effective Time"), by virtue of the Merger and without any further action on the part of Parent, Merger Sub, the Company or any stockholder of the Company, among other things, each share of common stock, par value $0.01 of the Company, and each share of preferred stock, par value $0.01, of the Company (collectively, the "Company Capital Stock") issued and outstanding immediately prior to the Effective Time (other than Excluded Shares (as defined below) will, by virtue of the Merger Agreement (and subject to the terms and conditions thereof) and without any action on the part of the holder thereof, be converted into and thereafter represent the right to receive a number of shares of the common stock, par value $0.0001 per share, of Parent (the "Parent Common Stock"), equal to the Exchange Ratio, without interest. As used herein, (i) the "Exchange Ratio" is the number of shares of Parent Common Stock to be received by holders of Company Capital Stock (other than Excluded Shares) in the Merger, which is derived from the agreed relative percentage ownership of the combined company by holders of the Company Capital Stock (referred to in the Merger Agreement as the "Company Valuation") and Parent Common Stock (referred to in Merger Agreement as the "Parent Valuation"); and (ii) "Excluded Shares" means (a) any shares of the Company Capital Stock held held as treasury stock by the Company or owned by Parent, Merger Sub or any Subsidiary of Parent or the Company immediately prior to the Effective Time (which such shares shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor); and (b) any shares of the Company Capital Stock held by a holder who is entitled to and properly demands appraisal rights in accordance with Section 262 of the Delaware General Corporation Law or Chapter 13 of the California Corporations Code. The Exchange Ratio is subject to certain adjustments set forth in the Merger Agreement; we express no opinion as to any such adjustments. The Merger and the other transactions summarized above are collectively referred to herein as the "Transaction." The terms and conditions of the Transaction are more fully set forth in the Merger Agreement.

We have been engaged by Parent to act as its financial advisor in connection with the Transaction and we will receive a fee from Parent for providing such services, a portion of which is payable upon

delivery of this opinion and the remaining (and principal) portion of which is contingent upon consummation of the Transaction. In addition, Parent has agreed to reimburse certain of our expenses arising, and indemnify us against certain liabilities that may arise, out of our engagement.

SVB Securities LLC is a full-service securities firm engaged in securities trading and brokerage activities as well as investment banking and financial advisory services. We have in the past provided, currently are providing and may in the future provide certain investment banking services to Parent and its affiliates from time to time, for which we have received and would expect to receive compensation, including having served as a joint book-running manager for Parent's December 2020 initial public offering. In the ordinary course of business, we and our affiliates have in the past provided, currently are providing and may in the future provide investment banking and commercial banking services to Parent, the Company or their respective affiliates and have received and would expect to receive customary fees for the rendering of such services. In the ordinary course of our business, we or our affiliates have in the past and may in the future hold positions, for our own account or the accounts of our customers, in equity, debt or other securities of Parent, the Company or their respective affiliates.

Consistent with applicable legal and regulatory requirements, we have adopted policies and procedures to establish and maintain the independence of our research department and personnel. As a result, our research analysts may hold views, make statements or investment recommendations and/or publish research reports with respect to Parent, the Company and the Transaction and other participants in the Transaction that differ from the views of our investment banking personnel.

In connection with this opinion, we have reviewed, among other things: (i) a draft of the Merger Agreement, dated July 20, 2022; (ii) Parent's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed by Parent with the Securities and Exchange Commission (the "SEC"); (iii) Parent's Quarterly Report on form 10-Q for the quarterly period ended March 31, 2022, as filed by Parent with the SEC; (iv) certain Current Reports on Form 8-K, as filed by Parent with, or furnished by Parent to, the SEC; (v) certain internal information, primarily related to expense forecasts, relating to the business, operations, earnings, cash flow, assets, liabilities and prospects of Parent, as furnished to us by the management of Parent; and (vi) certain internal information relating to the business, operations, earnings, cash flow, assets, liabilities and prospects of the Company, including certain financial forecasts, analyses and projections relating to the Company prepared by management of the Company, as modified by management of Parent and furnished to, and approved for use by, us by Parent for purposes of our analysis (the "Company Forecast") (collectively, the "Internal Data"). We have also conducted discussions with members of the senior management of Parent and the Company and their respective advisors and representatives regarding such Internal Data as well as the past and current business, operations, financial condition and prospects of each of Parent and the Company. In addition, we reviewed the historical trading prices and trading activity for the Parent Common Stock. Furthermore, we reviewed certain financial data for the Company and compared that data to similar publicly available market, financial and other data for certain other companies, the securities of which are publicly traded, that we believe to be comparable in certain respects to the Company. We also conducted such other financial studies and analyses and took into account such other information as we deemed appropriate.

We have assumed, without independent verification or any responsibility therefor, the accuracy and completeness of the financial, legal, regulatory, tax, accounting and other information supplied to, discussed with, or reviewed by us for purposes of this opinion and have, with your consent, relied upon such information as being complete and accurate. In that regard, we have been advised by Parent, and

have assumed, at your direction, that the Internal Data (including, without limitation, the Company Forecast) has been reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of Parent and the Company as to the matters covered thereby and we have relied, at your direction, on the Internal Data for purposes of our analysis and this opinion. We express no view or opinion as to the Internal Data (including, without limitation, the Company Forecast) or the assumptions on which it is based. In addition, at your direction, we have not made any independent evaluation or appraisal of any of the assets or liabilities (contingent, derivative, off-balance-sheet or otherwise) of Parent or the Company, nor have we been furnished with any such evaluation or appraisal, and we have not been asked to conduct, and did not conduct, a physical inspection of the properties or assets of Parent or the Company.

We have assumed, at your direction, that the final executed Merger Agreement will not differ in any respect material to our analysis or this opinion from the last draft of the Merger Agreement reviewed by us. We have also assumed, at your direction, that the representations and warranties made by the Company and Parent and Merger Sub in the Merger Agreement and the related agreements are and will continue to be true and correct in all respects material to our analysis. Furthermore, we have assumed, at your direction, that the Transaction will be consummated on the terms set forth in the Merger Agreement and in accordance with all applicable laws and other relevant documents or requirements, without delay or the waiver, modification or amendment of any term, condition or agreement, the effect of which would be material to our analysis or this opinion and that, in the course of obtaining the necessary governmental, regulatory and other approvals, consents, releases and waivers for the Transaction, no delay, limitation, restriction, condition or other change will be imposed, the effect of which would be material to our analysis or this opinion. We have not evaluated and do not express any opinion as to the solvency or fair value of Parent or the Company, or their respective abilities to pay their obligations when they come due, or as to the impact of the Transaction on such matters, under any state, federal or other laws relating to bankruptcy, insolvency, or similar matters. We are not legal, regulatory, tax or accounting advisors, and we express no opinion as to any legal, regulatory, tax or accounting matters. We express no view or opinion as to the price or range of prices at which the shares of stock or other securities or instruments of Parent or any third party may trade at any time, including subsequent to the announcement or consummation of the Transaction.

We express no view as to, and our opinion does not address, Parent's underlying business decision to proceed with or effect the Transaction, or the relative merits of the Transaction as compared to any alternative business strategies or transactions that might be available to Parent or in which Parent might engage. This opinion is limited to and addresses only the fairness, from a financial point of view, as of the date hereof, to Parent of the Exchange Ratio proposed to be paid by Parent pursuant to the terms of the Merger Agreement. We have not been asked to, nor do we express any view on, and our opinion does not address, any other term or aspect of the Merger Agreement or the Transaction, including, without limitation, the structure or form of the Transaction, or any other agreements or arrangements contemplated by the Merger Agreement or entered into in connection with or otherwise contemplated by the Transaction, including, without limitation, the fairness of the Transaction or any other term or aspect of the Transaction to, or any consideration to be received in connection therewith by, or the impact of the Transaction on, the holders of any other class of securities, creditors or other constituencies of Parent or any other party. In addition, we express no view or opinion as to the fairness (financial or otherwise) of the amount, nature or any other aspect of any compensation to be paid or payable to any of the officers, directors or employees of Parent or any other party, or class of such persons in connection with the Transaction, whether relative to the Exchange Ratio to be paid by

Parent pursuant to the terms of the Merger Agreement or otherwise. Our opinion is necessarily based on financial, economic, monetary, currency, market and other conditions and circumstances as in effect on, and the information made available to us as of, the date hereof, and we do not have any obligation or responsibility to update, revise or reaffirm this opinion based on circumstances, developments or events occurring after the date hereof. Our opinion does not constitute a recommendation to any stockholder of Parent as to whether or how such stockholder should vote with respect to the Merger or otherwise act with respect to the Transaction or any other matter.

Our financial advisory services and the opinion expressed herein are provided for the information and assistance of the Board of Directors of Parent (in their capacity as directors and not in any other capacity) in connection with and for purposes of its consideration of the Transaction. This opinion has been authorized by our Fairness Opinion Review Committee.

Based upon and subject to the foregoing, including the various assumptions, qualifications and limitations set forth herein, it is our opinion that, as of the date hereof, the Exchange Ratio proposed to be paid by Parent pursuant to the terms of the Merger Agreement is fair, from a financial point of view, to Parent.

Very truly yours,

/s/ SVB Securities LLC

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SILVERBACK THERAPEUTICS

P.O. BOX 8016, CARY, NC 27512-9903

YOUR VOTE IS IMPORTANT! PLEASE VOTE BY:

INTERNET
Go To: **www.proxypush.com/SBTX**
- Cast your vote online
- **Have your Proxy Card ready**
- Follow the simple instructions to record your vote

PHONE Call **1-866-355-8664**
- Use any touch-tone telephone
- **Have your Proxy Card ready**
- Follow the simple recorded instructions

MAIL
- Mark, sign and date your Proxy Card
- Fold and return your Proxy Card in the postage-paid envelope provided

You must register to attend the meeting online and/or participate at www.proxydocs.com/SBTX

Silverback Therapeutics, Inc.

Special Meeting of Stockholders

For Stockholders of record as of September 19, 2022

TIME: Friday, November 4, 2022 10:00 AM, Pacific Time
PLACE: Special Meeting to be held live via the Internet - please visit www.proxydocs.com/SBTX for more details.

This proxy is being solicited on behalf of the Board of Directors

The undersigned hereby appoints Jeffrey Pepe, Ph.D., J.D. and Russ Hawkinson (the "Named Proxies"), and each or either of them, as the true and lawful attorneys of the undersigned, with full power of substitution and revocation, and authorizes them, and each of them, to vote all the shares of capital stock of Silverback Therapeutics, Inc. which the undersigned is entitled to vote at said meeting and any adjournment thereof upon the matters specified and upon such other matters as may be properly brought before the meeting or any adjournment thereof, conferring authority upon such true and lawful attorneys to vote in their discretion on such other matters as may properly come before the meeting and revoking any proxy heretofore given.

THE SHARES REPRESENTED BY THIS PROXY WILL BE VOTED AS DIRECTED OR, IF NO DIRECTION IS GIVEN, SHARES WILL BE VOTED IDENTICAL TO THE BOARD OF DIRECTORS' RECOMMENDATION. This proxy, when properly executed, will be voted in the manner directed herein. In their discretion, the Named Proxies are authorized to vote upon such other matters that may properly come before the meeting or any adjournment or postponement thereof.

You are encouraged to specify your choice by marking the appropriate box (SEE REVERSE SIDE) but you need not mark any box if you wish to vote in accordance with the Board of Directors' recommendation. The Named Proxies cannot vote your shares unless you sign (on the reverse side) and return this card.

PLEASE BE SURE TO SIGN AND DATE THIS PROXY CARD AND MARK ON THE REVERSE SIDE

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Silverback Therapeutics, Inc.

Special Meeting of Stockholders

Please make your marks like this: [X]

THE BOARD OF DIRECTORS RECOMMENDS A VOTE:

FOR ON PROPOSALS 1 AND 2

	PROPOSAL	YOUR VOTE			BOARD OF DIRECTORS RECOMMENDS
		FOR	AGAINST	ABSTAIN	
1.	To approve (i) the issuance of shares of Silverback Common Stock or other securities of Silverback pursuant to the Merger, which will represent (or are convertible into) more than 20% of the shares of Silverback Common Stock outstanding immediately prior to the Merger, and (ii) the change of control resulting from the Merger, pursuant to Nasdaq Listing Rules 5635(a) and 5635(b), respectively; and	☐	☐	☐	FOR
2.	To approve a postponement or adjournment of the Silverback virtual special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal No. 1.	☐	☐	☐	FOR

You must register to attend the meeting online and/or participate at www.proxydocs.com/SBTX

Authorized Signatures - Must be completed for your instructions to be executed.

Please sign exactly as your name(s) appears on your account. If held in joint tenancy, all persons should sign. Trustees, administrators, etc., should include title and authority. Corporations should provide full name of corporation and title of authorized officer signing the Proxy/Vote Form.

Signature (and Title if applicable) Date

Signature (if held jointly) Date