

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

**November 4, 2022
Date of Report (Date of earliest event reported)**

ARS Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39756
(Commission
File Number)

81-1489190
(IRS Employer
Identification No.)

**11682 El Camino Real, Suite 120
San Diego, California**
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: (858) 771-9307

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	SPRY	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

On November 8, 2022, the Delaware corporation formerly known as “Silverback Therapeutics, Inc.” completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of July 21, 2022, as amended on August 11, 2022 and October 25, 2022 (the “Merger Agreement”), by and among Silverback Therapeutics, Inc. (“Silverback”), Sabre Merger Sub, Inc., a wholly owned subsidiary of Silverback (“Merger Sub”), and ARS Pharmaceuticals, Inc. (“ARS Pharma”), pursuant to which Merger Sub merged with and into ARS Pharma, with ARS Pharma surviving the merger as a wholly owned subsidiary of Silverback (the “Merger”). Additionally, on November 8, 2022, the Company changed its name from “Silverback Therapeutics, Inc.” to “ARS Pharmaceuticals, Inc.” (the “Company”). See Item 2.01 for additional information regarding completion of the Merger.

Item 1.01 Entry into a Material Definitive Agreement

ARS Pharma previously entered into various material collaboration and license agreements with its collaboration and licensing partners in connection with the development, manufacturing and potential commercialization of the Company’s product candidate *neffy* for the emergency treatment of Type I allergic reactions, including anaphylaxis. Such material collaboration and license agreements are summarized below.

License Agreement with Aegis

In June 2018, ARS Pharma entered into a license agreement with Aegis Therapeutics, LLC (“Aegis”), which was amended in July 2020 and January 2021 (as amended, the “Aegis License Agreement”). Pursuant to the Aegis License Agreement, Aegis granted ARS Pharma 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 ARS Pharma 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 Aegis License Agreement, ARS Pharma is 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 ARS Pharma’s consent.

Under the Aegis License 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. ARS Pharma made a \$0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019. ARS Pharma will also be required to pay Aegis a milestone payment of \$1.0 million to Aegis upon the U.S. Food and Drug Administration’s (“FDA’s”) acceptance of ARS Pharma’s New Drug Application for *neffy*, 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 Aegis License Agreement will continue until the expiration of the last-to-expire Aegis Royalty Term, unless sooner terminated. ARS Pharma has the right to terminate the Aegis License Agreement at any time after a specified notice period to Aegis. Either party may terminate the Aegis License 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.

The foregoing description of the Aegis License Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.1 hereto and is incorporated herein by reference.

Collaboration and License Agreement with Alfresa

In April 2020, ARS Pharma entered into a collaboration and license agreement (the “Alfresa Agreement”) with Alfresa Pharma Corporation (“Alfresa”). Pursuant to the Alfresa Agreement, ARS Pharma 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 ARS Pharma’s 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. ARS Pharma expressly reserved all rights to practice and grant licenses under ARS Pharma’s 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 Alfresa Agreement, (1) ARS Pharma and Alfresa are obligated to use commercially reasonable efforts to develop an 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 Alfresa Agreement, ARS Pharma received a one-time upfront payment of \$2.0 million and earned \$5 million upon the achievement of a clinical milestone during 2021. ARS Pharma is eligible to receive regulatory milestones of up to \$8.0 million in the aggregate. Further, ARS Pharma 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 *neffy* in Japan. ARS Pharma shares 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 ARS Pharma pursuant to which ARS Pharma 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 ARS Pharma a royalty payment on the net sales of drug product in the Alfresa Territory in an amount equal to monetary value ARS Pharma would receive by supplying drug product to Alfresa at the transfer price.

The Alfresa Agreement will continue until the later of (i) expiration of the last-to-expire valid claim of ARS Pharma’s 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 Alfresa Agreement (1) at any time after a specified notice period to ARS Pharma, or (2) upon notice to ARS Pharma if a binding decision is rendered invalidating any of ARS Pharma’s patents. Either party may terminate the Alfresa 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.

The foregoing description of the Alfresa Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.2 hereto and is incorporated herein by reference.

Collaboration and Distribution Agreement with Pediatrix

In March 2021, ARS Pharma entered into a collaboration and distribution agreement (the “Pediatrix Agreement”) with Pediatrix Therapeutics (“Pediatrix”). Pursuant to the Pediatrix Agreement, ARS Pharma granted Pediatrix (i) an exclusive, royalty-bearing, sublicensable license under ARS Pharma’s 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. ARS Pharma expressly reserved all rights to practice and grant licenses under its technology outside the scope of the licenses granted to Pediatrix. During the term of the Pediatrix 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 Pediatrix Agreement, ARS Pharma received a one-time upfront payment of \$3.0 million and is 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. ARS Pharma will receive a per unit supply price for any sale of commercial supply to Pediatrix. Additionally, ARS Pharma is 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 ARS Pharma 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 ARS Pharma’s 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 Pediatrix Agreement will continue until the expiration of the last-to-expire Pediatrix Royalty Term. Pediatrix has the right to terminate the Pediatrix Agreement at any time after a specified notice period to ARS Pharma. Either party may terminate the Pediatrix 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.

The foregoing description of the Pediatrix Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.3 hereto and is incorporated herein by reference.

License and Supply Agreement with Recordati Ireland

In September 2020, ARS Pharma entered into a license and supply agreement (the “Recordati Agreement”) with Recordati Ireland, Ltd (“Recordati Ireland”). Pursuant to the Recordati Agreement, ARS Pharma granted Recordati Ireland an exclusive, royalty-bearing, sublicensable license under its 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. ARS Pharma 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 Recordati Agreement, ARS Pharma 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 Recordati 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 Recordati Agreement, ARS Pharma received a one-time upfront payment of €10 million and is 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, ARS Pharma is 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, ARS Pharma has earned an upfront payment of €10.0 million and a regulatory milestone payment of €5.0 million.

The Recordati 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 Recordati Agreement on a country-by-country basis after providing written notice to ARS Pharma if the applicable marketing authorization application is finally rejected and there is no reasonable basis for approval. Either party may terminate the Recordati 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.

The foregoing description of the Recordati Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.4 hereto and is incorporated herein by reference.

Manufacturing Agreement with Renaissance

In September 2020, ARS Pharma entered into a manufacturing agreement (the “Renaissance Agreement”) with Renaissance Lakewood, LLC (“Renaissance”). Pursuant to the Renaissance Agreement, Renaissance agreed to manufacture for, and provide to ARS Pharma, *neffy* nasal unit dose sprays (“Renaissance Products”). ARS Pharma is obligated to provide Renaissance with certain supplies to manufacture the Renaissance Products and to purchase from Renaissance a mid-double digit percentage of ARS Pharma’s annual aggregate Renaissance Product requirements in the E.U., and a high-double digit percentage of ARS Pharma’s annual aggregate Renaissance

Product requirements in the U.S. The Renaissance 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. ARS Pharma may also request Renaissance perform certain services related to the Renaissance Product, for which ARS Pharma will pay reasonable compensation to Renaissance.

The initial term of the Renaissance 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 Renaissance 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) ARS Pharma has 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) ARS Pharma decided in its 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.

The foregoing description of the Renaissance Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.5 hereto and is incorporated herein by reference.

Item 2.01 Completion of Acquisition

As previously disclosed, on July 21, 2022, Silverback, Merger Sub and ARS Pharma entered into the Merger Agreement. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including the approval of the transaction by Silverback’s stockholders, Merger Sub would 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. Concurrently with the execution of the Merger Agreement, certain officers, directors and stockholders of ARS Pharma and Silverback entered into lock-up agreements (the “Lock-Up Agreements”), pursuant to which they accepted certain restrictions on transfers of the shares of the Company for the 180-day period following the effective time of the Merger.

On November 8, 2022, Silverback, Merger Sub and ARS Pharma consummated the transactions contemplated by the Merger Agreement following a Special Meeting of Silverback’s stockholders (as defined and described in Item 5.07 below). Pursuant to the Certificate of Merger, filed by Silverback, which became effective at 4:03 p.m. Eastern Time on November 8, 2022 (the “Merger Certificate”), Merger Sub was merged with and into ARS Pharma and ARS Pharma became a wholly owned subsidiary of the Company. At the effective time of the Merger, each outstanding share of 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 of

the Merger) was converted into the right to receive 1.1819 shares of common stock of Silverback, which resulted in the issuance by Silverback of an aggregate of 57,229,022 shares of its common stock to the stockholders of ARS Pharma in a transaction 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 the rules promulgated thereunder. In addition, Silverback assumed each option to purchase ARS Pharma common stock and each warrant to purchase ARS Pharma capital stock which became options and warrants to purchase shares of Silverback common stock.

The Merger was treated as a reverse recapitalization under U.S. generally accepted accounting principles. ARS Pharma is considered the accounting acquirer for financial reporting purposes.

Immediately prior to the consummation of the Merger, ARS Pharma filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation changing its name from “ARS Pharmaceuticals, Inc.” to “ARS Subsidiary, Inc.” and Silverback filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation (“Charter Amendment”), changing its name from “Silverback Therapeutics, Inc.” to “ARS Pharmaceuticals, Inc.”

Following the consummation of the Merger, the business previously conducted by ARS Pharma became the business conducted by the Company, which is now a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis. The Company is developing *neffy* (previously referred to as ARS-1), an intranasal epinephrine product in clinical development for patients and their caregivers with Type I allergic reactions including food, medications and insect bites that could lead to life-threatening anaphylaxis. The Company’s headquarters are located in San Diego, California (ARS Pharma’s former headquarters).

The Company’s common stock will be listed on The Nasdaq Global Market under the new name on November 9, 2022. The trading symbol will also change on that date from “SBTX” to “SPRY.”

Immediately following the consummation of the Merger, there were 93,770,165 shares of the Company’s common stock issued and outstanding, with ARS Pharma equityholders collectively owning approximately 62% of the Company and prior Silverback equityholders collectively own approximately 38% of the Company, in each case on a fully diluted basis using the treasury stock method and excluding out-of-the-money options of Silverback.

The foregoing description does not constitute a complete summary of the terms of the Charter Amendment or the Merger Certificate, and is qualified in its entirety by reference to the full text of the Charter Amendment and the Merger Certificate, copies of which are attached to this filing as Exhibits 3.1 and 3.2 hereto and are incorporated herein by reference. In addition, the description of the Merger Agreement is qualified in its entirety by reference to the Merger Agreement, a copy of which is attached to this filing as Exhibit 2.1 hereto and is incorporated herein by reference.

Item 3.02 Unregistered Sales of Securities

Pursuant to the Merger Agreement, Silverback issued 57,229,022 shares of common stock to the stockholders of ARS Pharma in accordance with the terms and conditions set forth in the Merger Agreement. In addition, Silverback assumed each option to purchase ARS Pharma common stock and each warrant to purchase ARS Pharma capital stock which became options and warrants to purchase shares of Silverback common stock. The nature of the transaction and the nature and amount of consideration received by ARS Pharma’s equityholders are described in Item 2.01 of this Form 8-K, which is incorporated by reference into this Item 3.02. Such issuances were exempt from registration under Section 4(a)(2) of the Securities Act and the rules promulgated thereunder.

Item 5.01 Changes in Control of Registrant

The disclosures contained in Items 2.01 and 3.02 above and Items 5.02 and 5.07 below are incorporated herein by reference.

Immediately following the consummation of the Merger, the prior ARS Pharma equityholders collectively owned approximately 62% of the Company and the prior Silverback equityholders collectively own approximately 38% of the Company, in each case on a fully diluted basis using the treasury stock method and excluding out-of-the-money options of Silverback. In addition, the eleven-member board of directors of the Company includes eight individuals who are designees of ARS Pharma and served as members of the board of directors of ARS Pharma immediately prior to the Merger. These directors possess a majority control of the board of directors of the Company.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangement of Certain Officers

Resignation of Directors and Termination of Executive Officers

In accordance with the terms of the Merger Agreement, (i) each of Vicki L. Capps, Robert Hershberg, M.D., Ph.D., Maria Koehler, M.D., Ph.D., Andrew Powell, J.D. and Jonathan Root, M.D. resigned from the Company's board of directors and any respective committee membership of the Company's board of directors, effective as of the consummation of the Merger, and (ii) each of Jeffrey Pepe, Ph.D., J.D., the Company's Interim Chief Executive Officer, General Counsel and Corporate Secretary, and Russ Hawkinson, the Company's Interim Chief Financial Officer, were terminated in connection with the Company's previously announced reduction in force.

Appointment of Directors and Executive Officers

At the effective time of the Merger, the Company's board of directors (and its committees) and executive officers were reconstituted to include the following directors and executive officers:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive Officers</i>		
Richard Lowenthal, M.S., MSEL	56	President, Chief Executive Officer and Class II 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 and Secretary
<i>Non-Employee Directors</i>		
Pratik Shah, Ph.D.	52	Chair of the Board and Class I Director
Rajeev Dadoo, Ph.D.	52	Class I Director
Saqib Islam, J.D.	53	Class III Director
Michael Kelly	57	Class I Director

Peter Kolchinsky, Ph.D.	46	Class II Director
Jonathan S. Leff	53	Class III Director
Brenton L. Saunders	52	Class II Director
Phillip Schneider	66	Class III Director
Laura Shawver, Ph.D.	65	Class III Director
Peter A. Thompson, M.D.	63	Class II Director

Class III directors have a term expiring in 2023, Class I directors have a term expiring in 2024 and Class II directors have a term expiring in 2025.

The members of the Audit Committee are Phillip Schneider (Chair), Michael Kelly and Rajeev Dadoo, Ph.D. The members of the Compensation Committee are Rajeev Dadoo, Ph.D. (Chair) and Saqib Islam, J.D. The members of the Nominating and Corporate Governance Committee are Peter Kolchinsky, Ph.D. (Chair) and Jonathan S. Leff.

Pursuant to the terms of the Merger Agreement, each of (i) Mr. Lowenthal, Dr. Shah, Dr. Dadoo, Mr. Kelly, Dr. Kolchinsky, Mr. Leff, Mr. Saunders and Mr. Schneider were appointed to the board of directors of the Company as designees of ARS Pharma and (ii) Mr. Islam, Dr. Shawver and Dr. Thompson remained on the board of directors of the Company as designees of Silverback.

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 board of directors of ARS Pharma 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. The Company believes Mr. Lowenthal is qualified to serve on its 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.

Non-Employee Directors

Pratik Shah, Ph.D., has served as a member of the board of directors of ARS Pharma since April 2016 and was appointed as the first Chair of the board of directors of ARS Pharma 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. The Company believes Dr. Shah is qualified to serve on its 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.

Rajeev Dadoo, Ph.D., has served as a member of the board of directors of ARS Pharma 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. The Company believes Dr. Dadoo is qualified to serve on its board of directors due to his experience as a venture capitalist in the life science industry, his product development experience and his educational background.

Saqib Islam, J.D., has served as a member of the board of directors of Silverback 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. The Company believes Mr. Saqib is qualified to serve on its board of directors based on his experience and expertise in operations management and executive leadership at various biopharmaceutical companies.

Michael Kelly, has served as a member of the board of directors of ARS Pharma 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. The Company believes Mr. Kelly is qualified to serve on its 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.

Peter Kolchinsky, Ph.D., has served as a member of the board of directors of ARS Pharma 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 business 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. Kolchinsky 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. The Company believes Dr. Kolchinsky is qualified to serve on its 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.

Jonathan S. Leff, has served as a member of the board of directors of ARS Pharma 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: PRT0), 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. The Company believes Mr. Leff is qualified to serve on its 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.

Brenton L. Saunders, has served as a member of the board of directors of ARS Pharma 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. The Company believes Mr. Saunders is qualified to serve on its 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 board of directors of ARS Pharma since May 2019. He also has served on the board of directors of Longboard Pharmaceuticals, Inc. (Nasdaq: LBPH) since December 2020. 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. The Company believes Mr. Schneider is qualified to serve on its board of directors due to his experience in finance and accounting and knowledge of the biotechnology industry.

Laura Shawver, Ph.D., has served as a member of the board of directors of Silverback since April 2020 and previously served as the Chief Executive Officer of Silverback from April 2020 through August 2022. Dr. Shawver has also served as the President and Chief Executive Officer of Capstan Therapeutics, Inc., a biotechnology company dedicated to developing and delivering precise *in vivo* cell engineering to patients, since September 2022. 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. The Company believes Dr. Shawver is qualified to serve on its 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 board of directors of Silverback since April 2016. Dr. Thompson previously served as the Chief Executive Officer of Silverback 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. The Company believes Dr. Thompson is qualified to serve on its board of directors due to his experience in management and venture capital in the biopharmaceutical industry.

Family Relationships

Mr. Lowenthal and Dr. Tanimoto are spouses.

Employment Agreements

ARS Pharma had entered into employment agreements with each of the executive officers named in this Current Report on Form 8-K. Such agreements remained effective following the consummation of the Merger and are described below.

ARS Pharma entered into an executive employment agreement with Mr. Lowenthal in September 2018, which governs the current terms of his employment with ARS Pharma. Pursuant to the agreement, Mr. Lowenthal is entitled to an initial annual base salary of \$400,000, which was increased to \$430,560 effective January 1, 2021 and to \$447,782 effective January 1, 2022, and is eligible to participate in ARS Pharma's benefit plans as in effect from time to time. Mr. Lowenthal's employment agreement also provides for severance benefits upon an involuntary termination, as described below.

ARS Pharma entered into an executive employment agreement with Ms. Scott in February 2022, which governs the current terms of her employment with ARS Pharma. Pursuant to the agreement, Ms. Scott is entitled to an initial annual base salary of \$195,000 reflecting a 50% part-time commitment, which was increased to \$390,000 upon Ms. Scott's full-time employment, and is eligible to participate in ARS Pharma's benefit plans as in effect from time to time. In addition, the agreement provides that Ms. Scott is eligible for an annual bonus at the discretion of the board of directors of ARS Pharma. In connection with the commencement of her employment with ARS Pharma, and pursuant to the terms of her employment agreement, the board of directors of ARS Pharma granted Ms. Scott an option to purchase 700,000 shares of ARS Pharma's common stock which vests over four years from the vesting commencement date with $\frac{1}{4}$ 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. Ms. Scott's employment agreement also provides for severance benefits upon an involuntary termination, as described below.

ARS Pharma entered into an executive employment agreement with Dr. Tanimoto as a part-time employee in September 2018, as amended in September 2021 to account for her status as a full-time employee, which governs the current terms of her employment with ARS Pharma. Pursuant to the agreement, Dr. Tanimoto is entitled to an initial annual base salary of \$120,000, which was increased to \$215,280 effective January 1, 2021, to \$409,000 effective September 2021 pursuant to the amendment to her agreement and to \$425,360 effective January 1, 2022. Dr. Tanimoto's employment agreement also provides that she is eligible to participate in ARS Pharma's benefit plans as in effect from time to time and for severance benefits upon an involuntary termination, as described below.

ARS Pharma entered into an executive employment agreement with Mr. Karas in February 2022, which governs the current terms of his employment with ARS Pharma. Pursuant to the agreement, Mr. Karas is entitled to an initial annual base salary of \$410,000, and is eligible to participate in ARS Pharma's benefit plans as in effect from time to time. In addition, the agreement provides that Mr. Karas is eligible for an annual bonus at the discretion of the board of directors of ARS Pharma. In connection with the commencement of his employment with ARS Pharma, and pursuant to the terms of his employment agreement, the board of directors of ARS Pharma granted Mr. Karas an option to purchase 520,000 shares of ARS Pharma's common stock which vests over four years from the vesting commencement date with $\frac{1}{4}$ 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. Mr. Karas' employment agreement also provides for severance benefits upon an involuntary termination, as described below. In addition, the terms of his employment agreement provide that, subject to his execution of a release of claims, if, within 12 months following a Change in Control (as defined in ARS Pharma's 2018 Equity Incentive Plan),

Mr. Karas' employment is terminated by ARS Pharma without "Cause" (other than as a result of death or disability) or by Mr. Karas for "Good Reason" (each as defined in his employment agreement), such termination or resignation constitutes a Separation from Service (as defined in his employment agreement) and Mr. Karas remains in compliance with the terms of his employment agreement and his confidential information agreement, then 100% of the shares underlying the foregoing option will automatically accelerate and become exercisable.

ARS Pharma entered into an executive employment agreement with Mr. Chakma in June 2019, which governs the current terms of his employment with ARS Pharma. Pursuant to the agreement, Mr. Chakma is entitled to an initial annual base salary of \$300,000, which was increased to \$306,125 effective January 1, 2020, reduced to \$276,125 effective on March 1, 2020, reflecting a 90% part-time commitment, which was subsequently increased to \$287,170, increased to \$331,841 effective as of January 1, 2022 upon full-time employment, and is eligible to participate in ARS Pharma's benefit plans as in effect from time to time. Under the agreement, ARS Pharma also agreed to pay for the costs for Mr. Chakma's relocation as a reimbursement of expenses based on actual costs incurred up to \$40,000. Mr. Chakma's employment agreement also provides for severance benefits upon an involuntary termination, as described below. In connection with the commencement of his employment with ARS Pharma, and pursuant to the terms of his employment agreement, the board of directors of ARS Pharma granted Mr. Chakma (i) an option to purchase 400,000 shares of ARS Pharma's common stock which vests over four years from June 1, 2019 with 1/4 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, and (ii) an option to purchase 200,000 shares of ARS Pharma's common stock which would vest upon the achievement of certain milestones, which option fully vested upon the closing of the Merger.

The respective employment agreements with Mr. Lowenthal, Ms. Scott, Dr. Tanimoto and Mr. Karas (each an "executive") provide that, subject to the executive's execution of a release of claims, if the executive's employment is terminated by ARS Pharma without "Cause" (other than as a result of death or disability) or the executive resigns for "Good Reason" (each, as defined in the executive's employment agreement), the executive will be entitled to receive: (i) continued payment of the executive's final base salary for 12 months, (ii) premiums for the executive's COBRA continuation health coverage for up to 12 months, and (iii) accelerated vesting of the outstanding unvested stock awards granted to the executive in an amount equal to the number of shares that would have vested had the executive remained employed by ARS Pharma for 12 months following termination or resignation.

Mr. Chakma's employment agreement provides that, if his employment is terminated by ARS Pharma without "Cause" (other than as a result of death or disability) or Mr. Chakma resigns for "Good Reason" (each, as defined in Mr. Chakma's employment agreement), he will be entitled to receive: (i) continued payment of his final base salary for 3 months and (ii) premiums for his COBRA continuation health coverage for up to 6 months, subject to his execution of a release of claims.

The foregoing descriptions of the executive employment agreements are not complete and are subject to and qualified in its entirety by reference to such agreements, copies of which are attached to this filing as Exhibits 10.6, 10.7, 10.8, 10.9 and 10.10 hereto and are incorporated herein by reference.

Related Party Transactions

Since January 1, 2020, ARS Pharma had entered into transactions with the directors or executive officers named in this Current Report that would be required to be disclosed under Item 404(a) of Regulation S-K. The transactions are described below.

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. Entities affiliated with Dr. Kolchinsky purchased 2,546,473 shares of ARS Pharma Series D convertible preferred stock for an aggregate purchase price of approximately \$15 million.

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. Mr. Lowenthal, Dr. Tanimoto, Dr. Shah and Dr. Kolchinsky were parties to these agreements or were affiliated with parties to these agreements. Pursuant to the terms of the Merger Agreement, these agreements terminated immediately prior to the Closing.

Consulting Arrangements

In April 2021, ARS Pharma entered into a consulting agreement, as amended on April 25, 2022 (as amended, the “Saunders Consulting Agreement”), with Mr. Saunders, 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 $\frac{1}{4}$ 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 ARS Pharma’s 2018 Equity Incentive Plan). Only service as a consultant pursuant to the Saunders Consulting Agreement will qualify as Continuous Service under ARS Pharma’s 2018 Equity Incentive 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 is the President of Marlinspike, which provides management and business consulting services as well as business development support to ARS Pharma for a monthly fee of \$20,000. Mr. Chakma 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 September 30, 2022, ARS Pharma incurred aggregate fees of \$180,000 to Marlinspike 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 and Dr. Tanimoto 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 September 30, 2022, ARS Pharma incurred aggregate fees of \$1.9 million to PLC during 2022 pursuant to the initial consulting agreement and the revised consulting agreement.

The foregoing descriptions of the consulting agreements are not complete and are subject to and qualified in its entirety by reference to such agreements, copies of which are attached to this filing as Exhibits 10.11, 10.12 and 10.13 hereto and are incorporated herein by reference.

Indemnification Agreements

ARS Pharma entered into indemnification agreements with its directors and executive officers. In connection with the closing of the Merger, the Company intends to enter into new indemnification agreements with each director and executive officer of ARS Pharma appointed as a director of the Company as of the effective time of the merger on the Company's standard form which was previously filed by the Company with the SEC.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year

Immediately prior to the consummation of the Merger, on November 8, 2022, Silverback filed the Charter Amendment changing its name from "Silverback Therapeutics, Inc." to "ARS Pharmaceuticals, Inc." The foregoing description of the Charter Amendment is not complete and is subject to and qualified in its entirety by reference to such Charter Amendment, a copy of which is attached to this filing as Exhibit 3.1 hereto and is incorporated herein by reference.

Item 5.07 Submission of Matters to a Vote of Security Holders.

On November 4, 2022, Silverback held a special meeting of stockholders (the "Special Meeting") to consider two proposals related to the Merger. Each of Silverback's proposals was approved by the requisite vote of Silverback's stockholders as described below.

At the close of business on September 19, 2022, the record date for the Special Meeting, Silverback had 35,798,117 shares of its common stock issued and outstanding. The holders of a total of 27,267,233 shares of common stock were represented at the Special Meeting by proxy or by attending the virtual meeting, representing approximately 76% of Silverback's issued and outstanding common stock as of the record date, which total constituted a quorum for the Special Meeting in accordance with Silverback's amended and restated bylaws.

The final voting results for each of the proposals voted upon at the Special Meeting is set forth below. Brokers had discretionary authority to vote for Proposal No. 2 for the shares of common stock held in street name, and as a result, no broker non-votes were received for Proposal No. 2. For more information on the proposals voted upon at the Special Meeting, please refer to Silverback's definitive proxy statement for the Special Meeting, originally filed with the Securities and Exchange Commission on October 6, 2022, as amended.

Proposal 1. To approve (i) the issuance of shares of common stock or other securities of Silverback pursuant to the Merger, which represent (or are convertible into) more than 20% of the shares of 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:

27,244,219 For	9,986 Against	13,028 Abstain	0 Broker Non-Votes
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Proposal 2. To approve a postponement or adjournment of the Special Meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal No. 1:

26,226,927 For	317,067 Against	723,239 Abstain	0 Broker Non-Votes
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Item 8.01. Other Events

On November 8, 2022, the Company issued a press release announcing the closing of the Merger. The press release contains statements intended as “forward-looking statements” which are subject to the cautionary statements about forward-looking statements set forth therein. The press release is attached to this filing as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(a) Financial Statements of Business Acquired

The financial statements and information required by this Item 9.01(a) will be filed by amendment to this report not later than 71 calendar days after the date on which this report is required to be filed.

(b) Pro Forma Financial Information

The financial statements and information required by this Item 9.01(b) will be filed by amendment to this report not later than 71 calendar days after the date on which this report is required to be filed.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
2.1¥	<u>Agreement and Plan of Merger and Reorganization, dated as of July 21, 2022, by and among Silverback Therapeutics, Inc., Sabre Merger Sub, Inc. and ARS Pharmaceuticals, Inc., as amended by the First Amendment, dated August 11, 2022 and the Second Amendment, dated October 25, 2022.</u>
3.1	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Silverback Therapeutics, Inc.</u>
3.2	<u>Certificate of Merger.</u>
4.1	<u>Warrant to purchase stock issued to Silicon Valley Bank, dated as of September 30, 2019, as amended on December 7, 2020.</u>
10.1*¥	<u>License Agreement, dated as of June 18, 2018, by and between ARS Pharmaceuticals, Inc. and Aegis Therapeutics, LLC, as amended by the First Amendment to License Agreement, dated as of July 15, 2020, and the Second Amendment to License Agreement, dated as of January 6, 2021.</u>
10.2*¥	<u>Collaboration and License Agreement, dated as of April 30, 2020, by and between ARS Pharmaceuticals, Inc. and Alfresa Pharma Corporation.</u>
10.3*¥	<u>Collaboration and Distribution Agreement, dated as of March 1, 2021, by and between ARS Pharmaceuticals, Inc. and Pediatrix Therapeutics.</u>
10.4*¥	<u>License and Supply Agreement, dated as of September 21, 2020, by and between ARS Pharmaceuticals, Inc. and Recordati Ireland, Ltd.</u>
10.5*¥	<u>Manufacturing Agreement, dated as September 9, 2020, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC.</u>

10.6+	<u>Executive Employment Agreement, dated as of September 14, 2018, by and between ARS Pharmaceuticals, Inc. and Richard E. Lowenthal.</u>
10.7+	<u>Executive Employment Agreement, dated as of February 9, 2022, by and between ARS Pharmaceuticals, Inc. and Kathleen Scott.</u>
10.8+	<u>Executive Employment Agreement, dated as of September 14, 2018, by and between ARS Pharmaceuticals, Inc. and Dr. Sarina Tanimoto, as amended by Amendment No. 1 to Executive Employment Agreement, dated as of September 1, 2021.</u>
10.9+	<u>Executive Employment Agreement, dated as of February 16, 2022, by and between ARS Pharmaceuticals, Inc. and Eric Karas.</u>
10.10+	<u>Executive Employment Agreement, dated as of June 1, 2019, by and between ARS Pharmaceuticals, Inc. and Justin Chakma.</u>
10.11+	<u>Consulting Agreement, dated as of April 26, 2021, by and between ARS Pharmaceuticals, Inc. and Brenton L. Saunders, as amended on April 25, 2022.</u>
10.12+	<u>Consulting Agreement, by and between ARS Pharmaceuticals, Inc. and Marlinspike Group, LLC, dated September 14, 2018.</u>
10.13+	<u>Consulting Agreement, by and between ARS Pharmaceuticals, Inc. and Pacific-Link Regulatory Consulting, Inc., dated July 1, 2022.</u>
99.1	<u>Press Release of ARS Pharmaceuticals, Inc., dated November 8, 2022</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

¥ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 8, 2022

ARS Pharmaceuticals, Inc.

By: /s/ Richard Lowenthal, M.S., MSEL

Name: Richard Lowenthal, M.S., MSEL

Title: President and Chief Executive Officer

**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:

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Exhibit B-2	Form of Parent Stockholder Support Agreement
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Exhibit D	Company Warrants
Exhibit E	Post-Closing Officers and Directors
Exhibit F	Form of Company Stockholder Written Consent
Exhibit G	Investor Questionnaire

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 with 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 (6th) 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

SECOND AMENDMENT TO THE

AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

This Second Amendment (this "**Amendment**") to the Agreement and Plan of Merger and Reorganization, 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**"), as amended by that First Amendment, dated as of August 11, 2022 (as amended, the "**Merger Agreement**"), is made and entered into as of October 25, 2022. Each of Parent, Merger Sub and the Company is a "**Party**," and collectively, the "**Parties**." Capitalized terms used but not otherwise defined in this Amendment will have the same meanings ascribed to such terms in the Merger Agreement.

WHEREAS, the Parties have entered Merger Agreement;

WHEREAS, pursuant to Section 8.5 of the Merger Agreement, the obligations of the Company to effect the Merger and otherwise consummate the Contemplated Transactions are subject to the satisfaction or the written waiver by the Company, at or prior to the Closing, of the condition that the Parent Net Cash shall not be greater than \$255,000,000 (the "**Parent Net Cash Ceiling**"); and

WHEREAS, the Parties wish to increase the Parent Net Cash Ceiling, amend the proviso set forth in Section 4.1(b)(i), which sets forth the definition of the term "Permitted Dividend," and amend Exhibit A, which sets forth the definition of the term "Parent Valuation", as set forth below.

NOW, THEREFORE, in connection with the Contemplated Transactions and in consideration of the premises and the mutual promises herein made, the Parties hereby agree and acknowledge as follows:

Amendment of Parent Net Cash Ceiling. The Parties hereby agree that Section 8.5 of the Merger Agreement is hereby amended and restated in its entirety to read as follows:

"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 \$265,000,000; *provided, however*, that if Parent Net Cash is greater than \$265,000,000, Parent may declare a Permitted Dividend in the amount of such excess to satisfy such condition."

Permitted Dividend. The Parties hereby agree that the proviso set forth in Section 4.1(b)(i) of the Merger Agreement be amended and restated in its entirety to read as follows:

"provided, however, that to the extent that Parent Net Cash is greater than \$265,000,000, Parent shall be permitted to declare any such excess amount as a dividend (a "**Permitted Dividend**");"

Amendment of Exhibit A. The Parties hereby agree that clause (i) in the definition of term “Parent Valuation” set forth in Exhibit A of the Merger Agreement be amended and restated in its entirety to read as follows:

“(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 \$25,000,000, Parent Net Cash exceeds \$240,000,000”.

Miscellaneous. Except as expressly modified hereby, the provisions of the Merger Agreement shall not be affected hereby and shall remain in full force and effect. The provisions of Section 10 of the Merger Agreement (as applicable) shall govern this Amendment.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned has executed this Amendment as of the date first above written.

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal
Name: Richard Lowenthal, M.S., MSEL
Title: Chief Executive Officer

ACKNOWLEDGED AND AGREED:

SILVERBACK THERAPEUTICS, INC.

By: /s/ Jeffrey C. Pepe
Name: Jeffrey C. Pepe, Ph.D., J.D.
Title: Interim Chief Executive Officer

SABRE MERGER SUB, INC.

By: /s/ Jeffrey C. Pepe
Name: Jeffrey C. Pepe, Ph.D., J.D.
Title: Secretary

**CERTIFICATE OF AMENDMENT TO
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF
SILVERBACK THERAPEUTICS, INC.**

SILVERBACK THERAPEUTICS, INC. (the “*Corporation*”), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the “*DGCL*”), does hereby certify:

FIRST: The name of the Corporation is Silverback Therapeutics, Inc.

SECOND: The date on which the Certificate of Incorporation of the Corporation was originally filed with the Secretary of State of Delaware is January 4, 2016, under the name “Silverback Therapeutics, Inc.”.

THIRD: The Board of Directors of the Corporation, acting in accordance with the provisions of Sections 141 and 242 of the DGCL, adopted resolutions amending the Corporation’s Amended and Restated Certificate of Incorporation (the “*Certificate*”), as follows:

Article First of the Certificate shall be amended and restated in its entirety to read as follows:

“The name of this corporation is ARS Pharmaceuticals, Inc. (the “*Company*”).”

FOUR: This Certificate of Amendment to Amended and Restated Certificate of Incorporation shall become effective as of November 8, 2022 at 4:02 pm Eastern Time, following the filing with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation as of November 7, 2022.

By: /s/ Jeffrey C. Pepe

Name: Jeffrey C. Pepe

Title: Interim Chief Executive Officer

CERTIFICATE OF MERGER

MERCING

SABRE MERGER SUB, INC.,
A DELAWARE CORPORATION

WITH AND INTO

ARS SUBSIDIARY, INC.,
A DELAWARE CORPORATION

Pursuant to Title 8, Section 251 of the General Corporation Law of the State of Delaware

ARS Subsidiary, Inc., a Delaware corporation (the "Company"), does hereby certify as follows:

FIRST: Each of the constituent corporations (the "Constituent Corporations"), the Company and Sabre Merger Sub, Inc., a Delaware corporation ("Merger Sub"), is a corporation duly organized and existing under the laws of the State of Delaware.

SECOND: An Agreement and Plan of Merger and Reorganization, dated as of July 21, 2022, as amended by that certain amendment dated August 11, 2022 and further amended by that certain amendment dated October 25, 2022 (the "Merger Agreement"), by and among the Company, ARS Pharmaceuticals, Inc., a Delaware corporation, and Merger Sub, setting forth the terms and conditions of the merger of Merger Sub with and into the Company (the "Merger"), has been approved, adopted, certified, executed and acknowledged by each of the Constituent Corporations in accordance with Section 228 and Section 251 of the Delaware General Corporation Law.

THIRD: Company shall be the surviving corporation in the Merger (the "Surviving Corporation"). The name of the Surviving Corporation shall be ARS Subsidiary, Inc.

FOURTH: Upon the effectiveness of the Merger, the certificate of incorporation of the Surviving Corporation shall be amended and restated such that, upon the effectiveness of the Merger, the certificate of incorporation attached hereto as Exhibit A shall be the certificate of incorporation of the Surviving Corporation.

FIFTH: An executed copy of the Merger Agreement is on file at the principal place of business of the Surviving Corporation at the following address:

11682 El Camino Real, Suite 120
San Diego, CA 92130

SIXTH: A copy of the Merger Agreement will be furnished by the Surviving Corporation, on request and without cost, to any stockholder of either Constituent Corporation.

SEVENTH: The Merger shall become effective as of November 8, 2022, at 4:03 pm Eastern Time, following the filing of this Certificate of Merger with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, ARS Subsidiary, Inc. has caused this Certificate of Merger to be executed by the undersigned authorized officer as of November 7, 2022.

ARS SUBSIDIARY, INC.

/s/ Richard Lowenthal

Name: Richard Lowenthal

Title: Chief Executive Officer

Exhibit A

AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION

OF

ARS SUBSIDIARY, INC.

FIRST: The name of the corporation is:

ARS SUBSIDIARY, INC.

SECOND: The address of its registered office in the State of Delaware is 1209 Orange Street – Corporation Trust Center, City of Wilmington, County of New Castle, 19801 and the name of the registered agent of the corporation in the State of Delaware at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware (the “DGCL”).

FOURTH: The corporation is authorized to issue one class of stock, to be designated “Common Stock”, with a par value of \$0.001 per share. The total number of shares of Common Stock that the corporation shall have authority to issue is one thousand (1,000).

FIFTH: The business and affairs of the corporation shall be managed by or under the direction of the Board of Directors (the “Board”). In addition to the powers and authority expressly conferred upon them by statute or by this Certificate of Incorporation or the Bylaws of the corporation (the “Bylaws”), the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the corporation. Election of directors need not be by written ballot, unless the Bylaws so provide.

SIXTH: The Board is authorized to make, adopt, amend, alter or repeal the Bylaws of the corporation. The stockholders shall also have power to make, adopt, amend, alter or repeal the Bylaws of the corporation.

SEVENTH: To the fullest extent permitted by law, a director of the corporation shall not be personally liable to the corporation or its stockholder for monetary damages for a breach of fiduciary duty as a director. If the DGCL or any other law of the state of Delaware is amended after approval by the stockholders to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Any repeal or modification of the foregoing provisions shall not adversely affect any right or protection of a director of the corporation existing at the time of, or increase the liability of any director of the corporation with respect to any acts or omissions of such director occurring prior to such appeal or modification.

* * * *

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

WARRANT TO PURCHASE PREFERRED STOCK

Company: ARS PHARMACEUTICALS, INC., a Delaware corporation

Number of Shares: 19,230 (the "Initial Shares"), plus all Additional Shares (as defined in Section 1.7) which Holder is entitled to purchase

Type/Series of Stock: Series C Preferred Stock

Warrant Price: \$2.60 per share

Issue Date: September 30, 2019

Expiration Date: September 30, 2029 See also Section 5.1(b).

Credit Facility: This Warrant to Purchase Preferred Stock ("**Warrant**") is issued in connection with that certain Loan and Security Agreement of even date herewith between Silicon Valley Bank and the Company (the "**Loan Agreement**").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, SILICON VALLEY BANK (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "**Holder**") is entitled to purchase the number of fully paid and non-assessable shares (the "**Shares**") of the above-stated Type/Series of Stock (the "**Class**") of the above-named company (the "**Company**") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. Reference is made to Section 5.4 of this Warrant whereby Silicon Valley Bank shall transfer this Warrant to its parent company, SVB Financial Group.

SECTION 1. EXERCISE.

1.1 Method of Exercise. Holder may at any time and from time to time through the Expiration Date exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise. On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

$$X = Y(A-B)/A$$

where:

X = the number of Shares to be issued to the Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);

A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and

B = the Warrant Price.

1.3 Fair Market Value. If the Company's common stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "**Trading Market**") and the Class is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company's common stock is then traded in a Trading Market and the Class is a series of the Company's convertible preferred stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company's common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company multiplied by the number of shares of the Company's common stock into which a Share is then convertible. If the Company's common stock is not traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

1.4 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

1.5 Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

1.6 Treatment of Warrant Upon Acquisition of Company.

(a) Acquisition. For the purpose of this Warrant, “**Acquisition**” means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company’s domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company’s (or the surviving or successor entity’s) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company’s then-total outstanding combined voting power. Notwithstanding the foregoing, “Acquisition” shall exclude any transaction consisting of the sale of the Company’s equity securities in a bona fide equity financing transaction for capital raising purposes provided that the Company is the surviving entity and no other stockholder receives cash consideration in connection therewith.

(b) Treatment of Warrant at Acquisition. In the event of an Acquisition in which the consideration to be received by the Company’s stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a “**Cash/Public Acquisition**”), and the fair market value of one Share as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date immediately prior to such Cash/Public Acquisition, and Holder has not exercised this Warrant pursuant to Section 1.1 above as to all Shares, then this Warrant shall automatically be deemed to be Cashless Exercised pursuant to Section 1.2 above as to all Shares for which it is then exercisable effective immediately prior to and contingent upon the consummation of a Cash/Public Acquisition. In connection with such Cashless Exercise, Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as of the date thereof and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon exercise. In the event of a Cash/Public Acquisition where the fair market value of one Share as determined in accordance with Section 1.3 above would be less than the Warrant Price in effect immediately prior to such Cash/Public Acquisition, then this Warrant will expire immediately prior to the consummation of such Cash/Public Acquisition.

(c) Upon the closing of any Acquisition other than a Cash/Public Acquisition defined above, the acquiring, surviving or successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

(d) As used in this Warrant, “**Marketable Securities**” means securities meeting all of the following requirements, determined as of immediately prior to and after giving effect to the closing of an Acquisition: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), and is then current in its filing of all required reports and other

information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise or convert this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

1.7 Number of Shares. The number of Shares for which this Warrant is exercisable shall be equal to (i) the Initial Shares, plus (ii) upon the funding of each Term Loan Advance (as defined in the Loan Agreement) made by Silicon Valley Bank to the Company, a number of Shares equal to (I) the number obtained by multiplying (y) the aggregate principal amount of the applicable Term Loan Advance, by (z) one percent (1.00%), divided by (II) the Warrant Price (any such additional Shares issued pursuant to this sub-clause (ii), the "**Additional Shares**").

SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

2.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in common stock or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Warrant Price shall be proportionately increased and the number of Shares shall be proportionately decreased.

2.2 Reclassification, Exchange, Combinations or Substitution. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, this Warrant will be exercisable for the number, class and series of Company securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, and subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, combinations substitutions, replacements or other similar events.

2.3 Conversion of Preferred Stock. If the Class is a class and series of the Company's convertible preferred stock, in the event that all outstanding shares of the Class are converted, automatically or by action of the holders thereof, into common stock pursuant to the provisions of the Company's Certificate of Incorporation, as then in effect, including, without limitation, in connection with the Company's initial, underwritten public offering and sale of its

common stock pursuant to an effective registration statement under the Act (the "**IPO**"), then from and after the date on which all outstanding shares of the Class have been so converted, this Warrant shall be exercisable for such number of shares of common stock into which the Shares would have been converted had the Shares been outstanding on the date of such conversion, and the Warrant Price shall equal the Warrant Price in effect as of immediately prior to such conversion divided by the number of shares of common stock into which one Share would have been converted, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant.

2.4 Adjustments for Diluting Issuances. Without duplication of any adjustment otherwise provided for in this Section 2, the number of shares of common stock issuable upon conversion of the Shares shall be subject to anti-dilution adjustment from time to time in the manner set forth in the Company's Certificate of Incorporation, as then in effect, as if the Shares were issued and outstanding on and as of the date of any such required adjustment.

2.5 No Fractional Share. No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

2.6 Notice/Certificate as to Adjustments. Upon each adjustment of the Warrant Price, Class and/or number of Shares, the Company, at the Company's expense, shall notify Holder in writing within a reasonable time setting forth the adjustments to the Warrant Price, Class and/or number of Shares and facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer, including computations of such adjustment and the Warrant Price, Class and number of Shares in effect upon the date of such adjustment.

SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties. The Company represents and warrants to, and agrees with, the Holder as follows:

(a) The initial Warrant Price referenced on the first page of this Warrant is not greater than the price per share at which shares of the Class were last sold and issued prior to the Issue Date hereof in an arms-length transaction in which at least \$500,000 of such shares were sold.

(b) All Shares which may be issued upon the exercise of this Warrant, and all securities, if any, issuable upon conversion of the Shares, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class, common stock and other securities as will be sufficient to permit the exercise in full of this Warrant and the conversion of the Shares into common stock or such other securities.

(c) The Company's capitalization table attached hereto as Schedule 1 is true and complete, in all material respects, as of the Issue Date.

3.2 Notice of Certain Events. If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Class or common stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to the holders of the outstanding shares of the Class any additional shares of any class or series of the Company's stock (other than pursuant to contractual pre-emptive rights);

(c) effect any reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class;

(d) effect an Acquisition or to liquidate, dissolve or wind up; or

(e) effect an IPO;

then, in connection with each such event, the Company shall give Holder:

(1) at least seven (7) Business Days prior written notice of the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any, in respect of the matters referred to in (a) and (b) above;

(2) in the case of the matters referred to in (c) and (d) above at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice); and

(3) with respect to the IPO, at least seven (7) Business Days prior written notice of the date on which the Company proposes to file its registration statement in connection therewith.

Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements; provided, however, that all confidential information received by Holder under this Section 3.2 shall be treated and held by Holder in confidence in accordance with the terms of the confidentiality provisions of the Loan Agreement (regardless of whether the Loan Agreement is then still in force and effect).

SECTION 4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

4.1 Purchase for Own Account. This Warrant and the securities to be acquired upon exercise of this Warrant by Holder are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

4.2 Disclosure of Information. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

4.3 Investment Experience. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

4.4 Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

4.5 The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that this Warrant and the Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

4.6 Market Stand-off Agreement. The Holder agrees that the Shares shall be subject to the Market Standoff provisions in Section 2.11 of that certain Investor Rights Agreement dated September 14, 2018, by and among the Company and the persons and entities listed on Exhibit A thereto, as the same may be amended from time to time, or any similar agreement.

4.7 No Voting Rights. Holder, as a Holder of this Warrant, will not have any voting rights until the exercise of this Warrant.

SECTION 5. MISCELLANEOUS.

5.1 Term and Automatic Conversion Upon Expiration.

(a) Term. Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

5.2 Legends. The Shares (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) shall be imprinted with a legend in substantially the following form (as well as any other applicable legends required by the Company's Certificate of Incorporation or Bylaws, in each case as amended from time to time, or any other agreement by and among the Company and holders of its capital stock to which Holder is a party as of the date of issuance of the Shares):

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE PREFERRED STOCK ISSUED BY THE ISSUER TO SILICON VALLEY BANK DATED SEPTEMBER 30, 2019, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

5.3 Compliance with Securities Laws on Transfer. This Warrant and the Shares issuable upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the

Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to SVB Financial Group (Silicon Valley Bank's parent company) or any other affiliate of Holder, provided that any such transferee is an "accredited investor" as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.

5.4 Transfer Procedure. After receipt by Silicon Valley Bank of the executed Warrant, Silicon Valley Bank will transfer all of this Warrant to its parent company, SVB Financial Group. By its acceptance of this Warrant, SVB Financial Group hereby makes to the Company each of the representations and warranties set forth in Section 4 hereof and agrees to be bound by all of the terms and conditions of this Warrant as if the original Holder hereof. Subject to the provisions of Section 5.3 and upon providing the Company with written notice, SVB Financial Group and any subsequent Holder may transfer all or part of this Warrant or the Shares issuable upon exercise of this Warrant (or the securities issuable directly or indirectly, upon conversion of the Shares, if any) to any transferee, provided, however, in connection with any such transfer, SVB Financial Group or any subsequent Holder will give the Company notice of the portion of the Warrant being transferred with the name, address and taxpayer identification number of the transferee and Holder will surrender this Warrant to the Company for reissuance to the transferee(s) (and Holder if applicable); and provided further, that any subsequent transferee other than SVB Financial Group shall agree in writing with the Company to be bound by all of the terms and conditions of this Warrant. Notwithstanding any contrary provision herein, at all times prior to the IPO, Holder may not, without the Company's prior written consent, transfer this Warrant or any portion hereof, or any Shares issued upon any exercise hereof, or any shares or other securities issued upon any conversion of any Shares issued upon any exercise hereof, to any person or entity who directly competes with the Company, except in connection with an Acquisition of the Company by such a direct competitor.

5.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by facsimile or electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 5.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

SVB Financial Group
Attn: Treasury Department

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address:

ARS PHARMACEUTICALS, INC.
Attn: Richard Lowenthal, Chief Executive Officer

5.6 Waiver. This Warrant and any term hereof may be changed, waived, discharged or terminated (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.7 Attorney's Fees. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.

5.8 Counterparts; Facsimile/Electronic Signatures. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement. Any signature page delivered electronically or by facsimile shall be binding to the same extent as an original signature page with regards to any agreement subject to the terms hereof or any amendment thereto.

5.9 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

5.10 Headings. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

5.11 Business Days. "**Business Day**" is any day that is not a Saturday, Sunday or a day on which Silicon Valley Bank is closed.

[Remainder of page left blank intentionally]
[Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

“COMPANY”

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal
Name: Richard Lowenthal
(Print)
Title: CEO and President

“HOLDER”

SILICON VALLEY BANK

By: /s/ Kristine Rohmer
Name: Kristine Rohmer
(Print)
Title: Vice President

[Signature Page to Warrant to Purchase Stock]

APPENDIX 1

NOTICE OF EXERCISE

1. The undersigned Holder hereby exercises its right to purchase _____ shares of the Common/Series C Preferred [circle one] Stock of **ARS PHARMACEUTICALS, INC.** (the "Company") in accordance with the attached Warrant To Purchase Stock, and tenders payment of the aggregate Warrant Price for such shares as follows:

- check in the amount of \$_____ payable to order of the Company enclosed herewith
 - Wire transfer of immediately available funds to the Company's account
 - Cashless Exercise pursuant to Section 1.2 of the Warrant
 - Other [Describe] _____
2. Please issue a certificate or certificates representing the Shares in the name specified below:

Holder's Name

(Address)

3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Section 4 of the Warrant to Purchase Stock as of the date hereof.

HOLDER:

By: _____

Name: _____

Title: _____

(Date): _____

AMENDMENT TO WARRANT

This Amendment to Warrant (the "Amendment") is made as of December 7, 2020 by and between **SVB FINANCIAL GROUP** ("Holder") and **ARS PHARMACEUTICALS, INC.**, a Delaware corporation ("Company").

RECITALS

A. Company and **SILICON VALLEY BANK** ("SVB") executed a Warrant to Purchase Preferred Stock, dated September 30, 2019, as the same may from time to time be further amended, modified, supplemented or restated together with all schedules and exhibits thereto (the "Warrant"). Pursuant to the terms and conditions in the Warrant, SVB transferred its interest in the Warrant to Holder.

B. Company and Holder wish to amend the Warrant to clarify the vesting schedule pursuant to which the Number of Shares of Common Stock for which the Warrant is exercisable is earned as more fully set forth below.

NOW, THEREFORE, the parties agree as follows:

1. Section 1.7 of the Warrant hereby is amended and restated in its entirety to read as follows:

"1.7 Number of Shares. The number of Shares for which this Warrant is exercisable shall be equal to (i) the Initial Shares, plus (ii) upon the funding of each of the Tranche B Term Loan Advance and Tranche C Term Loan Advance (each as defined in the Loan Agreement), if any, made by Silicon Valley Bank to the Company, a number of Shares equal to (I) the number obtained by multiplying (y) the aggregate principal amount of the applicable Term Loan Advance, by (z) one percent (1.00%), divided by (II) the Warrant Price (any such additional Shares issued pursuant to this sub-clause (ii), the "**Additional Shares**").

2. This Amendment amends certain terms of the Warrant. Company confirms that, except as amended by this Amendment, the Warrant remains in full force and effect. Unless otherwise defined, all terms capitalized in this Amendment shall have the meanings assigned in the Warrant. This Amendment, together with the Warrant, constitutes the entire agreement of the parties with respect to the subject matter hereof, and supersedes all prior agreements and negotiations.

3. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same instrument.

4. Time is of the essence for the performance of all obligations set forth in this Amendment.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the date first written above.

COMPANY:

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal
Name: Richard Lowenthal
Title: CEO and President

HOLDER:

SVB FINANCIAL GROUP

By: /s/ David Busch
Name: David Busch
Title: Sr. Manager, Corporate
Investments & Funding

[Signature Page to Amendment to Warrant]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.**

Confidential

LICENSE AGREEMENT

between

ARS PHARMACEUTICALS, INC.

and

AEGIS THERAPEUTICS, LLC

Effective Date as of June 18, 2018

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "License Agreement") effective as of June 18, 2018 (the "Effective Date"), by and between **AEGIS THERAPEUTICS, LLC**, a California limited liability company ("AEGIS"), and **ARS PHARMACEUTICALS, INC.**, a Delaware corporation ("ARS") and together with "AEGIS," the "Parties").

Recitals

A. AEGIS has rights in certain proprietary technology regarding the chemically synthesizable delivery enhancement and stability agents that, among other things, allow non-invasive systemic delivery of potent peptide, protein, and large molecule drugs.

B. ARS desires to develop and commercialize therapeutic products that utilize such proprietary technology of AEGIS for the delivery of the Compound (as defined in Exhibit A).

C. ARS desires to obtain from AEGIS, and AEGIS is willing to grant to ARS, a license to develop and commercialize such therapeutic products, on the terms and conditions set forth below.

In consideration of the foregoing Recitals and the mutual covenants set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

For purposes of this License Agreement, the terms defined in Exhibit A attached hereto shall have the defined meanings as set forth in Exhibit A, and the terms defined in this License Agreement shall have the corresponding meanings set forth in this License Agreement.

2. REPRESENTATIONS AND WARRANTIES

2.1 Both Parties. Each Party represents and warrants to the other Party as follows:

2.1.1 Organization. Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

2.1.2 Authorization and Enforcement of Obligations. Such Party (a) has the requisite power and authority and the legal right to enter into this License Agreement and to perform its obligations hereunder; and (b) has taken all requisite action on its part to authorize the execution and delivery of this License Agreement and the performance of its obligations hereunder. This License Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

2.1.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by such Party in connection with this License Agreement have been obtained.

2.1.4 No Conflict. The execution and delivery of this License Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies; and (b) do not conflict with, or constitute a default under, any contractual obligation of such Party.

2.2 AEGIS Additional Representations and Warranties. AEGIS hereby represents and warrants to ARS that:

2.2.1 Intellectual Property Matters.

(a) Exhibit B sets forth a true, correct and complete list of all AEGIS Patents Rights existing as of the Effective Date, and for each such patent and patent application AEGIS has identified (i) the owner, (ii) the countries in which such listed item is patented or registered or in which an application for patent or for registration is pending, (iii) the application number, (iv) the patent or registration number, as applicable, (v) the earliest relied upon priority filing date for determination of the expiration date, (vi) the expiration date, as applicable, including any applicable patent term extensions or supplemental protection certificates, and (vii) the due date(s) for any applicable maintenance, annuity or renewal fee.

(b) Each of the patents and patent applications included on Exhibit B properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such patent is issued or such application is pending.

(c) Each person, including without limitation any employee, independent contractor, consultant, or agent of AEGIS, who has or has had any rights in or to each of the patents and patent applications included in the AEGIS Patents Rights has executed an agreement assigning his, her or its entire right, title and interest in and to such AEGIS Patents Rights to the owner thereof as identified on Exhibit B.

(d) To AEGIS' knowledge, each owner and inventor of each of the AEGIS Patents Rights has complied with all applicable duties of candor and good faith in dealing with any patent office, including the duty to disclose to any applicable patent office all information known to be material to patentability.

(e) To AEGIS' knowledge, neither AEGIS nor any third party has undertaken or omitted to undertake any acts, and to its knowledge, no circumstances or grounds exist, that would invalidate, reduce or eliminate, in whole or in part, the enforceability, validity or scope of any of the AEGIS Patents Rights.

(f) AEGIS is the sole and exclusive owner or exclusive licensee of the patents and patent applications listed in Exhibit B, free and clear of all Encumbrances. Subject to the license granted to ARS hereunder, AEGIS has the exclusive right to Exploit the AEGIS Technology, including without limitation any and all patent rights licensed to AEGIS by UAB pursuant to the UAB Agreement, for use with the Compound in the Field in the Territory. AEGIS has the right to grant all rights and licenses it grants to ARS under this License Agreement with respect to the AEGIS Technology, including without limitation any and all patent rights licensed to AEGIS by UAB pursuant to the UAB Agreement.

(g) Other than pursuant to this License Agreement and the Prior Agreements, AEGIS has not assigned, licensed, sublicensed, granted any interest in or options to, nor has AEGIS otherwise entered into any existing agreement with respect to, the AEGIS Technology for use with the Compound in the Field and shall not do so prior to the expiration or termination of this License Agreement.

(h) AEGIS has taken commercially reasonable precautions to protect the secrecy, confidentiality and value of the AEGIS Technology.

(i) As of the Effective Date, to AEGIS' knowledge, the use of the AEGIS Technology in accordance with the terms of this License Agreement does not infringe the intellectual property rights of any third party and does not constitute a misappropriation of the trade secrets or other intellectual property rights of any third party in the Territory.

(j) As of the Effective Date, to AEGIS' knowledge, no third party has interfered with, infringed upon or misappropriated the AEGIS Technology in the Field for use with the Compound.

(k) As of the Effective Date, AEGIS has not been served with notice of any interference action or litigation with respect to the AEGIS Technology nor has AEGIS received any written communication which expressly threatens any interference action, requests that AEGIS obtain a license from any third party or otherwise threatens or contemplates litigation with respect to the AEGIS Technology, whether before any patent and trademark office, court, or any other governmental authority. To AEGIS' knowledge, as of the Effective Date: (i) no such action or litigation has been threatened, and (ii) no event has occurred or circumstance exists that may give rise to or serve as a basis for the commencement of any such action or litigation.

2.2.2 Regulatory Matters.

(a) As of the Effective Date, to AEGIS' knowledge, AEGIS holds, and is operating in compliance with, any and all exceptions, permits, licenses, franchises, authorizations and clearances of the FDA and/or any other governmental authority required in connection with the development to date of the Excipients.

(b) AEGIS has not received any warning letters or written correspondence from the FDA and/or any other governmental authority requiring the termination, suspension or modification of any clinical or pre-clinical studies or tests with respect to the Excipients.

(c) As of the Effective Date, there are no actual or, to AEGIS' knowledge, threatened enforcement actions relating to any Excipient by the FDA or any other governmental authority which has jurisdiction over AEGIS' or any applicable third-party manufacturer's operations or products, including, without limitation, any fines, injunctions civil or criminal penalties, investigations, debarments or suspensions.

(d) AEGIS is not, and to AEGIS' knowledge, no person involved in the performance of AEGIS' or any services under this License Agreement is, debarred or suspended under 21 U.S.C. §335(a) or (b).

2.2.3 Compliance with Laws. As of the Effective Date, to AEGIS' knowledge, AEGIS is in compliance in all respects with all Laws that are applicable to the ownership, operation or use of any of the Excipients or AEGIS Technology. To AEGIS' knowledge, there are no events, conditions, circumstances, activities, practices, incidents or actions of AEGIS relating to the AEGIS Technology that would interfere with or prevent compliance with or give rise to any liabilities or investigative, corrective or remedial obligations with respect to the AEGIS Technology under applicable Laws.

2.2.4 Supply Matters. Any Excipients supplied by AEGIS will be done so in accordance with the Supply Agreement.

2.2.5 UAB Licensing Agreement. The UAB Licensing Agreement is a legal and valid obligation binding upon the parties thereto and enforceable in accordance with its terms. Attached hereto as Exhibit C is a true and correct copy of the UAB Licensing Agreement, with the financial terms and sponsored research terms redacted. No provisions of the UAB Licensing Agreement or any other agreement with any third party restrict or limit AEGIS' right to grant ARS the rights and licenses granted by AEGIS to ARS in this License Agreement. AEGIS has not received any notice of default, and is not in default, of any of its obligations under the UAB Licensing Agreement, and no circumstances or grounds

exist that would reasonably be expected to give rise to a claim of material breach or right of rescission, termination, revision, or amendment of the UAB Licensing Agreement. To AEGIS' knowledge, UAB is not in default, of any of its obligations under the UAB Licensing Agreement. AEGIS has obtained all required consents from UAB for it to grant to ARS the rights and licenses granted by AEGIS hereunder.

2.3 Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 2, AEGIS MAKES NO REPRESENTATIONS OR WARRANTIES IN THIS LICENSE AGREEMENT, EXPRESS OR IMPLIED, REGARDING THE AEGIS TECHNOLOGY, INCLUDING WITHOUT LIMITATION ANY REPRESENTATION OR WARRANTY REGARDING VALIDITY, ENFORCEABILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT, AND ALL RIGHTS IN THE AEGIS TECHNOLOGY PROVIDED TO MOTIF HEREUNDER ARE PROVIDED "AS IS."

3. LICENSE GRANTS; SUBLICENSING AND SUBCONTRACTING

3.1 AEGIS Technology. AEGIS hereby grants to ARS an exclusive (even as against AEGIS except for use pursuant to and in accordance with the Supply Agreement), sublicensable (as set forth in Section 3.2), worldwide license, under the AEGIS Technology, to Exploit Compound(s) and Product(s) in the Field.

3.2 Sublicenses. ARS shall have the right to grant sublicenses under any portion or all of the license set forth in Section 3.1 to one or more Affiliates and/or third parties without the prior written consent of AEGIS. ARS shall give AEGIS prompt written notice of each sublicense under this License Agreement, and shall deliver a copy of each sublicense to AEGIS within [***] after execution of the same. Each sublicense shall be subject to the applicable terms and conditions of this License Agreement, including an obligation on the sublicensee to file royalty reports to ARS, which reports shall be subject to audit by ARS (but not AEGIS). ARS agrees to audit such sublicensees at AEGIS' reasonable request; provided that the timing and scope of any such audit are consistent with ARS's business practices and such requests by AEGIS shall not exceed [***] request per [***]. ARS shall remain liable to AEGIS for sublicensee's exercise of any of ARS's rights and sublicensee's performance of ARS's obligations under this License Agreement, including, but not limited to, payment of royalties, keeping of records and reporting of sales as if the sublicensee's sales were ARS's sales. For purposes of clarity, the right to "have manufactured" and to "have sold" shall not be considered to be a sublicense under this License Agreement.

3.3 Manufacture; Right of Reference.

3.3.1 Except as set forth in this Section 3.3 or the Supply Agreement, notwithstanding the license granted under Section 3.1 to manufacture Excipients, ARS hereby covenants and agrees to not exercise such right to make or have made Excipients except as specified in the Supply Agreement. If and when ARS becomes entitled to manufacture the Excipients, as specified in the Supply Agreement, AEGIS shall provide reasonable assistance to ARS to facilitate the disclosure and transfer of copies of any AEGIS Know-How Rights or other technology reasonably required to permit ARS or any such contract manufacturer to manufacture Excipients.

3.3.2 ARS shall have the right to reference the AEGIS Data in connection with the Exploitation of Product(s), including without limitation the applicable drug master files pertaining to the Excipients. Such right shall extend to any contract manufacturer engaged by ARS, any of its Affiliates and/or any sublicensees to manufacture Excipients. As requested by ARS, AEGIS shall provide a letter of authorization to the FDA authorizing the FDA to access AEGIS' drug master files exclusively for submissions associated with the Product(s).

3.4 Contract Research.

3.4.1 The license granted under Section 3.1 to conduct research and to develop Products shall automatically extend to any contract research organization and/or contract analytical organization engaged by ARS, any of its Affiliates and/or any sublicensee in connection with research and development efforts for the Products. At ARS's request, AEGIS shall provide reasonable assistance to ARS to facilitate the disclosure and transfer of copies of any AEGIS Know-How Rights or other technology reasonably required to permit any such contract research organization and/or contract analytical organization to conduct research and development efforts for the Products, [***].

3.4.2 In the event that ARS desires to engage a contract research organization in connection with its research and development efforts, if any, solely related to the Excipients, ARS agrees to provide a request for quotation of services to UAB at the same time as when providing such requests to other potential service providers. Such request shall allow for a commercially reasonable period of time to provide a response from all potential contractors. The Parties understand and agree that ARS shall have no obligation to utilize the services of UAB or any other party and that this Section 3.4.2 shall not apply to the development of the Product or any other development matters not related solely to the Excipients.

3.5 Exclusivity; Non-Competition.

3.5.1 Until the expiration of the Royalty Term in each country in the Territory, neither AEGIS nor any of its Affiliates shall, directly or indirectly (including without limitation by selling, offering for sale, licensing, offering for license, agreeing to sell or license, divesting or transferring rights, including without limitation any AEGIS Technology, to any third party) engage in any activities or participate in any business or otherwise compete with ARS anywhere in the Territory with respect to the Exploitation of any therapeutic containing the same active pharmaceutical ingredient, derivative or active metabolite as any Product without the prior written consent of ARS.

3.5.2 Each of the Parties recognizes that the restrictions contained in, and the terms of, this Section 3.5 are properly required for the adequate protection of the license set forth in Section 3.1 and ARS's rights under this License Agreement, and agree that if any provision in this Section 3.5 is determined by any court to be unenforceable by reason of its extending for too great a period of time or over too great a geographic area, or by reason of its being too extensive in any other respect, such covenant shall be interpreted to extend only for the longest period of time and over the greatest geographic area, and to otherwise have the broadest application as shall be enforceable.

3.6 Technology Disclosure; Assistance. Within [***] after the Effective Date, AEGIS shall deliver, at [***], to ARS, or provide ARS with copies of, (a) the AEGIS Know- How Rights, consisting of (i) copies of any publications related to the application of Excipients, including without limitation the Excipient known as Intravail®, (ii) basic formulation ingredients, concentration data, formulation protocols, etc., (iii) access to all toxicology and safety information relating to Excipients, including without limitation the Excipient known as Intravail® (excluding third party confidential information), and (iv) access to the drug master file(s) (excluding the CMC portion and third party confidential information) pertaining to the Excipients; and (b) all AEGIS Patent Rights and all relevant material information related thereto available to AEGIS. Additionally, at such time in the future during the term of this License Agreement if AEGIS or its Affiliates acquires additional AEGIS Technology which AEGIS reasonably believes to be necessary or useful for ARS to Exploit the Product, Aegis shall [***] disclose the same to ARS, together with the material information and documents concerning the same which are available to Aegis. At ARS's request [***], throughout the term of this License Agreement, Aegis shall provide reasonable assistance to ARS to facilitate the disclosure and transfer of copies of any Aegis Data, Aegis Know-How Rights, or other technology reasonably required to permit ARS to Exploit the Excipients for the Product(s), including without limitation to permit ARS or any sublicensee or contract manufacturer of ARS to develop and/or manufacture Excipients for purposes of manufacturing Product(s) if and when permitted in accordance with Section 3.3, but subject to the limitation of Section 3.1.

3.7 Diligence Efforts.

3.7.1 ARS shall use Commercially Reasonable Efforts (defined below) to obtain regulatory approval for the Product and to thereafter maximize sales of the Product in the Territory.

3.7.2 The term “Commercially Reasonable Efforts” shall mean that [***].

3.7.3 In the event ARS does not (directly or with or through any of its Affiliates or sublicensees) use Commercially Reasonable Efforts to Exploit a Product, then AEGIS will have the right to terminate the License with respect to such Product as provided in this Section 3.7.3, and such termination shall be the sole remedy for such failure. Said termination will occur upon AEGIS delivering to ARS a written notice of termination, unless ARS responds within [***] after receipt of said notice with evidence which demonstrates that ARS (or any of its Affiliates or sublicensees) is using Commercially Reasonable Efforts to Exploit a Product.

i) If there is a dispute between the Parties regarding whether ARS (or any of its Affiliates or sublicensees) is using Commercially Reasonable Efforts to Exploit a Product, the dispute resolution procedures pursuant to Section 10.2 shall apply and no termination will occur unless and until it is finally determined pursuant to such procedures that ARS has not (directly or with or through any of its Affiliates or sublicensees) used Commercially Reasonable Efforts to Exploit such Product. In the event that it is finally determined pursuant to such procedures that ARS has not (directly or with or through any of its Affiliates or sublicensees) used Commercially Reasonable Efforts to Exploit such Product, then AEGIS shall not have the right to terminate the License for such Product if ARS puts in place and begins implementation of a commercially reasonable plan, mutually agreed to by the Parties, for compliance with its obligation to use Commercially Reasonable Efforts to Exploit such Product within [***] after such final determination.

ii) If AEGIS terminates the License granted with respect to a Product as permitted by Section 3.7.3, ARS shall assign and transfer exclusively to AEGIS (even as to ARS) all data and intellectual property and any Joint Patent Rights owned by ARS that relate solely to such Product, [***]. AEGIS' rights to terminate the License under this Section 3.7.3 shall not begin until [***] after the Effective Date.

iii) In the event the License Agreement has been terminated and ARS has assigned and transferred exclusively to AEGIS all data and intellectual property and any Joint Patent Rights owned by ARS that relate solely to such Product, including but not limited to all preclinical and clinical data, related protocols and all rights to any and all patents and patent applications specific to the Product, then AEGIS shall agree to pay to ARS an amount equal to [***] of the net proceeds from any royalties or other amounts that AEGIS receives from third party licensees on net sales of the Product up to [***] of the actual documented third party development costs incurred by ARS specific to the development of the Product.

3.8 Research and Development Plans and Reports.

3.8.1 During the term of this License Agreement and subject to third party confidentiality, AEGIS may offer its recommendations to ARS for development as to any ways which may be more effective for utilizing the Excipient(s). For avoidance of doubt, neither party shall have any legally binding obligations or liabilities concerning the foregoing recommendations.

3.8.2 Within [***] following the end of each Calendar Year during the term of this License Agreement, ARS shall prepare and deliver to AEGIS a written report which shall describe, in reasonable detail, ARS's efforts and results for researching and developing Products during such Calendar Year.

3.8.3 The plans and report and contents thereof shall be owned exclusively by ARS. AEGIS shall treat the foregoing plans and reports and their contents as Confidential Information of ARS consistent with Section 7.

3.8.4 ARS shall furnish to AEGIS a copy of all clinical protocol(s) and the related patient informed consent form for any clinical trial study, which involves an Excipient or the AEGIS Technology; and AEGIS shall be entitled to share such documents with the AEGIS insurance carriers to the extent required to comply with its contractual obligations to such entities. AEGIS agrees that any personally identifiable information or protected health information, which comes into AEGIS' possession under this License Agreement will be protected and acted on in accordance with applicable data protection legislation, such as the Health Insurance Portability and Accountability Act of 1996 as well as all other applicable laws and regulations."

3.9 Excipient Toxicity Studies. In the event that ARS conducts any toxicity studies solely related to the Excipient or the Material, in whole or in part, (the "Material Tox Studies"), ARS agrees to provide to AEGIS a draft copy of the intended protocol(s) to be used for such Material Tox Studies; and ARS will give due considerations to any recommendations which AEGIS may give for improving the protocol(s) for the Material Tox Studies. ARS agrees to provide any data arising from the Material Tox Studies ("Material Tox Data") to AEGIS within [***] after ARS receives the Material Tox Data. AEGIS may include in its Drug Master File(s) ("DMF") for the Excipient such portions of or information from the Material Tox Data as is required or appropriate for inclusion in its DMF and may provide copies of such Material Tox Data to its licensees, provided that prior to sharing with any third party, AEGIS and ARS shall redact all ARS Confidential Information including all references to ARS, the Product and/or the Compound; provided however that the Material Tox Data added to the DMF shall not be redacted.

4. **PAYMENTS**

4.1 License Issuance Fee.

4.1.1 As partial consideration for the grant to ARS of the License, ARS shall pay to AEGIS a one-time, nonrefundable and noncreditable license fee of Fifty Thousand U.S. dollars (U.S. \$50,000) upon the Effective Date which shall be paid by ARS to Aegis payable in cash and due on or before June 30, 2018.

4.1.2 Aegis may, but shall not be obligated, to provide ARS with invoices for the above Section 4.1.1 payments, which failure by Aegis to provide ARS with invoices shall not change when any such payment is due. ARS'S failure to make any payment when due shall constitute a breach and AEGIS shall have the right at its option to terminate this License Agreement, subject to any cure provisions, pursuant to Section 9.2.1.

4.2 Regulatory Milestone Payments.

4.2.1 As partial consideration for the grant to ARS of the rights under Section 3.1 the Parties agree to the following payments within [***] of the Milestone event:

<u>Milestone</u>	<u>Amount</u> <u>U.S. Dollars</u>
Successful Completion of NDA enabling PK Study or its equivalent	\$ 450,000
Acceptance of the NDA filing or its equivalent	\$1,000,000
Approval of the first NDA or its equivalent	\$2,500,000

4.2.2 At the time when any milestone payment listed in the table above is due, if ARS has not paid all other milestone payments (if any) previously listed in such table, then at such time ARS shall pay all such unpaid previous milestone payments.

4.2.3 The term "Successful Completion" shall mean [***].

4.3 Commercialization Milestones. As partial consideration for the grant to ARS of the rights under Section 3.1, the following milestone payments will be paid, on a Product-by-Product basis. For Annual Net Sales milestones, the first time in the first Calendar Year that the total aggregate Net Sales of the applicable Product in a Calendar Year by ARS, its Affiliates and its sublicensees in the Territory reach the amounts set forth in the table in this Section 4.3, below. Within [***] following the achievement of each of the following milestones, ARS shall give written notice to AEGIS thereof and shall pay to AEGIS the corresponding one time only milestone payments described below.

<u>Milestone</u>	<u>Amount</u> <u>U.S. Dollars</u>
First commercial sale of the first Product	\$5,000,000
[***]	\$ [***]
[***]	\$ [***]

4.4 Royalties.

4.4.1 Within [***] following the First Commercial Sale of a Product in each country in the Territory, ARS shall give written notice to AEGIS thereof.

4.4.2 As partial consideration for the grant to ARS of the rights under Section 3.1, during the applicable Royalty Term, ARS shall pay to AEGIS royalties on Annual Net Sales of Products, on a country-by-country and Product-by-Product basis in accordance with this Section 4.4, in an amount equal to the applicable rate set forth in the table in this Section 4.4.2, below, times the Annual Net Sales of Products by ARS, its sublicensees and their respective Affiliates, subject to the applicable reductions as set forth in Sections 4.4.3 through 4.4.6; but in no event will the royalty rate be reduced pursuant to Sections 4.4.3 through 4.4.6 by more than [***] (although any such unused reduction sum will be carried forward and applied against future payments).

4.4.3 The royalty percentage then applicable under this Section 4.4 to Net Sales of any Product made in any country in the Territory shall be reduced by [***] from [***] to [***] if at the time of the sale of such Product in such country, the use, manufacture, offer for sale, sale and import of such Product in such county is not covered by a Valid Claim.

4.4.4 The royalty percentage then applicable to Net Sales of any Product made in any country in the Territory shall be further reduced by [***] from that in Section 4.4.3 from [***] to [***], if, at the time of the sale of such Product in such country, there are Competing Products that collectively account for [***] or more of all sales across all indications for which the Products are marketed in that country. In the event that Competing Products in any country no longer collectively account for [***] or more of all sales across all indications for which the Products are marketed in that country, then such [***] reduction shall be suspended.

The term “Competing Product” shall mean [***].

4.4.5 If the level of competition, patent protection or the general commercial environment for such Product in such country materially affect the commercial viability of such Product in such country at the royalty rate then applicable under this Section 4.4, then AEGIS shall, upon written notice by ARS, negotiate and agree with ARS in good faith a reduction of such royalty rates, as applicable to such Product in such country.

4.4.6 Third Party Licenses.

(a) If ARS determines, in its reasonable judgment (subject to subpart b below), that the intellectual property rights of a third party are necessary for the practice of any AEGIS Technology in accordance with this License Agreement, then the royalty and milestone amounts owed to AEGIS hereunder for Exploiting the AEGIS Technology in the country (or countries) where such third party intellectual property rights are enforceable shall be subject to a credit reduction in an amount equal to [***] of the amount of any payments that ARS (or any of its sublicensees) pays such third party to use such third party intellectual property rights; provided, no payment to AEGIS shall be reduced by more than [***] of the amount payable before any reductions or credits (although any unused excess credit may be carried forward and applied against future payments).

(b) If AEGIS disputes ARS’s determination under Section 4.4.6(a) that the technology, and/or a license to intellectual property rights, of such third party is necessary for the practice of any AEGIS Technology in accordance with this License Agreement, AEGIS may submit such dispute to an independent third party arbiter, mutually agreed to by the Parties, such agreement not to be unreasonably withheld, delayed, or conditioned, and such arbiter to have at least [***] experience in the biopharmaceutical industry overseeing drug development or patent law, who shall determine within [***] whether, in the absence of rights granted by such third party, the practice of any AEGIS Technology in accordance with this License Agreement would likely or actually infringe or misappropriate such third party’s intellectual property. Such arbiter’s determination shall be final and binding on the Parties, and any dispute with respect to such arbiter’s determination shall not be submitted for resolution pursuant to Section 10.2. Additionally, any determination of likely or actual infringement shall be deemed a determination that such license to intellectual property rights of a third party is “necessary” for purposes of Section 4.4.6(a).

4.4.7 ARS, its sublicensees or their respective Affiliates shall not intentionally sell any Product to a third party at a discount in order to induce the same third party to purchase any other products or services.

4.5 Royalty Reports.

4.5.1 After the First Commercial Sale of the first Product, ARS shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales, and to enable the royalties payable to AEGIS under Section 4.4 to be determined.

4.5.2 Within [***] after the end of each Calendar Quarter during the term of this License Agreement following the First Commercial Sale of the first Product by ARS, its sublicensees or their respective Affiliates, ARS shall furnish to AEGIS a written report showing in reasonably specific detail, on a country-by-country and Product-by-Product basis, (a) the gross sales of Products sold by ARS, its Affiliates and sublicensees during such Calendar Quarter and the calculation of Net Sales from such gross sales; (b) the calculation of the royalties which shall have accrued based upon such Net Sales; (c) the withholding taxes, if any, required by law to be deducted with respect to such Net Sales; and (d) the exchange rates, if any, used in determining the amount of U.S. dollars.

4.5.3 All royalties shown to have accrued by each royalty report provided under this Section 4.5 shall be payable on the date such royalty report is due. Payment of royalties in whole or in part may be made in advance of such due date.

4.6 Audits.

4.6.1 Upon the written request of AEGIS and not more than [***] in each Calendar Year, ARS shall permit an independent certified public accounting firm of nationally recognized standing, selected by AEGIS and reasonably acceptable to ARS, [***], to have access during normal business hours to such of the records of ARS as may be reasonably necessary to verify the accuracy of the royalty reports under Section 4.5 for any year ending not more than [***] prior to the date of such request. The accounting firm shall be required to sign a confidentiality agreement for the benefit of, and in a form reasonably acceptable to, ARS, and shall disclose to AEGIS and ARS only whether the reports are correct or not and the specific details concerning any discrepancies. No other information shall be shared.

4.6.2 If such accounting firm concludes that additional royalties were owed during the audited period, ARS shall pay such additional royalties within [***] after the date AEGIS delivers to ARS such accounting firm's written report so concluding. If such accounting firm concludes that ARS has overpaid royalties during the audited period, ARS shall have the right to credit the amount of the overpayment against each subsequent quarterly payment due to AEGIS until the overpayment has been fully applied to pay such additional royalties. If the overpayment is not fully applied prior to the final quarterly payment of royalties due hereunder, AEGIS shall [***] refund to ARS an amount equal to any remaining overpayment. The fees charged by such accounting firm shall be paid by AEGIS; provided, however, if the audit discloses that the royalties payable by ARS for such period are more than [***] of the royalties actually paid for such period, then [***] shall pay the reasonable fees and expenses charged by such accounting firm.

4.6.3 ARS shall include in each permitted sublicense granted by it pursuant to the License Agreement a provision requiring the sublicensee to make reports to ARS, and to keep and maintain records of sales made pursuant to such sublicense, and to permit audits by ARS of such records. ARS shall grant access to such reports by AEGIS' independent accountant as set forth in Section 4.6.1.

4.6.4 AEGIS shall treat all financial information subject to review under this Section 4.5 as Confidential Information of ARS consistent with Section 7, and shall cause its accounting firm to retain all such financial information in confidence.

4.7 Payment Method. All payments owed under this License Agreement shall be paid in United States Dollars in immediately available funds and shall be made by wire transfer from a United States bank located in the United States to such bank account as designated from time to time by AEGIS to ARS. For the purposes of computing Net Sales of Products commercialized by ARS that are sold in a currency other than U.S. dollars, such currency shall be converted into U.S. dollars as calculated at the actual average rates of exchange for the pertinent month as reported in the Wall Street Journal, or at such other exchange ratio as the Parties may mutually approve in writing.

4.8 Taxes and Duties. If ARS is required to withhold any tax to the tax or revenue authorities in any country regarding any payment to AEGIS due to the applicable laws of such country, such amount shall be deducted from the payment to be made by ARS, and ARS shall promptly notify AEGIS of such withholding. Within a reasonable amount of time after making such deduction, ARS shall furnish AEGIS with copies of any documentation evidencing such withholding and the related payment by ARS to the applicable tax authority. Each Party agrees to cooperate with the other in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect, and in obtaining papers from or filing papers with the applicable tax authority. [***].

5. OWNERSHIP AND RIGHTS FOR DATA AND TECHNOLOGY

5.1 AEGIS Technology. Subject to the rights and licenses specified in this License Agreement, AEGIS shall solely own all right title and interest in the AEGIS Data, AEGIS Inventions, AEGIS Know-How Rights, and AEGIS Patent Rights.

5.2 ARS Technology. Subject to the rights and licenses specified in this License Agreement, ARS shall solely own all right title and interest in the ARS Data, ARS Inventions, ARS Know-How Rights, and ARS Patent Rights.

5.3 Inventorship. Inventorship of Inventions shall be determined in accordance with U.S. patent laws (Title 35, United States Code), and, except as expressly provided otherwise in Section 5.4, 5.5 or 5.6, the inventor of an invention (whether Aegis, ARS, or Aegis and ARS jointly) shall be the owner of such Inventions and any patent rights and other intellectual property rights in and to such Inventions. AEGIS personnel have executed, or will be caused to execute, agreements requiring such personnel to assign to AEGIS all Inventions made by such personnel, and ARS personnel have executed, or will be caused to execute, agreements requiring such personnel to assign to ARS all Inventions made by such personnel.

5.4 Inventions Related to the Compound.

5.4.1 Ownership. As between AEGIS and ARS, ARS is the owner of all right, title and interest in and to the Compound, which shall be included in ARS Technology, and all existing patents and patent applications ("ARS Patents") and:

(a) AEGIS shall not (and shall not attempt or purport to) file or prosecute in any country any patent application which claims or uses or purports to claim or use solely the Compound or the Product, or any information or other materials directly or indirectly derived therefrom, without the prior express written consent of ARS.

(b) If there is an Invention related solely to Compound made or conceived by employees, consultants, agents and others conducting work on behalf of AEGIS or its Affiliate, whether alone or jointly with one or more employees, consultants, agents and others conducting work on behalf of ARS, AEGIS agrees to [***] disclose such invention to ARS and supply ARS with a copy of the disclosure for ARS'S evaluation purposes. ARS shall have the sole right to determine what, if any, patent applications should be filed on such Invention. AEGIS hereby assigns to ARS all right, title and interest in any such Inventions and shall execute, and require its and its Affiliates personnel and contractors to execute, any documents reasonably required to confirm ARS's ownership of such Inventions, and any documents required to apply for, maintain and enforce any patent rights in such Inventions.

(c) Any new Invention claiming Compounds and/or ARS Technology, and not claiming Excipients or Products or Aegis Technology, that is invented in whole or in part by ARS, regardless of whether it may be commercially useful, shall be owned solely by ARS. Nothing herein shall affect the right of ARS to invent and seek intellectual property protection for inventions that do not claim AEGIS Technology. ARS shall obtain Aegis' prior written approval, which shall not be unreasonably withheld, conditioned or delayed, to the disclosure of the Excipient as a known excipient, and to the disclosure and use of information from studies involving the Excipient or Product, in the specification of any ARS Patent (which pursuant to Section 5.5.1 shall not claim or purport to claim the Excipient, and pursuant 5.6 shall not claim or purport to claim a Joint Invention).

5.4.2 No Implied License. This License Agreement shall not grant any license or other rights to AEGIS in any patent rights or other intellectual property rights of ARS, and no rights are provided to AEGIS under any patents, patent applications, trade secrets or other proprietary rights of ARS. In particular, no rights are provided to use the Compound and any patents or intellectual property of any kind to AEGIS for profit-making, commercial or research purposes, including but not limited to sale of the Compound, use in manufacturing, provision of a service to a third party in exchange for consideration, or use in research or consulting by a commercial or not for-profit entity.

5.5 Inventions Related to the Excipient.

5.5.1 Ownership. As between AEGIS and ARS, AEGIS is the owner of all right, title and interest in and to the Excipient, which shall be included in AEGIS Technology and all existing patents and patent applications ("AEGIS Patents") and;

(a) ARS shall not (and shall not attempt or purport to) file or prosecute in any country any patent application which, discloses claims or uses or purports to claim or use the Excipient, or any information or other materials directly or indirectly derived therefrom without the prior express written consent of AEGIS.

(b) If there is an Invention related to Excipient made or conceived by employees, consultants, agents and others conducting work on behalf of ARS, whether alone or jointly with one or more employees, consultants, agents and others conducting work on behalf of AEGIS, ARS agrees to promptly disclose such invention to AEGIS and supply AEGIS with a copy of the disclosure for AEGIS' evaluation purposes. AEGIS shall have the sole right to determine what, if any, patent applications should be filed on such Invention. ARS hereby assigns to AEGIS all right, title and interest in any such Inventions and shall execute, and require its and its Affiliates personnel and contractors to execute, any documents reasonably required to confirm AEGIS' ownership of such Inventions, and any documents required to apply for, maintain and enforce any patent rights in such Inventions. For the avoidance of doubt, such Inventions shall be AEGIS Technology and be subject to the terms of the License.

5.5.2 No Implied License. Except for the License, this License Agreement shall not be construed to grant any license or other rights to ARS in the AEGIS Technology (other than Joint Inventions and Joint Patent Rights).

5.6 Joint Inventions. “Joint Invention” shall mean: (a) any Invention that embodies or claims a Product, including without limitation any invention relating to the use of Excipient for administering or stabilizing such Compound or any application of Excipient related to such Compound or Product; or (b) any Invention that is (i) made or conceived jointly by one or more employees, consultants, agents and others conducting work on behalf of AEGIS and one or more employees, consultants, agents and others conducting work on behalf of ARS in connection with the performance of, and during the term of, this License Agreement and/or the Supply Agreement and/or any of the Prior Agreements and (ii) is not an Invention subject to the provisions of Section 5.4.1 or Section 5.5.1 shall be a “Joint Invention”. As between AEGIS and ARS, AEGIS shall be the owner of the Joint Inventions.

5.7 Invention Rights and Obligations. In the event that any patent application(s) to one or more Invention(s) recites embodiments including an Excipient and/or Product, and claims to such embodiments can be pursued reasonably and in good faith, they will be pursued in good faith by the Party taking responsibility for prosecution. In the fulfilment of their obligations under Sections 5.4.1(b), 5.5.1(b), and 5.6, the Parties agree to disclose such Inventions to each other, and to cooperate in the preparation and prosecution of such applications pursuant to Sections 6.1 6.2 and 6.3. However, the Parties acknowledge that Inventions may be made which do not necessarily rely upon the Excipient, but in which we are nevertheless obligated to disclose the inclusion of embodiments reciting an Excipient and/or Product, and/or may disclose data from studies which involved a Product; and the parties acknowledge that patent applications may be filed upon such Inventions which would support both claims reciting Products included in an application containing claims not reciting Products.

For the avoidance of doubt, Inventions wherein disclosure of data from studies which involved a Product are used to support claims that do not recite a Product or Excipient, they will be ARS Technology; the mention of an Excipient in the specification of an application does not make an Invention a Joint Invention or Aegis Technology; however the mention of an Excipient in a claim does make an Invention a Joint Invention or Aegis Technology. However, ARS covenants to pursue claims reciting embodiments including an Excipient and/or Product in good faith, if claims to such embodiments can be pursued reasonably and in good faith by either Party, either in the first application or one or more continuing applications. When such claims are presented in an application, ARS agrees that such application will be owned by Aegis and Aegis may at its option assume primary responsibility for prosecution of the application. If ARS decides, in good faith and at its sole discretion, not to pursue such claims, Aegis shall have the option to pursue such claims at its own expense.

6. PATENT RIGHTS

6.1 Prosecution and Maintenance of AEGIS Patent Rights.

6.1.1 AEGIS shall have the sole right (but not the obligation), [***] to prepare, file, prosecute and maintain the AEGIS Patent Rights. AEGIS shall give ARS a reasonable opportunity, before filing, to review and comment on the text of any patent application within the AEGIS Patent Rights that covers the Product and shall provide ARS with a copy of such patent application as filed, together with notice of its filing date and serial number. ARS shall, [***] cooperate with AEGIS, execute all lawful papers and instruments and make all rightful oaths and declarations as may be necessary in the preparation, prosecution and maintenance of the AEGIS Patent Rights.

6.1.2 To the extent reasonably expected to adversely affect the AEGIS Patent Rights or the Product, AEGIS shall [***] provide ARS with copies of correspondence or materials received from the PCT, the U.S. Patent & Trademark Office, or equivalent intellectual property regulatory authority in any other country.

6.1.3 If ARS reasonably believes that AEGIS may fail to make any required payments or take any action required for the preparation, filing, prosecution, defense or maintenance of the AEGIS Patent Rights within a reasonable time, ARS shall provide AEGIS with written notice of such deficiency. If AEGIS fails to take any action required for the preparation, filing, prosecution, defense or maintenance of the AEGIS Patent Rights within the shorter of (i) [***] of notice from ARS or (ii) [***] before the deadline for taking such action, ARS shall have the right to thereafter make any such required payments or take any such required action, and deduct and offset such payments and any related costs and expenses from any milestone payments, royalties or other payments which may be required under this License Agreement or otherwise by ARS, its Affiliates or sublicensees to AEGIS.

6.1.4 ARS shall reimburse AEGIS for actual costs incurred by AEGIS under the AEGIS Patent Rights that are specific only to the Compound(s) and/or Product(s), including but not limited to all divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patents and patent applications.

6.2 Prosecution and Maintenance of ARS Patent Rights. ARS shall have the sole right (but not the obligation), [***] to prepare, file, prosecute and maintain the ARS Patent Rights. [***] AEGIS shall cooperate with ARS, execute all lawful papers and instruments and make all rightful oaths and declarations as may be necessary in the preparation, prosecution and maintenance of the ARS Patent Rights.

6.3 Orange Book Listings. ARS shall have the sole right (but not the obligation) to list any appropriate patents within the AEGIS Patent Rights, Joint Patent Rights, and ARS Patent Rights in the FDA Orange Book with respect to any Product.

6.4 Enforcement.

6.4.1 Notification. Each Party shall notify the other Party of any infringement known to such Party of any AEGIS Patent Rights, ARS Patent Rights, or Joint Patent Rights for any Product for use in the Field and shall provide the other party with the available evidence, if any, of such infringement.

6.4.2 Paragraph IV Claims. Except to the extent otherwise agreed by the Parties in writing, the costs for any patent infringement litigation suit based on a Paragraph IV certification or any equivalent action outside the United States (i.e., an ANDA patent infringement litigation involving a patent listed pursuant to 21 U.S.C. Section 355(a)(2)(A)(iv)) involving the AEGIS Patent Rights, Joint Patent Rights or ARS Patent Right (to the extent covering a Product), brought by a third party where ARS is a named defendant, or by ARS where ARS is a named plaintiff, in both cases irrespective of whether AEGIS is also named as a defendant or plaintiff (a "Paragraph IV Claim"), [***]. ARS shall have sole right to institute, prosecute and control such litigation. AEGIS shall cooperate fully in such litigation, and in the case where ARS desires to bring such litigation, at ARS's request, AEGIS agrees to join any such litigation to enforce the AEGIS Patent Rights or Joint Patent Rights against the third party or parties that made such Paragraph IV certification. AEGIS shall have the right to approve any settlement that would adversely affect the AEGIS Patent Rights or AEGIS's rights under this License Agreement or result in any liability or admission on behalf of AEGIS, such approval not to be unreasonably withheld, conditioned or delayed. Any recovery realized as a result of such litigation shall be first applied to the prorata reimbursement of any reasonable litigation expenses of ARS and AEGIS under this Section 6.4.2. Any remaining recovery realized from litigation brought pursuant to this Section 6.4.2 shall be treated as profits on sales of Products for purposes of determining Net Sales under this License Agreement, with AEGIS receiving the applicable royalty for purposes of Section 4.4 on such deemed Net Sales, and ARS receiving the remainder. [***].

6.4.3 AEGIS Patent Rights. Except as set forth in Section 6.4.2, AEGIS, [***] shall have the right to determine the appropriate course of action to enforce the AEGIS Patent Rights or otherwise abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the AEGIS Patent Rights, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the AEGIS Patent Rights, and shall consider, in good faith, the interests of ARS in so doing. If AEGIS does not, within [***] after receipt of any notice from ARS under Section 6.4.1, either abate the infringement of the AEGIS Patent Rights for any Product in the Field or file suit to enforce the AEGIS Patent Rights against at least one infringing party, or, to the extent UAB has the first right to do so pursuant to the UAB Licensing Agreement, cause UAB to do so, ARS shall have the right, upon prior written notice to AEGIS, to take whatever action it deems appropriate to enforce the AEGIS Patent Rights for any Product in the Field; provided, however, that, within [***] after receipt of notice of ARS's intent to file such suit, AEGIS shall have the right to either (a) join such suit as a co-plaintiff or co-defendant with ARS and to fund up to [***] the costs of such suit or (b) request that ARS not take any such action or file such suit, and, if ARS informs AEGIS that it intends to take such action or file such suit, AEGIS may submit such dispute to an independent third party arbiter, mutually agreed to by the Parties, with at least [***] experience in patent law, who shall determine within [***] whether taking such action or filing such suit would have a reasonable likelihood of successfully enforcing patent rights covering Product(s) and/or Excipient(s) used in Product(s). Such arbiter's determination shall be final and binding on the Parties, and any dispute with respect to such arbiter's determination shall not be submitted for resolution pursuant to Section 10.2.

6.4.4 Joint Patent Rights.

(a) ARS, [***] shall have the right to determine the appropriate course of action to enforce any Joint Patent Rights that claim Compound(s), Product(s), and/or Excipient(s) used in Product(s) or otherwise abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce such Joint Patent Rights, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to such Joint Patent Rights, and shall consider, in good faith, the interests of AEGIS in so doing. If ARS does not, within [***] after receipt of any notice from AEGIS under Section 6.4.1, either abate the infringement of such Joint Patent Rights or file suit to enforce such Joint Patent Rights against at least one infringing party, AEGIS shall have the right, upon prior written notice to ARS, to take whatever action it deems appropriate to enforce such Joint Patent Rights; provided, however, that, within [***] after receipt of notice of AEGIS' intent to file such suit, ARS shall have the right to join such suit as a co-plaintiff or co-defendant with AEGIS and to fund up to [***] the costs of such suit.

(b) AEGIS [***] shall have the right to determine the appropriate course of action to enforce the Joint Patent Rights that claims Excipient(s), and do not claim Compound(s), Product(s), and/or Excipient(s) used in Product(s), or otherwise abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce such Joint Patent Rights, to control

any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to such Joint Patent Rights, and shall consider, in good faith, the interests of ARS in so doing. If AEGIS does not, within [***] after receipt of any notice from ARS under Section 6.4.1, abate the infringement of such Joint Patent Rights or file suit to enforce such Joint Patent Rights against at least one infringing party, ARS shall have the right, upon prior written notice to AEGIS, to take whatever action it deems appropriate to enforce such Joint Patent Rights; provided, however, that, within [***] after receipt of notice of ARS's intent to file such suit, AEGIS shall have the right to join such suit as a co-plaintiff or co-defendant with ARS and to fund up to [***] the costs of such suit.

6.4.5 Cooperation; Recovery. ARS and AEGIS shall reasonably cooperate with each other in the planning and execution of any action under Sections 6.4.3 or 6.4.4. The Party controlling any such enforcement action shall not settle the action or otherwise consent to an adverse judgment in such action that diminishes the rights or interests of the non-controlling Party without the prior written consent of the other Party. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery realized as a result of such litigation shall be first applied to the prorata reimbursement of any reasonable litigation expenses of ARS and AEGIS. Any remaining recovery realized from such litigation shall be treated as profits on sales of Products for purposes of determining Net Sales under this License Agreement, with AEGIS receiving the applicable royalty for purposes of Section 4.4 on such deemed Net Sales, and ARS receiving the remainder. [***].

6.4.6 ARS Patent Rights. ARS, [***] shall have the right to determine the appropriate course of action to enforce the ARS Patent Rights or otherwise abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the ARS Patent Rights, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the ARS Patent Rights.

6.5 FDA Matters. AEGIS covenants that it will not in the performance of its obligations under this License Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). AEGIS will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Food, Drug and Cosmetic Act.

7. **CONFIDENTIALITY**

7.1 Confidentiality. During the term of this License Agreement and for a period of [***] following the expiration or earlier termination hereof, each Party shall maintain in confidence the Confidential Information of the other Party, shall not use or grant the use of the Confidential Information of the other Party except as expressly permitted hereby, and shall not disclose the Confidential Information of the other Party. Notwithstanding the previous sentence, the receiving Party may disclose the Confidential Information of the disclosing Party solely on a "need to know basis", to Affiliates, and their and each of the Parties' respective directors, employees, contractors and agents, each of whom prior to disclosure must be bound by obligations of nondisclosure and non-use no less restrictive than the obligations set forth in this Section 7; provided, however, that, in each of the above situations, the receiving Party shall remain responsible for any failure by any person or entity that receives Confidential Information pursuant to this Section 7.1 to treat such Confidential Information as required under this

Section 7. To the extent that disclosure to any person is authorized by this License Agreement, prior to disclosure, a Party shall obtain written agreement of such person to hold in confidence and not disclose, use or grant the use of the Confidential Information of the other Party except as expressly permitted under this License Agreement. Each Party shall notify the other Party [***] upon discovery of any unauthorized use or disclosure of the other party's Confidential Information.

7.2 Terms of License Agreement. Neither party shall disclose any terms or conditions of this License Agreement to any third party without the prior consent of the other Party; provided, however, that a Party may disclose the terms or conditions of this License Agreement, (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, and (b) to a third party in connection with (i) an equity investment in, or lending arrangement with, such third party, (ii) a sublicense, collaboration, co-promotion, strategic partnership, merger, consolidation or similar transaction by such Party, or (iii) the sale of all or substantially all of the assets of such Party. In addition, ARS acknowledges that AEGIS is required and shall have the right to provide a copy of this License Agreement (and any subsequent amendment hereto), to UAB under the confidentiality provisions of the UAB Licensing Agreement. AEGIS shall use reasonable efforts to enforce the confidentiality provisions of the UAB Licensing Agreement to the fullest extent permitted thereby so as to preserve the confidentiality of this License Agreement and its terms, and shall not consent to any disclosure of this License Agreement or its terms to any third party by UAB. Notwithstanding the foregoing, either Party may disclose the fact that the Parties have entered into this exclusive license agreement, and a general description of the AEGIS Patent Rights, the Product, and the Field covered by this License Agreement.

7.3 Permitted Disclosures. The confidentiality obligations under this Section 7 shall not apply to any portion of Confidential Information to the extent that a Party is required to disclose such portion by applicable Law, regulation or order of a governmental agency or a court of competent jurisdiction; provided, however, that such Party shall provide written notice thereof to the other Party, consult with the other Party with respect to such disclosure and provide the other Party sufficient opportunity to object to any such disclosure or to request confidential treatment thereof.

7.4 Publicity. If either Party wishes to make a public disclosure concerning this License Agreement, such Party shall provide the other Party in advance with a copy of such proposed disclosure and the other Party shall have [***] within which to approve or disapprove the content of the proposed disclosure. Neither Party shall unreasonably withhold approval of such disclosure. Failure to respond within such [***] period shall constitute approval. Either Party may disclose the existence of this License Agreement and the terms and conditions hereof, without the prior written consent of the other Party, as may be required by applicable Law (including, without limitation, disclosure requirements of any Regulatory Authority (including without limitation the FDA and the U.S. Securities and Exchange Commission, or the NYSE, NASDAQ or any other stock exchange), in which case the Party seeking to disclose the information shall provide written notice thereof to the other Party, consult with the other Party with respect to such disclosure and provide the other Party sufficient opportunity to object to any such disclosure or to request confidential treatment thereof. Once a Party has approved the substance of any disclosure concerning this License Agreement, whether in a press release, a filing with a Regulatory Authority or otherwise, such Party may thereafter republish such disclosure in any other medium without again obtaining the prior approval of the other Party.

8. INDEMNIFICATION AND INSURANCE

8.1 Indemnification by ARS. Except to the extent that AEGIS is obligated to indemnify ARS under Section 8.2, ARS shall indemnify and hold harmless AEGIS, and its directors, officers, employees and agents, from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs, arising from any claims, demands, actions or other proceedings by any third party arising

from (a) the breach of any representation, warranty or covenant by ARS under this License Agreement; or (b) the Exploitation of the AEGIS Technology or Products by ARS, its sublicensees or their respective Affiliates; provided, however, that such indemnification right shall not apply to any losses, liabilities, damages or expenses to the extent directly attributable to the negligence, reckless misconduct, or intentional misconduct of a Party seeking indemnification under this Section 8.1.

8.2 Indemnification by AEGIS. AEGIS shall indemnify and hold harmless ARS, and its directors, officers, employees and agents, from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs, arising from any claims, demands, actions or other proceedings by any third party arising from (a) the breach of any representation, warranty or covenant by AEGIS under this License Agreement; (b) the Exploitation of the AEGIS Technology or Excipient(s) by AEGIS, its licensees (excluding ARS) or their respective Affiliates; or (c) any claim of any third party that AEGIS willfully disclosed or made available to ARS any AEGIS Technology in violation of an obligation of AEGIS to such third party; provided, however, that such indemnification right shall not apply to any losses, liabilities, damages or expenses to the extent directly attributable to the negligence, reckless misconduct, or intentional misconduct of a Party seeking indemnification under this Section 8.2.

8.3 Procedure. A Party that intends to claim indemnification under this Section 8 (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") in writing of any claim, demand, action or other proceeding for which the Indemnitee intends to claim indemnification; provided, however, that the failure to provide written notice of such claim within a reasonable period of time will not relieve the Indemnitor of any of its obligation hereunder, except to the extent that the Indemnitor is prejudiced by such failure to provide prompt notice. The Indemnitor shall have the right to participate in, and to the extent the Indemnitor so desires to assume the defense thereof with counsel selected by the Indemnitor; provided, however, that the Indemnitee, shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of the Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceedings. The Indemnitor may not settle or otherwise consent to an adverse judgment in any such claim, demand, action or other proceeding, that diminishes the rights or interests of the Indemnitee without the prior express written consent of the Indemnitee, which consent shall not be unreasonably withheld, delayed, or conditioned, unless (a) there is no finding or admission of any violation of Law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee and (b) the sole relief provided is monetary damages that are paid in full by the Indemnitor.

8.4 Insurance. Each Party shall maintain insurance with respect to its activities under this License Agreement as is normal and customary in the pharmaceutical industry generally for parties similarly situated. Each Party shall, upon request of the other Party, provide the requesting Party with a copy of the foregoing policies of insurance, along with any amendments and revisions thereto. ARS shall be named as an additional insured on any such policies maintained hereunder by AEGIS, and AEGIS shall be named as an additional insured on any such policies maintained hereunder by ARS. If there are any additional costs for adding a Party as an additional insured, that Party shall pay such additional costs.

9. **TERM; TERMINATION**

9.1 Term. This License Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to Section 9.2 or 9.3, shall continue in effect until the expiration of ARS's obligation to pay royalties hereunder.

9.2 Termination for Breach or Bankruptcy.

9.2.1 If ARS has breached any of its obligations to pay any of the payments to which AEGIS is entitled under Section 5, and such breach shall continue for [***] after written notice of such breach was provided to ARS by AEGIS, AEGIS shall have the right at its option to terminate this License Agreement effective at the end of such [***] period.

9.2.2 If a Party has materially breached any of its obligations under this License Agreement (except as specified in Section 9.2.1), and such material breach shall continue for [***] after written notice of such breach was provided to the breaching Party by the nonbreaching Party, the nonbreaching Party shall have the right at its option to terminate this License Agreement effective at the end of such [***] period.

9.2.3 Either Party may terminate this License Agreement, to the extent permissible under applicable Law, upon the occurrence of one or more of the following:

(a) immediately upon written notice to the other Party in the event such other Party becomes insolvent or initiates a voluntary proceeding under the U.S. Bankruptcy Code (beginning at 11 U.S.C. 101, as amended) (the “Bankruptcy Code”); or

(b) immediately upon written notice to the other Party in the event such other Party becomes the subject of an involuntary proceeding under the U.S. Bankruptcy Code and such proceeding is not dismissed or stayed within [***] of its commencement.

9.3 Termination by ARS. ARS may terminate this License Agreement at any time upon [***] prior written notice to AEGIS for any reason or no reason.

9.4 Effect of Expiration or Termination.

9.4.1 Expiration or termination of this License Agreement shall be without prejudice to any rights which shall have accrued to the benefit of a Party prior to the effective date of such expiration or termination. Without limiting the foregoing, Sections 1, 5, 7, 8, 10 and Sections 4.6, 6.1, 6.2, 6.4, and 9.4 shall survive any expiration or termination of this License Agreement.

9.4.2 Upon expiration of this License Agreement under Section 9.1, ARS shall have a non-exclusive, paid-up license for the same rights previously covered by this License Agreement.

9.4.3 If ARS elects to terminate this License Agreement under Section 9.2.2, ARS may nevertheless continue to have the same license rights previously covered by this License Agreement, so long as ARS continues to pay royalties, milestones, and other sums that are payable to AEGIS under this License Agreement; provided that ARS shall have the right to credit against any such royalties, milestones, and other sums payable an amount equal to any actual direct damages suffered by ARS as a result of the breach by AEGIS which gave rise to the termination under Section 9.2.2.

9.4.4 Except as may be necessary or useful for the exercise of the licenses set forth in Sections 9.4.1, 9.4.2 and 9.4.3, promptly upon the expiration or earlier termination of this License Agreement, (a) ARS shall destroy or return [***] to AEGIS (as AEGIS shall direct) all AEGIS Technology; and (b) each Party shall return to the other Party all tangible items regarding the Confidential Information of the other Party and all copies thereof; provided, however, that each Party shall have the right to retain one (1) copy for its legal files for the sole purpose of determining its obligations hereunder.

10. GENERAL PROVISIONS

10.1 Governing Law. This License Agreement shall be governed by, interpreted and construed in accordance with the laws of the State of California, without giving effect to any conflicts of law principles that would result in the application of the laws of any state other than the State of California.

10.2 Arbitration. Any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this License Agreement, or the performance by either Party of any obligation under this License Agreement, whether before or after termination of this License Agreement, shall be finally resolved by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any such arbitration shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association by a panel of three arbitrators appointed in accordance with such rules. Any such arbitration shall be held in San Diego, California. The method and manner of discovery in any such arbitration proceeding shall be governed by the Commercial Arbitration Rules of the American Arbitration Association. Each Party shall choose one (1) arbitrator within [***] after receipt of notice of the intent to arbitrate. Such arbitrators shall thereafter choose a third arbitrator within [***] of their appointment. If one or both of the Parties fails to make a timely appointment of its arbitrator, then such missing arbitrator(s) will be appointed by the American Arbitration Association. The arbitrators shall have the authority to grant specific performance and to allocate between the Parties the costs of arbitration in such equitable manner as they determine. The arbitrators shall make their award and decision by majority approval, which shall be made in accordance with the terms of this License Agreement and applicable law. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the foregoing, (i) either Party shall have the right, without waiving any right or remedy available to such Party under this License Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder, and (ii) any and all issues regarding the scope, construction, validity, and enforceability of one or more patents shall be determined in a court of competent jurisdiction under the local patent laws of the jurisdictions having issued the patent or patents in question. Each of the Parties agrees that if certain material obligations under this License Agreement are not performed in accordance with their specific terms or are otherwise breached, (a) severe and irreparable damage would occur, (b) no adequate remedy at law would exist and (c) damages would be difficult to determine. Each of the Parties agrees that, in such case, the injured Party or Parties shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, as well as any other relief permitted by applicable law, and the breaching Party shall waive any requirement that such Party or Parties post bond as a condition for obtaining any such relief. All proceedings and decisions of the arbitrator(s) shall be deemed Confidential Information of each of the Parties, and shall be subject to Section 7.

10.3 Modification; Waiver. This License Agreement may not be altered, amended, supplemented, or modified in any way except by a writing signed by each Party. No waiver by a Party of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. The failure by either Party to take any action or assert any right hereunder shall in no way be construed to be a waiver of such right, nor in any way be deemed to affect the validity of this License Agreement or any part hereof, or the right of a Party to thereafter enforce each and every provision of this License Agreement.

10.4 Rights Under U.S. Bankruptcy Code. All rights and licenses granted under or pursuant to this License Agreement by AEGIS are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses to intellectual property as defined under Section 101 of the Bankruptcy Code. AEGIS agrees that ARS shall retain and may fully exercise its rights and elections under the Bankruptcy Code.

10.5 Assignment. Neither this License Agreement nor any right or obligation hereunder may be assigned or delegated, in whole or part, by either Party without the prior express written consent of the other; provided, however, that (i) ARS may, without the written consent of AEGIS, assign this License Agreement and its rights and delegate its obligations hereunder in connection with the transfer or sale of all or substantially all of its business related to the Product, or in the event of its merger, consolidation, change in control or similar transaction; (ii) AEGIS may, without the written consent of ARS, assign this License Agreement and its rights and delegate its obligations hereunder in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger, consolidation, change in control or similar transaction; and (iii) neither Party shall unreasonably withhold, delay or condition its consent to any proposed assignment in any situation whereby all of its rights and entitlements are unaffected. Any permitted assignee shall assume all obligations of its assignor under this License Agreement. Any purported assignment in violation of this Section 10.5 shall be void. For avoidance of doubt, AEGIS may have the Excipients manufactured by a third party contract manufacturer for the benefit of AEGIS and/or ARS, which shall not be deemed to be an assignment or delegation restricted by this Section 10.5.

10.6 Independent Contractors. The relationship of the Parties is that of independent contractors. The Parties are not deemed to be agents, partners or joint venturers of the others for any purpose as a result of this License Agreement or the transactions contemplated thereby.

10.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further documents and instruments and to perform all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this License Agreement.

10.8 Notices. Any notice, report, communication, or consent required or permitted by this License Agreement shall be in writing and shall be sent by a Party (a) by prepaid registered or certified mail, return receipt requested, (b) by overnight express delivery service by a nationally recognized courier, or (c) via confirmed facsimile, followed within [***] by a copy mailed in the preceding manner, addressed to the other Party at the address shown below or at such other address as such Party gives notice hereunder. Such notice will be deemed to have been given when delivered or, if delivery is not accomplished by some fault of the addressee, when tendered.

If to AEGIS:

AEGIS THERAPEUTICS, LLC

[***]

with a copy to (which alone shall not constitute notice):

DLA Piper US LLP
[***]

If to ARS:

ARS PHARMACEUTICALS, INC.
[***]

with a copy to (which alone shall not constitute notice):
[***]

10.9 No Implied Licenses. Only licenses and rights granted expressly herein shall be of legal force and effect. No license or other right shall be created hereunder by implication, estoppel or otherwise.

10.10 Force Majeure. Nonperformance of a Party (other than for the payment of money) shall be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the nonperforming Party; provided, however, that the nonperforming Party shall use commercially reasonable efforts to resume performance as soon as reasonably practicable.

10.11 No Consequential Damages. EXCEPT WITH RESPECT TO A BREACH OF SECTION 7, IN NO EVENT SHALL A PARTY BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF THIS LICENSE AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS LICENSE AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.11 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTION 8.

10.12 Complete Agreement. This License Agreement, the Supply Agreement, and the Prior Agreements, constitute the entire agreement between the Parties regarding the subject matter hereof, and all prior and contemporaneous representations, understandings and agreements regarding the subject matter hereof, either written or oral, expressed or implied, are superseded and shall be and of no effect; provided, however, that the terms of certain Mutual Confidentiality Agreement between AEGIS and ARS dated as of September 17, 2015, shall remain in full force and effect as to all confidential information disclosed thereunder.

10.13 Counterparts. This License Agreement may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same agreement. A facsimile copy of this License Agreement bearing the signature (original or facsimile or .PDF version) of both Parties shall be binding on the Parties.

10.14 Severability. If any provision of any provision of this License Agreement shall be found by a court to be void, invalid, or unenforceable, the same shall be reformed to comply with applicable law or stricken if not so conformable, so as not to affect the validity or enforceability of this License Agreement; provided that no such reformation or striking shall be effective if the result materially changes the economic benefit of this License Agreement to any Party. In the event that any provision of this License Agreement becomes or is declared by a court of competent jurisdiction to be void, invalid, or unenforceable, and reformation or striking of such provision would materially change the economic benefit of this License Agreement to any Party, the Parties shall modify such provision in accordance with Section 10.3 to obtain a legal, valid, and enforceable provision and provide an economic benefit to the Parties that most nearly effects the Parties' intent on entering into this License Agreement.

10.15 Headings. The captions to the several sections hereof are not a part of this License Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

[SIGNATURE PAGE NEXT]

IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the Effective Date.

AEGIS THERAPEUTICS, LLC

By: /s/ Edward T. Maggio
Edward T. Maggio, Ph.D. Chief Executive Officer

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal
Richard Lowenthal, MS, MBA (MSEL)
Chief Executive Officer

EXHIBIT A

DEFINITIONS

“AEGIS” shall have the meaning set forth in the preamble to the License Agreement and the Supply Agreement.

“AEGIS Data” shall mean any data regarding the Compound(s), Excipient(s), and/or Product(s) in which AEGIS has an ownership or licensable interest at any time during the term of the License Agreement and/or Supply Agreement, including without limitation all relevant and available sections of the drug master file(s) for the Excipients, as filed by AEGIS or its Affiliates with the FDA or any other governmental authority from time to time, but excluding third party confidential information.

“AEGIS Invention” shall mean any Invention made or conceived by employees, consultants, agents and others conducting work on behalf of Aegis that relates to Compound(s), Excipient(s), and/or Product(s), but excluding a Joint Invention.

“AEGIS Know-How Rights” shall mean, collectively, all trade secret and other know-how rights relating to the Compound(s), Excipient(s), and/or Product(s) in which AEGIS has an ownership or licensable interest at any time during the term of the License Agreement.

“AEGIS Patent Rights” shall mean, collectively, (a) any patent and patent application, which is owned by AEGIS, licensed to AEGIS or otherwise controlled by AEGIS or any of its Affiliates, as of the Effective Date or during the term of this Agreement and is necessary or useful to Exploit the Product, including without limitation those certain patent applications listed on Exhibit B attached to the License Agreement and any patent rights for an AEGIS Invention; (b) all patents that have issued or in the future may issue from any of the foregoing patent applications, including without limitation utility models, design patents and certificates of invention; (c) all divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patents and patent applications; and (d) all patents and patent applications that may issue or be prepared in the future based on AEGIS Inventions, including without limitation utility models, design patents, certificates of invention, and all divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patents and patent applications.

“AEGIS Technology” shall mean, collectively, (a) AEGIS Data; (b) AEGIS Patent Rights; (c) AEGIS Know-How Rights; (d) AEGIS Inventions; and (e) AEGIS’ interest in any Joint Inventions and/or Joint Patent Rights.

“Affiliate” shall mean, with respect to any person or entity, any other person or entity that controls, is controlled by or is under common control with such person or entity. For purposes of this definition, a person or entity shall be in “control” of an entity if it owns or controls at least fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority), or otherwise has the power to control the management and policies of such other entity.

“Annual Net Sales” shall mean, with respect to any Annual Net Sales Period, the Net Sales earned in such Annual Net Sales Period.

“Annual Net Sales Period” shall mean each of (a) the period from the date of the First Commercial Sale of the first Product through December 31 of the Calendar Year in which the First Commercial Sale of the first Product takes place, and (b) each Calendar Year thereafter.

“Approval” shall mean, with respect to any Product in any jurisdiction, all approvals from any Regulatory Authority necessary for the sale of the Product in such jurisdiction in accordance with applicable Laws, including without limitation receipt of pricing and reimbursement approvals, where required.

“ARS” shall have the meaning set forth in the preamble to the License Agreement.

“ARS Data” shall mean any data regarding the Compound(s), Excipient(s), and/or Product(s) developed by employees, consultants, agents and others on behalf of ARS.

“ARS Invention” shall mean any Invention made or conceived by employees, consultants, agents and others conducting work on behalf of ARS that relates to Compound(s), Excipient(s), or Product(s), but excluding a Joint Invention.

“ARS Know-How Rights” shall mean, collectively, all trade secret and other know-how rights relating to the Compound(s), Excipient(s), and/or Product(s) in which ARS has an ownership or licensable interest at any time during the term of the License Agreement.

“ARS Patent Rights” shall mean, collectively, (a) any patent and patent application relating to Excipient(s), Compound(s) or Product(s) which are owned, licensed or otherwise controlled by ARS or any of its Affiliates as of the Effective Date or thereafter; (b) all patents that have issued or in the future may issue from any of the foregoing patent applications, including without limitation utility models, design patents and certificates of invention; (c) all divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patents and patent applications; and (d) all patents and patent applications that may issue or be prepared in the future based on ARS Inventions, including without limitation utility models, design patents, certificates of invention, and all divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patents and patent applications.

“ARS Technology” shall mean, collectively, (a) ARS Data; (b) ARS Inventions; (c) ARS Know- How Rights; and (d) ARS Patent Rights.

“Bankruptcy Code” shall have the meaning set forth in Section 9.2.3(a) of the License Agreement.

“Business Day” means any day that is not a Saturday or a Sunday or a day on which the New York Stock Exchange is closed.

“Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (a) the first Calendar Quarter of the License Agreement and the Supply Agreement shall extend from the commencement of such respective agreement to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter shall end upon the expiration or termination of the License Agreement or the Supply Agreement, as applicable.

“Calendar Year” means (a) for the first Calendar Year of the term of the License Agreement and the Supply Agreement, the period beginning on the Effective Date and ending on December 31, 2008, (b) for each Calendar Year of the term of the License Agreement or the Supply Agreement, as applicable, thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the last Calendar Year of the term of the License Agreement or the Supply Agreement, the period beginning on January 1 of the Calendar Year in which the License Agreement or the Supply Agreement, respectively, expires or terminates and ending on the effective date of expiration or termination of the License Agreement or the Supply Agreement, respectively.

“Commercially Reasonable Efforts” shall have the meaning set forth in Section 3.7.2 of the License Agreement.

“Competing Product” shall have the meaning set forth in Section 4.5.4 of the License Agreement.

“Compound” shall mean epinephrine and any metabolite, salt, ester, hydrate, anhydride, solvate, isomer, isotope, enantiomer, free acid form, free base form, crystalline form, co-crystalline form, complexes, amorphous form, pro-drug (including ester pro-drug) form, racemate, polymorph, chelate, isomer, tautomer, or optically active form of the foregoing.

“Confidential Information” shall mean, with respect to a Party, all information (and all tangible and intangible embodiments thereof), that is owned or controlled by such Party, is disclosed by or on behalf of such Party to the other Party pursuant to the License Agreement and/or the Supply Agreement, and (if disclosed in writing or other tangible medium) is marked or identified as confidential at the time of disclosure to the receiving Party or (if otherwise disclosed) is identified as confidential at the time of disclosure to the receiving Party and described as such in writing within [***] after such disclosure. Notwithstanding the foregoing, Confidential Information of a Party shall not include information which, and only to the extent, the receiving Party can establish by written documentation (a) has been generally known prior to disclosure of such information by the disclosing Party to the receiving Party; (b) has become generally known, without the fault of the receiving Party, subsequent to disclosure of such information by the disclosing Party to the receiving Party; (c) has been received by the receiving Party at any time from a source, other than the disclosing Party, rightfully having possession of and the right to disclose such information free of confidentiality obligations; (d) has been otherwise known by the receiving Party free of confidentiality obligations prior to disclosure of such information by the disclosing Party to the receiving Party; or (e) has been independently developed by employees or others on behalf of the receiving Party without use of such information disclosed by the disclosing Party to the receiving Party (each, a “Confidentiality Exception”).

“Confidentiality Exception” shall have the meaning set forth in the preceding definition.

“DMF” shall have the meaning set forth in Section 3.9 of the License Agreement.

“Effective Date” shall have the meaning set forth in the preamble to the License Agreement.

“EMA” shall mean the European Medicines Agency, or the successor thereto.

“Encumbrance” shall mean any lien, mortgage, deed of trust, pledge, security interest, charge, condition, equitable interest, right of first refusal, community property interest, covenant, option, title defect, claim, restriction, variance, exception, license, or other adverse claim or interest or encumbrance of any kind or nature whatsoever, whether or not perfected, including any restriction on use, voting, transfer, receipt of income or exercise of any other attribute of ownership

“Excipients” shall mean AEGIS’s proprietary chemically synthesizable delivery enhancement agents (including without limitation the Intravail® absorption enhancement agents), that, among other things, allow non-invasive systemic delivery of potent peptide, protein, and small and large molecule drugs.

“EU” shall mean the countries comprising the European Union as it may be constituted from time to time, and any successors to, or new countries created from, any of the foregoing.

“Exploit,” “Exploiting” or “Exploitation” shall mean to research, develop, make, have made, use, sell, have sold, offer for sale, import, export and/or otherwise commercialize and dispose of.

“FDA” shall mean the Food and Drug Administration of the United States, or the successor thereto.

“Field” shall mean any and all indications, uses, or purposes of Compound(s) and/or Product(s) in any and all formulations, including without limitation for the treatment, palliation, diagnosis, or prevention of any human or animal disease, disorder, or condition.

“First Commercial Sale” shall mean, with respect to a Product, the first sale for which payment has been received for use or consumption by the general public of such Product.

“GAAP” shall mean generally accepted accounting principles.

“GMP” shall mean Good Manufacturing Practices, as specified by FDA, or similar standards or guidelines promulgated by the FDA from time-to-time, or equivalent Regulatory Authority in countries other than the United States, as applicable.

“Government Approval Application” shall mean, with respect to each country of the Territory, all filings with the FDA or the EMA (or the equivalent health regulatory authority in each country within the Territory) for registrations, permits, licenses, authorizations, approvals, or notifications that are required to develop, make, use, sell, import or export a Product, including without limitation the equivalent of an NDA, as required by the FDA or the EMA or the counterpart of the FDA or the EMA in each such country.

“IND” shall mean an investigational new drug application or similar application which is required to be filed with the FDA prior to commencing a clinical investigation of a drug pursuant to 21 C.F.R. 312.

“Indemnitee” shall have the meaning set forth in Section 8.3 of the License Agreement.

“Indemnitor” shall have the meaning set forth in Section 8.3 of the License Agreement.

“Intravail®” shall mean the Material described on Exhibit B attached to the Supply Agreement, manufactured in compliance with all applicable Laws, including without limitation GMP.

“Invention” shall mean any invention, discovery, know-how, technology or other enhancement, whether or not patentable that is made or conceived by employees, consultants, agents and others conducting work on behalf of AEGIS, ARS or both, in connection with the performance of, and during the term of, the License Agreement and/or the Supply Agreement or any of the Prior Agreements.

“Joint Invention” shall have the meaning set forth in Section 5.6 of the License Agreement.

“Joint Patent Rights” shall mean, collectively, all patents and patent applications that may issue or be prepared in the future, which claim or purport to claim a Joint Invention, including without limitation utility models, design patents, certificates of invention, and all divisionals, continuations, continuations-in-part, reissues, renewals, extensions or additions to any such patents and patent applications.

“Law” shall mean any federal, state or local law, statute or ordinance, or any rule, regulation, or published guidelines promulgated by any governmental authority, including the United States Food, Drug and Cosmetic Act and applicable regulations promulgated thereunder.

“License Agreement” shall have the meaning set forth in the preamble to that certain License Agreement entered into by ARS and AEGIS as of the Effective Date.

“Material” shall mean any Excipient supplied by AEGIS to ARS pursuant to the Supply Agreement, including without limitation the AEGIS product known as Intravail[®], as further described in Exhibit B to the Supply Agreement, manufactured in compliance with all applicable Laws, including without limitation GMP.

“Material Tox Data” shall have the meaning set forth in Section 3.9 of the License Agreement.

“Material Tox Studies” shall have the meaning set forth in Section 3.9 of the License Agreement.

“NDA” shall mean a New Drug Application, Biologics License Application, Product License Application, or similar application which is required to be filed with the FDA to obtain a marketing approval of a Product in the United States.

“Net Proceeds” shall have the meaning set forth in Section 4.2.5 of the License Agreement.

“Net Sales” with respect to any Product, the invoiced sales price of such Product by ARS, its sublicensees and their respective Affiliates billed to independent customers who are not Affiliates, less [***].

“Paragraph IV Claim” shall have the meaning set forth in Section 6.4.2 of the License Agreement.

“Party” shall mean either AEGIS or ARS.

“Phase III Trial” means a human clinical trial of a product, the principal purpose of which is to gather evidence as to the effectiveness and safety in individuals or patients, as described in 21 C.F.R. 312.21(c), or a similar clinical study prescribed by the relevant Regulatory Authorities in a foreign country.

“Prior Agreements” shall mean (a) that certain Material Transfer, Option and Research License Agreement between Aegis and ARS dated as of July 14, 2016; and (b) that certain Mutual Confidentiality Agreement between Aegis and ARS dated as of September 17, 2015.

“Product” shall mean any product containing a Compound and formulated using the Excipient(s).

“Regulatory Authority” shall mean any national or supranational governmental authority, including without limitation the FDA, EMA, or Koseisho, that has responsibility over the development and/or commercialization of a Compound, an Excipient and/or a Product.

“Royalty Term” shall mean, with respect to a Product in a country, the period that begins on the date of First Commercial Sale of such Product in such country and ends on the later of: (a) expiration of the last Valid Claim that covers the manufacture, use, offer for sale, sale, or import of such Product in such country or (b) the earlier of (i) fifteen (15) years after the date of the First Commercial Sale of such Product in such country.

“Subsequent Product” shall mean a new Product (in addition to a previous Product) for which a new NDA Approval is required by the FDA for marketing the Product.

“Successful Completion” shall have the meaning set forth in Section 4.2.3 of the License Agreement.

“Supply Agreement” shall have the meaning set forth in the preamble to that certain Supply Agreement entered into by ARS and AEGIS as of the Effective Date.

“Territory” shall be worldwide.

“UAB” shall mean The UAB Research Foundation, a not-for-profit corporation.

“UAB Licensing Agreement” shall mean the Licensing Agreement between AEGIS and UAB, effective February 12, 2004.

“Valid Claim” shall mean, on a country-by-country basis, either (a) a claim of an issued and unexpired patent in the AEGIS Patent Rights, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a claim of a pending patent application in the AEGIS Patent Rights, which claim was filed in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application, and in any event has not been pending for more than [***].

**FIRST AMENDMENT
TO LICENSE
AGREEMENT**

This First Amendment to License Agreement (this “**First Amendment**”) is made and effective as of July 15, 2020 (the “**First Amendment Date**”) by and between **AEGIS THERAPEUTICS, LLC**, a California limited liability company (“**AEGIS**”), and **ARS PHARMACEUTICALS, INC.**, a Delaware corporation (“**ARS**” and together with AEGIS, the “**Parties**”).

RECITALS

WHEREAS, AEGIS and ARS are parties to that certain License Agreement dated June 18, 2018 (the “**Agreement**”);

WHEREAS, Section 4.4.5 of the Agreement provides that AEGIS will, upon written notice by ARS, negotiate and agree with ARS in good faith a reduction of the royalty rate payable on Products on a country-by-country basis if the level of competition, patent protection or the general commercial environment for such Product in such country materially affects the commercial viability of such Product in such country, and ARS has requested that AEGIS negotiate and agree to such a royalty rate reduction in connection with royalties payable with respect to sales of Products by sublicensees; and

WHEREAS, AEGIS and ARS now wish to amend the Agreement to modify the provisions of the Agreement regarding the royalty rate payable on Annual Net Sales of Products on the terms and subject to the conditions set forth herein.

AGREEMENT

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, AEGIS and ARS hereby agree as follows:

1. Defined Terms. Capitalized terms used but not otherwise defined in this First Amendment shall have the meanings provided in the Agreement.

2. Section 4.4 of the Agreement is hereby amended and restated to read in its entirety as follows:

“**4.4 Royalties.**

4.4.1 Within [***] following the First Commercial Sale of a Product in each country in the Territory, ARS shall give written notice to AEGIS thereof.

4.4.2 As partial consideration for the grant to ARS of the rights under Section 3.1, during the applicable Royalty Term, subject to Section 4.4.8, ARS shall pay to AEGIS royalties on Annual Net Sales of Products, on a country-by-country and Product-by-Product basis in accordance with this Section 4.4 in an amount equal to the applicable rate set forth in the table in this Section 4.4.2, below, times the Annual Net Sales of Products by ARS, its sublicensees and their respective Affiliates, subject to the applicable reductions as set forth in Sections 4.4.3 through 4.4.6; but in no event will the royalty rate be reduced pursuant to Sections 4.4.3 through 4.4.6 by more than [***] (although any such unused reduction sum will be carried forward and applied against future payments).

4.4.3 The royalty percentage then applicable under this Section 4.4 to Net Sales of any Product made in any country in the Territory shall be reduced by [***] from [***] to [***] if at the time of the sale of such Product in such country, the use, manufacture, offer for sale, sale and import of such Product in such county is not covered by a Valid Claim.

4.4.4 The royalty percentage then applicable to Net Sales of any Product made in any country in the Territory shall be further reduced by [***] from that in Section 4.4.3 from [***] to [***], if, at the time of the sale of such Product in such country, there are Competing Products that collectively account for [***] or more of all sales across all indications for which the Products are marketed in that country. In the event that Competing Products in any country no longer collectively account for [***] or more of all sales across all indications for which the Products are marketed in that country, then such [***] reduction shall be suspended.

The term "Competing Product" shall mean [***].

4.4.5 If the level of competition, patent protection or the general commercial environment for such Product in such country materially affect the commercial viability of such Product in such country at the royalty rate then applicable under this Section 4.4, then AEGIS shall, upon written notice by ARS, negotiate and agree with ARS in good faith a reduction of such royalty rates, as applicable to such Product in such country.

4.4.6 Third Party Licenses.

(a) If ARS determines, in its reasonable judgment (subject to subpart b below), that the intellectual property rights of a third party are necessary for the practice of any AEGIS Technology in accordance with this License Agreement, then the royalty and milestone amounts owed to AEGIS hereunder for Exploiting the AEGIS Technology in the country (or countries) where such third party intellectual property rights are enforceable shall be subject to a credit reduction in an amount equal to [***] of the amount of any payments that ARS (or any of its sublicensees) pays such third party to use such third party intellectual property rights; provided, no payment to AEGIS shall be reduced by more than [***] of the amount payable before any reductions or credits (although any unused excess credit may be carried forward and applied against future payments).

(b) If AEGIS disputes ARS's determination under Section 4.4.6(a) that the technology, and/or a license to intellectual property rights, of such third party is necessary for the practice of any AEGIS Technology in accordance with this License Agreement, AEGIS may submit such dispute to an independent third party arbiter, mutually agreed to by the Parties, such agreement not to be unreasonably withheld, delayed, or conditioned, and such arbiter to have at least [***] experience in the biopharmaceutical industry overseeing drug development or patent law, who shall determine within [***] whether, in the absence of rights granted by such third party, the practice of any AEGIS Technology in accordance with this License Agreement would likely or actually infringe or misappropriate such third party's intellectual property. Such arbiter's determination shall be final and binding on the Parties, and any dispute with respect to such arbiter's determination shall not be submitted for resolution pursuant to Section 10.2. Additionally, any determination of likely or actual infringement shall be deemed a determination that such license to intellectual property rights of a third party is "necessary" for purposes of Section 4.4.6(a).

4.4.7 ARS, its sublicensees or their respective Affiliates shall not intentionally sell any Product to a third party at a discount in order to induce the same third party to purchase any other products or services.

4.4.8 In the event that the amount of (a) any payments (such as royalties, profit-sharing, revenue-sharing, or other similar payments, but not milestone payments) required to be paid by an ARS sublicensee to ARS or any of its Affiliates based on the Net Sales of any Product in any of the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Russia and the Commonwealth of Independent States, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom, by such sublicensee or its Affiliates or sublicensees in any Calendar Quarter ("**Sublicensee Net Sales**") less (b) the COGS for such Product (to the extent that such sublicensee or its Affiliates or sublicensees do not pay or reimburse ARS or any of its Affiliates for any such COGS) ("**Sublicensee Sales-Based Profits**") is less [***] due to AEGIS as calculated pursuant to Sections 4.4.2 through 4.4.6 on such Sublicensee Net Sales, then, in lieu of such royalties payable to AEGIS as calculated pursuant to Sections 4.4.2 through 4.4.6, the royalties payable to AEGIS for such Calendar Quarter with respect to such Sublicensee Net Sales shall be [***] of such Sublicensee Sales-Based Profits for such Calendar Quarter. During each Calendar Quarter, such calculation shall be performed and shall be included in each royalty report provided pursuant to Section 4.5 and the applicable royalty shall be paid for such Calendar Quarter. For the avoidance of doubt, the maximum royalty payable to AEGIS under this Section 4.4 is [***] of Annual Net Sales of Products, on a country-by- country and Product-by-Product basis. An example of such calculation is set forth on Exhibit D, attached hereto. For purposes of this Section 4.4.8, "COGS" shall mean, with respect to any Product, and solely to the extent incurred by ARS or its Affiliate: [***];

and (ii) in the case of manufacturing services performed by a ARS or its Affiliate, including manufacturing services to support products and services acquired from Third Parties as contemplated in subsection (i), [***]. “Actual Unit Costs” shall mean [***]. “Direct Material Costs” shall mean [***]. “Direct Labor Costs” shall mean [***]. “Manufacturing Overhead” attributable to such Product (in bulk or finished form) shall mean [***].”

3. The Exhibit D attached to this First Amendment in ATTACHMENT 1 is hereby added to the Agreement.

4. **Effectiveness of Agreement.** Except as expressly amended by this First Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

5. **Counterparts.** This First Amendment may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or by email of a .pdf attachment shall be deemed to be original signatures.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this First Amendment to be duly executed by its authorized representative under seal, in duplicate as of the First Amendment Date.

AEGIS THERAPEUTICS, LLC

By: /s/ Craig Chambliss

Craig Chambliss
Chief Executive Officer

ARS PHARMACEUTICALS, INC.

By: /s/ Richard E. Lowenthal

Richard E. Lowenthal
President and Chief Executive Officer

SIGNATURE PAGE TO FIRST AMENDMENT
TO LICENSE AGREEMENT

**SECOND AMENDMENT TO
LICENSE AGREEMENT**

This Second Amendment to License Agreement (this “**Second Amendment**”) is made and effective as of January 6, 2021 (the “**Second Amendment Date**”) by and between **AEGIS THERAPEUTICS, LLC**, a California limited liability company (“**AEGIS**”), and **ARS PHARMACEUTICALS, INC.**, a Delaware corporation (“**ARS**” and together with AEGIS, the “**Parties**”).

RECITALS

WHEREAS, AEGIS and ARS are parties to that certain License Agreement dated June 18, 2018 (the “**Agreement**”) and certain First Amendment to the License Agreement dated July 15, 2020 (the “**First Amendment**”);

WHEREAS, the First Amendment provides that the royalties payable to AEGIS under the Agreement are adjusted when net sales payments to ARS from its sublicensees in certain countries are below a specific threshold as calculated in the First Amendment.

WHEREAS, AEGIS and ARS now wish to amend the Agreement to modify the provisions of the Agreement regarding the list of countries to which the First Amendment is applicable on the terms and subject to the conditions set forth herein.

AGREEMENT

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, AEGIS and ARS hereby agree as follows:

1. Defined Terms. Capitalized terms used but not otherwise defined in this Second Amendment shall have the meanings provided in the Agreement and the First Amendment

2. Section 4.4.8 of the Agreement is hereby amended with the addition of the following underlined text to expand the list of countries to include China. For avoidance of doubt, only this underlined text below, and no other language in either the Agreement or First Amendment, is agreed to be amended herein.

4.4.8 In the event that the amount of (a) any payments [***] required to be paid by an ARS sublicensee to ARS or any of its Affiliates based on the Net Sales of any Product in any country in China (which includes China, Hong Kong, Macau and Taiwan), Europe (which includes Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Russia and the Commonwealth of Independent States, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom) by such sublicensee or its Affiliates or sublicensees in any Calendar Quarter (“**Sublicensee Net Sales**”) [***]

[***] (“**Sublicensee Sales-Based Profits**”) is [***] as calculated pursuant to Sections 4.4.2 through 4.4.6 on such Sublicensee Net Sales, then, in lieu of such royalties payable to AEGIS as calculated pursuant to Sections 4.4.2 through 4.4.6, the royalties payable to AEGIS for such [***] with respect to such Sublicensee Net Sales shall be [***] of such Sublicensee Sales-Based Profits for such [***]. During each [***], such calculation shall be performed and shall be included in each royalty report provided pursuant to Section 4.5 and the applicable royalty shall be paid for such [***]. For the avoidance of doubt, the maximum royalty payable to AEGIS under this Section 4.4 is [***] of Annual Net Sales of Products, on a country-by- country and Product-by-Product basis. An example of such calculation is set forth on Exhibit D, attached hereto. For purposes of this Section 4.4.8, “COGS” shall mean, with respect to any Product, and [***]: (i) in the case of products and services acquired from Third Parties relating directly to the manufacture of such Product, including quality control and quality assurance services, freight, shipping and warehousing payments made to such Third Parties, [***]; and (ii) in the case of manufacturing services performed by a ARS or its Affiliate, including manufacturing services to support products and services acquired from Third Parties as contemplated in subsection [***]. “Actual Unit Costs” shall mean [***]. “Direct Material Costs” shall mean the [***]. “Direct Labor Costs” shall mean [***]. “Manufacturing Overhead” attributable to such Product (in bulk or finished form) shall mean [***].”

3. Effectiveness of Agreement. Except as expressly amended by this Second Amendment, the Agreement shall remain in full force and effect in accordance with its terms.

4. Counterparts. This Second Amendment may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or by email of a .pdf attachment shall be deemed to be original signatures.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Second Amendment to be duly executed by its authorized representative under seal, in duplicate as of the Second Amendment Date.

AEGIS THERAPEUTICS, LLC

By: /s/ Craig Chambliss

Craig Chambliss
Chief Executive Officer

ARS PHARMACEUTICALS, INC.

By: /s/ Richard E. Lowenthal

Richard E. Lowenthal
President and Chief Executive Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*],
HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE
REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.**

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the “*Agreement*”) is entered into as of April 30, 2020 (the “*Effective Date*”), by and between **ARS PHARMACEUTICALS, INC.**, a Delaware corporation (“*ARS*”), having an address of 3525 Del Mar Heights Rd., #855, San Diego, CA 92130, U.S., and **ALFRESA PHARMA CORPORATION**, a corporation organized under the laws of Japan (“*ALFRESA*”), having an address of 2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan. ARS and ALFRESA may be referred to herein individually as a “*Party*” or collectively as the “*Parties*”.

RECITALS

WHEREAS, ARS is developing its proprietary Composition referred to as ARS-1, and owns or Controls certain ARS Technology (as each of these capitalized terms is defined below) relating to such Composition;

WHEREAS, ALFRESA is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, ALFRESA desires to obtain from ARS, and ARS desires to grant to ALFRESA, an exclusive license to develop, register, import, manufacture and commercialize products containing ARS-1 in the ALFRESA Territory (as defined below), all subject to the terms and conditions of this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, ARS and ALFRESA hereby agree as follows:

1. DEFINITIONS

1.1 “Affiliate” means, with respect to a Party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party, but for only so long as such control exists. As used in this **Section 1.1**, “*control*” means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital or other equity interest in such entity. Notwithstanding the foregoing, for the purpose of this Agreement, as for ALFRESA, ALFRESA’s Affiliate or Affiliate of ALFRESA as the case may be, shall only mean an entity which ALFRESA controls, and entities which control ALFRESA or which are under the common control with ALFRESA shall be excluded from ALFRESA’s Affiliates or Affiliates of ALFRESA as the case may be, except that if ALFRESA is involved in a merger or acquisition transaction, then any such entity which controls or is under common control with ALFRESA after such merger or acquisition transaction and is engaged in the research, Development, manufacture, testing, use, or importation, offer for sale or sale of any Composition or Product in the Territory shall be included as an Affiliate of ALFRESA..

1.2 “ALFRESA Data” has the meaning set forth in **Section 10.1(a)**.

1.3 “ALFRESA Indemnitee” has the meaning set forth in **Section 12.1**.

1.4 “ALFRESA Know-How” means all Know-How that ALFRESA or its Affiliates Control as of the Effective Date or during the Term that is necessary or reasonably useful for the research, Development, manufacture, testing, use, or importation of any Composition, or the research, Development, manufacture, use, importation, offer for sale or sale of any Product, in each case in the Field. The ALFRESA Know-How includes the ALFRESA Data.

1.5 “ALFRESA Patents” means all Patents that ALFRESA or its Affiliates Control as of the Effective Date or during the Term that would be infringed, absent a license or other right to practice granted under such Patents, by the research Development, manufacture, testing, use, or importation of any Composition, or the research Development, manufacture, use, importation, offer for sale or sale of any Product, in each case in the Field (considering, for this purpose, pending patent applications to be issued with the then-pending claims).

1.6 “ALFRESA Technology” means the ALFRESA Know-How and the ALFRESA Patents, including ALFRESA’s interest in the Joint Inventions and Joint Patents.

1.7 “ALFRESA Territory” means Japan.

1.8 “Alliance Manager” has the meaning set forth in **Section 3.7**.

1.9 “Applicable Laws” means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

1.10 “ARS Collaborator” means any Third Party licensee of ARS with respect to the Development and Commercialization of Compositions and Products in any country outside the ALFRESA Territory.

1.11 “ARS Data” has the meaning set forth in **Section 10.1(a)**.

1.12 “ARS Indemnitee” has the meaning set forth in **Section 12.2**.

1.13 “ARS Know-How” means all Know-How that ARS Controls as of the Effective Date or during the Term, including the Joint Inventions, that is necessary or reasonably useful for the research, Development, manufacture, testing, use, or importation of any Composition, or the research, Development, manufacture, testing, use, or importation, offer for sale or sale of any Product, in each case in the Field in the ALFRESA Territory. The ARS Know-How includes the ARS Data. For clarity, the ARS Know-How includes the know-how and data of ARS’s CMO to the extent that these are necessary or reasonably useful for the manufacture of any Composition or Product; provided such Know-How is in ARS’s possession and ARS has the legal right to transfer such Know-How.

1.14 “ARS Patents” means all Patents in the ALFRESA Territory that ARS Controls as of the Effective Date or during the Term that would be infringed, absent a license or other right to practice granted to ALFRESA under such Patents, by the research, Development, manufacture, use, or importation of any Composition, or research, Development, manufacture, use, importation, offer for sale or sale of any Product, in the Field in the ALFRESA Territory (considering patent applications to be issued with the then-pending claims). The ARS Patents existing as of the Effective Date are set forth in Exhibit 1 hereof. Such list may be amended and updated from time to time when a new ARS Patent subject to the license contemplated under this Agreement is filed.

1.15 “ARS Technology” means the ARS Know-How, the ARS Patents, including ARS’s interest in the Joint Inventions and Joint Patents.

1.16 “Business Day” means a day other than a Saturday, Sunday or a bank or other public holiday in California, United States or in Osaka, Japan.

1.17 “Calendar Quarter” means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, or December 31.

1.18 “**Calendar Year**” means each respective period of twelve (12) consecutive months ending on December 31.

1.19 “**Claim**” has the meaning set forth in **Section 12.3**.

1.20 “**CMC**” means chemistry, manufacturing, and control.

1.21 “**CMO**” means a Third-Party company who has contracted with either Party to Manufacture, or engage in Manufacturing activities, of Composition or the Product.

1.22 “**Commercial Strategy**” has the meaning set forth in **Section 6.1**.

1.23 “**Commercial Supply Agreement**” has the meaning set forth in **Section 7.2(a)**.

1.24 “**Commercialization**” means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Products to customers) of Products in the Field [***] including: (i) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training, and sales and distribution; (ii) scientific and medical affairs; and (iii) post- approval clinical trials. “**Commercialize**” and “**Commercializing**” have correlative meanings.

1.25 “**Commercialization Plan**” has the meaning set forth in **Section 6.2**.

1.26 “**Commercially Reasonable Efforts**” means [***].

1.27 “**Committee**” means the JSC, JDC, JCC or any subcommittee established by the JSC, as applicable.

1.28 “**Composition**” means (a) the combination of epinephrine + [***], or (b) [***].

1.29 “**Confidential Disclosure Agreement**” means that certain Confidential Disclosure Agreement between ARS and ALFRESA dated as of [***].

1.30 “**Confidential Information**” means all Know-How and other proprietary scientific, marketing, financial or commercial information or data that is not publicly available, and that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic or visual form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement. All ARS Technology will be ARS’s Confidential Information, all ALFRESA Technology will be deemed ALFRESA’s Confidential Information, and all Joint Inventions and Joint Patents will be deemed both Parties’ Confidential Information.

1.31 “Control” or “Controlled” means, with respect to any Know-How, Patents or other intellectual property rights, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license or a sublicense of or under such Know-How, Patents or other intellectual property rights to the other Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.32 “Cost of Goods” means, with respect to any Composition or Product, the [***] cost and expense to manufacture or supply such Composition or Product, which means: (a) in the case of products and services acquired from Third Parties, [***]; and (b) in the case of manufacturing services performed by a Party or its Affiliates, including manufacturing services to support products and services acquired from Third Parties as contemplated in **subsection (a)**, [***]. Actual unit costs shall consist of [***], all calculated in accordance with U.S. generally accepted accounting principles. Direct material costs shall include [***]. Direct labor costs shall include the cost of: [***] and [***]. Manufacturing overhead attributable [***].

1.33 “Data” means any and all scientific, technical, test, marketing or sales data pertaining to any Composition or Product that is generated by or on behalf of ALFRESA or its Affiliates or Sublicensees, or by or on behalf of ARS or its Affiliates or, to the extent Controlled by ARS with a right to disclose to ALFRESA, ARS Collaborators, including research data, clinical pharmacology data, CMC data (including analytical, manufacturing and quality control data and stability data), pre-clinical data, clinical data or submissions made in association with an IND or MAA with respect to any Product.

1.34 “Develop” means to develop (including clinical, non-clinical and CMC development), analyze, test and conduct preclinical, clinical and all other regulatory trials for Product, [***]. “**Developing**” and “**Development**” have correlative meanings.

1.35 “Development Costs” means those [***] costs reasonably documented and actually incurred by or on behalf of a Party or any of its Affiliates in performing its obligations under and in accordance with the Agreement, that are [***]. These costs include [***].

1.36 “Development Plan” is described in **Section 4.2**.

1.37 “Development Supply Agreement” has the meaning set forth in **Section 7.1(a)**.

- 1.38 “*Debarred*” has the meaning set forth in **Section 11.2(b)**.
- 1.39 “*Discontinued ARS Patent*” has the meaning set forth in **Section 10.2(a)(ii)**.
- 1.40 “*Discontinued ALFRESA Patent*” has the meaning set forth in **Section 10.2(b)(ii)**.
- 1.41 “*Discontinued Joint Patent*” has the meaning set forth in **Section 10.2(c)(ii)**.
- 1.42 “*Drug Product*” has the meaning set forth in **Section 7.1(a)**.
- 1.43 “*EPI-JP-01 Study*” means the clinical trial conducted by ARS under the EPI-JP-01 protocol synopsis that was provided to ALFRESA prior to the Effective Date.
- 1.44 “*EU*” means the European Union and the United Kingdom.
- 1.45 “*Excluded Claim*” has the meaning set forth in **Section 15.3(f)**.
- 1.46 “*Exclusive License*” has the meaning set forth in **Section 2.1(a)**.
- 1.47 “*Executive Officers*” has the meaning set forth in **Section 3.5**.
- 1.48 “*Export Control Laws*” means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).
- 1.49 “*FCPA*” means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended; the UK Anti-Bribery Act, and all applicable local anti-bribery laws and regulations.
- 1.50 “*FDCA*” has the meaning set forth in **Section 11.2(b)**.
- 1.51 “*Field*” means the treatment, management, prophylaxis or diagnosis of any diseases in humans.
- 1.52 “*First Commercial Sale*” means, on a Product-by-Product and country-by-country basis, the first sale by ALFRESA or any of its Affiliates or Sublicensees to a Third Party for end use or consumption of a Product in the ALFRESA Territory after Regulatory Approval has been granted with respect to such Product in such country. Any sale of Product by a ALFRESA to its Affiliate or Sublicensee shall not constitute a First Commercial Sale unless there is no subsequent resale of such Product by such Affiliate or Sublicensee.
- 1.53 “*GAAP*” means the generally accepted accounting principles of the applicable country or jurisdiction, consistently applied.
- 1.54 “*Global Trial*” means a clinical trial designed to obtain data to be used to support filing for and obtaining Regulatory Approval of a Product in the Field in both (a) Japan and (b) either the U.S. or EU.
- 1.55 “*Governmental Authority*” means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.56 “**ICH**” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.57 “**IND**” means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence human clinical trials in the applicable country.

1.58 “**Indemnitee**” has the meaning set forth in **Section 12.3**.

1.59 “**Indemnitor**” has the meaning set forth in **Section 12.3**.

1.60 “**Infringement Claim**” has the meaning set forth in **Section 10.5**.

1.61 “**Initiation**” means, with respect to a clinical trial, the first dosing of the first subject in such clinical trial.

1.62 “**Inventions**” means all inventions, whether or not patentable, discovered, made or conceived as a result of performance of activities contemplated by this Agreement.

1.63 “**JCC**” and “**Joint Commercialization Committee**” has the meaning set forth in **Section 3.3**.

1.64 “**JDC**” and “**Joint Development Committee**” has the meaning set forth in **Section 3.2**.

1.65 “**Joint Invention**” means any Invention discovered, made or conceived jointly by one (1) or more employees or contractors of ALFRESA or its Affiliates and by one (1) or more employees or contractors of ARS.

1.66 “**Joint Patent**” means any Patent to the extent it claims any Joint Invention.

1.67 “**JSC**” and “**Joint Steering Committee**” has the meaning set forth in **Section 3.1**.

1.68 “**Know-How**” means all technical information, know-how and data, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical materials, expertise and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, nonclinical and clinical data, regulatory documents, data and filings, instructions, processes, formulae, expertise and information, relevant to the research, development, manufacture, use, importation, offering for sale or sale of, or which may be useful in studying, testing, developing, producing or formulating, products, or intermediates for the synthesis thereof. Know-How excludes Patents.

1.69 “**Losses**” has the meaning set forth in **Section 12.1**.

1.70 “**MAA**” means a marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory Authority in any country or jurisdiction.

1.71 “**Manufacture**” or “**Manufacturing**” shall mean the activities required to manufacture Compositions or Products by ARS, itself or through its Affiliate or CMO, including test method development and stability testing, formulation development, process development, manufacturing scale up, process validation, the manufacturing of the starting material, fill and finish activities and quality assurance/quality control.

1.72 “**Manufacturing License Condition**” means any event identified in **Section 2.1(b)**.

1.73 “**Materials**” has the meaning set forth in **Section 4.7**.

1.74 “**MHLW**” means the Ministry of Health, Labour and Welfare, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in Japan.

1.75 “**Milestone Event**” means any event identified in **Section 8.2**.

1.76 “**Milestone Payment**” means any payment identified in **Section 8.2** to be made by ALFRESA to ARS on the occurrence of a Milestone Event.

1.77 “**NHI**” means the National Health Insurance system insurance programs, or any successor agency having the administrative authority to regulate the pricing and reimbursement of human pharmaceutical products or biological therapeutic products in Japan.

1.78 “**Patents**” means (a) all national, regional and international patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, and (b) any renewals, divisions, continuations (in whole but not in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.79 “**PMDA**” means the Pharmaceuticals and Medical Devices Agency or any successor thereto.

1.80 “**Pricing and Reimbursement Approval**” means, with respect to a Product, the approval, agreement, determination or decision of any Regulatory Authority establishing the price or level of reimbursement for such Product, as required in a given country or jurisdiction prior to sale of such Product in such jurisdiction.

1.81 “**Product**” means any pharmaceutical product containing a Composition as an active ingredient in any dosage form or formulation.

1.82 “**Provisional Exclusive License**” has the meaning set forth in **Section 2.1(a)**.

1.83 “**Public Official or Entity**” means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international governmental organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

1.84 “**Regulatory Approval**” means any and all approvals, licenses, registrations, permits, notifications and authorizations (or waivers) of any Regulatory Authority that are necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of a Product in any country or jurisdiction.

1.85 “**Regulatory Authority**” means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a given jurisdiction, including the MHLW and PMDA in Japan. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority shall also include any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.86 “Regulatory Filing” means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications and authorizations (or waivers) with respect to the testing, Development, manufacture or Commercialization of any Product made to or received from any Regulatory Authority in a given country, including any INDs and MAAs.

1.87 “Safety Data” means Data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities in or outside the ALFRESA Territory. Safety Data also includes “*adverse events*”, “*adverse drug reactions*” and “*unexpected adverse drug reactions*” as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

1.88 “SEC” means the U.S. Securities and Exchange Commission, or any successor entity.

1.89 “[*]”** has the meaning set forth in **Section 15.3(a)**.

1.90 “[*]”** has the meaning set forth in **Section 15.3(a)**.

1.91 “Sublicensee” means a Third Party to whom ALFRESA grants a sublicense to research, Develop, make, have made, use, import, promote, distribute, offer for sale or sell any Product in the Field in the ALFRESA Territory (either independently from or in cooperation with ALFRESA), beyond the mere right to purchase Products from ALFRESA and its Affiliates. In no event shall ARS or any of its Affiliates be deemed a Sublicensee.

1.92 “Tax Withholding Avoidance Documents” means documents prepared by ARS in order for ARS obtain benefits under any applicable tax treaty, including the reduction or exemption from any withholding tax and the procurement of any available tax refunds, as described in **Section 9.2(b)**.

1.93 “Term” has the meaning set forth in **Section 14.1**.

1.94 “Third Party” means any entity other than ARS or ALFRESA or an Affiliate of ARS or ALFRESA, respectively.

1.95 “Transfer Price” means any event identified in **Section 7.2(a)**.

1.96 “U.S.” means the United States of America, including its territories and possessions and the District of Columbia.

1.97 “Valid Claim” means (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a pending patent application that has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

2. GRANT OF LICENSES

2.1 Licenses Granted to ALFRESA. Subject to the terms and conditions of this Agreement, ARS hereby grants to ALFRESA, as for ARS Patents until expiration of the last-to-expire Valid Claim in such ARS Patents, and as for ARS Technology other than ARS Patents, during the Term:

(a) exclusive (even as to ARS, except as expressly set forth herein), royalty-bearing licenses, which are defined as “Kari Senyou Jisshi Ken” in Article 34.2 of the Japanese Patent Act (hereinafter referred to as the “**Provisional Exclusive License**”) and “Senyou Jisshi Ken” in Article 77 of the Japanese Patent Act (hereinafter referred to as the “**Exclusive License**”) with the right to grant sublicenses as provided in **Section 2.2**, under the ARS Technology to Develop, use and import Compositions and Products in the Field and in the ALFRESA Territory and to promote, distribute, offer for sale and sell Products in the Field and in the ALFRESA Territory, which license includes the rights (i) to incorporate ARS Data in Regulatory Filings with Regulatory Authorities in the ALFRESA Territory or in Commercialization materials and (ii) to cross-reference Regulatory Filings Controlled by ARS outside the ALFRESA Territory, in each case (i) and (ii) solely for the purposes of (A) obtaining Regulatory Approval for Products in the Field in the ALFRESA Territory or (B) supporting Commercialization activities for Products in the Field in the ALFRESA Territory.

(b) a non-exclusive, royalty-bearing license, with the right to grant sublicenses as provided in **Section 2.2** only to a Sublicensee that is granted a sublicense to Manufacture and Commercialize Products under the license granted in **Section 2.1(a)**, under the ARS Technology to make and have made Compositions and Products in the ALFRESA Territory pursuant to **Section 7.2, 7.3 and 7.3**, solely for the purpose of exercising the license in the ALFRESA Territory as granted in **Section 2.1(a)**; provided that the license in this **Section 2.1(b)** shall be subject to and effective only upon satisfaction of the following conditions: (i) demonstration by ALFRESA to the reasonable satisfaction of ARS that ALFRESA or its Affiliate or CMO is able to manufacture Compositions and Products in a manner and at a level of quality that is no less than the manner and quality of manufacture of Compositions and Products by ARS or its Affiliates or CMOs; and (ii) ALFRESA and ARS agree in writing to an amendment to this Agreement and the Commercial Supply Agreement that provides for payment by ALFRESA to ARS of a royalty payment for sales of Products in the ALFRESA Territory that is economically equivalent to and in lieu of the payment of the Transfer Price (the “**Manufacturing License Conditions**”).

(c) a non-exclusive, royalty-bearing license, with the right to grant sublicenses as provided in **Section 2.2** only to a Sublicensee that is granted a sublicense to Manufacture and Commercialize Products under the license granted in **Section 2.1(a)**, under the ARS Technology to make and have made Compositions and Products outside the ALFRESA Territory solely for the purpose of exercising the license in the ALFRESA Territory as granted in **Section 2.1(a)**; provided that (i) the license in this **Section 2.1(c)** shall be subject to and effective only upon satisfaction of the Manufacturing License Conditions; (ii) ALFRESA must obtain prior written approval from ARS when ALFRESA intends to manufacture or have manufactured Compositions and Products outside the ALFRESA Territory; and (iii) neither ALFRESA nor any of its Affiliates or Sublicensees shall promote, distribute, sell or offer for sale any of the Composition and Products manufactured by or for ALFRESA or its Affiliates or Sublicensees to any Third Party outside the ALFRESA Territory or any Third Party that to the knowledge of ALFRESA intends to use, promote distribute, sell or offer for sale such Composition and Products outside the ALFRESA Territory.

(d) ALFRESA may, alone, apply for the registration of the Provisional Exclusive License and Exclusive License on ARS Patents to the Japan Patent Office pursuant to the terms and conditions of this Agreement and ARS shall agree and approve such application and registration. All the fees and costs for such registration and application shall be borne by [***]. ARS shall cooperate with ALFRESA in the application and registration of the Provisional Exclusive License and Exclusive License and concurrently with the execution of this Agreement, shall provide all the documents (including but not limited to the approval for such registration and application by the joint patent holder of ARS Patents) necessary for such application for registration.

2.2 Sublicenses. ALFRESA shall have the right to grant sublicenses under the licenses granted in **Section 2.1 (i)** to any Affiliate with the prior written notice to ARS, and (ii) to any Third Party in the ALFRESA Territory with the prior written consent of ARS, which consent shall be made or denied by ARS within [***] of ALFRESA's written request, [***]. All sublicenses granted under the licenses granted in **Section 2.1** shall be in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement. ALFRESA shall be responsible for the compliance of its Sublicensees with the terms and conditions of this Agreement. When ALFRESA requests ARS's consent to any sublicense, ALFRESA shall provide ARS with a full and complete copy of such sublicense agreement. ALFRESA may redact from the copy of the sublicense agreement any financial terms and other conditions therein which shall not be necessary to verify the compliance with the terms and conditions of this Agreement. Within [***] after entering into any such sublicense, ALFRESA shall deliver a fully executed and redacted (to the extent necessary) copy of the agreement to ARS.

2.3 Licenses Granted to ARS. Subject to the terms and conditions of this Agreement, ALFRESA hereby grants to ARS:

(a) an exclusive (even as to ALFRESA and its Sublicensees, except as expressly set forth herein and to the extent permitted by Applicable Law), royalty-free, fully-paid, irrevocable, perpetual license, with the right to sublicense through multiple tiers, under the ALFRESA Technology to research, Develop, make, have made, use, import, promote, sell and offer for sale Compositions and Products in the Field outside the ALFRESA Territory, which license includes the rights (i) to incorporate ALFRESA Data in Regulatory Filings with Regulatory Authorities outside the ALFRESA Territory and (ii) to cross-reference Regulatory Filings Controlled by ALFRESA in the ALFRESA Territory, in each case solely for the purpose of (A) obtaining Regulatory Approval for Products in the Field outside the ALFRESA Territory or (B) supporting Commercialization activities for Products in the Field outside the ALFRESA Territory; and

(b) a non-exclusive, royalty-free, fully-paid, irrevocable, perpetual license, with the right to sublicense through multiple tiers, under the ALFRESA Technology to make and have made Compositions and Products in the ALFRESA Territory solely for the purpose of exercising the license granted in **Section 2.3(a)** and the reserved rights in **Section 2.4**.

2.4 Reserved Rights. ARS hereby expressly reserves (a) all rights to practice, and to grant licenses under, the ARS Technology outside of the scope of the licenses granted in **Section 2.1**, for any and all purposes, (b) the right to conduct all activities to be conducted by ARS as contemplated by this Agreement, and as contemplated by the Supply Agreement, and (c) the right to manufacture Compositions and Products in the ALFRESA Territory. Provided, that ARS must obtain prior written approval from ALFRESA when ARS intends to manufacture Composition and Products in the ALFRESA Territory and that ARS shall not promote, distribute, sell or offer for sale any of the Composition and Products manufactured by or for ARS or its Affiliates or sublicensee to any Third Party in the ALFRESA Territory or any Third Party that, to the knowledge of ARS, intends to use, promote, distribute, sell or offer for sale such Composition and Products in the ALFRESA Territory. Subject only to the rights expressly granted under **Section 2.3**, ALFRESA hereby expressly reserves all rights to practice, and to grant licenses under, the ALFRESA Technology for any and all purposes.

2.5 No Implied Licenses; Negative Covenant. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How or other intellectual property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or sublicensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.6 Disclosure of Know-How. ARS shall [***] disclose and make available to ALFRESA, in whatever form ALFRESA may reasonably request (including by providing copies thereof), all ARS Know-How not previously provided to ALFRESA, promptly after the earlier of the development, making, conception or reduction to practice of such ARS Know-How. ALFRESA shall and shall cause its Affiliates to [***] disclose and make available to ARS, in whatever form ARS may reasonably request (including by providing copies thereof), any ALFRESA Know-How not previously provided to ARS, promptly after the earlier of the development, making, conception or reduction to practice of such ALFRESA Know-How.

3. GOVERNANCE

3.1 Joint Steering Committee. Promptly after the Effective Date, the Parties shall establish a joint steering committee (the “*Joint Steering Committee*” or the “*JSC*”), composed of [***] of senior officers of each Party (initially [***]) to oversee and guide the strategic direction of the collaboration of the Parties under this Agreement. The JSC shall in particular:

(a) coordinate the activities of the Parties under this Agreement, and provide a forum for and facilitate communications between the two Parties under this Agreement;

(b) discuss and determine a strategy for the Development and Commercialization of the Product in the ALFRESA Territory, and approve any (i) Development Plans, and ii) amendments to the Development Plan (including budgets therein);

(c) review and coordinate strategy for Regulatory Filings for the Product in the ALFRESA Territory;

(d) review and discuss the Commercialization Plan for Commercialization of the Product in the ALFRESA Territory;

(e) facilitate exchange of ARS Data and ALFRESA Data;

(f) direct and oversee operation of the JDC, JCC and any other joint subcommittee established by the JSC including attempts to resolve any disputed matters of these committees; and

(g) perform such other functions as appropriate to further the purpose of this Agreement, as expressly set forth in the Agreement or allocated to it by the Parties’ written agreement.

3.2 Joint Development Committee. Promptly after the Effective Date, the Parties shall establish a joint development committee (the “*Joint Development Committee*” or the “*JDC*”), composed of [***] representatives of each Party, to review and discuss the Development of Compositions and Products in the Field in the ALFRESA Territory (and if applicable pursuant to **Section 3.3**, outside the ALFRESA Territory for the purpose of Regulatory Approval in the ALFRESA Territory), at the operational level. Each JDC representative shall have knowledge and expertise in the clinical development of products similar to Products. The JDC shall in particular:

(a) coordinate and monitor the Development activities of the Parties, and report to the JSC on all significant Development activities in the ALFRESA Territory;

(b) provide a forum for and facilitate communications and coordination between the Parties with respect to the Development of Products in the ALFRESA Territory;

(c) review and approve any clinical trial protocols for the Products in the ALFRESA Territory, including investigator-initiated clinical trial plans and protocols, and statistical analysis plans (and any amendments thereto);

(d) review Data from clinical trials of the Product, including the EPI-JP-01 Study;

(e) review the status of Product manufacturing and supply activities associated with Development activities in the ALFRESA Territory;

(f) provide a forum for evaluation of Japanese regulatory actions, communications and submissions for the Products, and pharmacovigilance and safety matters in Japan; and

(g) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the activities leading up to Commercialization of Products, including endeavoring to resolve any disputes between the Parties arising from the deliberations of the JDC, or as otherwise directed by the JSC.

3.3 Joint Commercialization Committee. At a time to be determined by the JSC but in no event later than the commencement of the first filing of an MAA in the ALFRESA Territory, the Parties shall establish a joint commercialization committee (the “**Joint Commercialization Committee**” or the “**JCC**”), composed of [***] representatives of each Party, to monitor and discuss the Commercialization of Products in the Field in the ALFRESA Territory at the operational level. Each JCC representative shall have knowledge and expertise in the commercialization of products similar to Products. The JCC shall in particular:

(a) report to the JSC on significant Commercialization activities by ALFRESA in the ALFRESA Territory;

(b) review and recommend the Commercialization Plans and related activities;

(c) provide a forum for and facilitate communications and coordination between Parties with respect to Commercialization in the ALFRESA Territory;

(d) review the status of material Product manufacturing and supply activities and strategies associated with Commercialization in the ALFRESA Territory;

(e) review and discuss the major findings of ALFRESA’s market research with respect to any Product in the ALFRESA Territory, if any;

(f) review and discuss the branding and product positioning strategy for Products in the ALFRESA Territory and evaluate ALFRESA’s brand strategy for the Product in the ALFRESA Territory for consistency with the then-current global brand strategy for the Product;

(g) discuss Product list price and status of reimbursement in the ALFRESA Territory;

(h) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Commercialization of Products in the ALFRESA Territory, including endeavoring to resolve any disputes between the Parties arising from the deliberations of the JCC, or as otherwise directed by the JSC.

3.4 Committee Membership and Meetings.

(a) **Committee Members.** Each Committee representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make [***] arising within the scope of the applicable Committee’s responsibilities. Each Party may replace its representatives on any Committee on written notice to the other Party, but each Party shall strive to maintain continuity in the representation of its Committee members. Each Party shall appoint [***] of its representatives on each Committee to act as a co-chairperson of such Committee. The co-chairpersons shall jointly prepare and circulate agendas to Committee members at least [***] before each Committee meeting and shall direct the preparation of reasonably detailed minutes for each Committee meeting, which shall be approved by the co-chairpersons and circulated to Committee members within [***] of such meeting.

(b) Meetings. Each Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than [***], unless otherwise agreed by the Parties in writing. Upon reasonable written request by any Party to hold ad-hoc meetings, both Parties agree to schedule such ad-hoc meetings within a reasonable time frame. Meetings of any Committee may be held in person, or by audio or video teleconference; provided that unless otherwise agreed by both Parties, at least [***] per [***] for each Committee shall be held in person, and all in-person Committees shall be held at locations alternately selected by the Parties. Each Party shall be responsible for all of its own expenses of participating in any Committee meetings. No action taken at any meeting of a Committee shall be effective unless at least one representative of each Party is participating.

(c) Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend the Committee meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least [***] prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting [***]. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.5 Decision-Making. All decisions of each Committee shall be made by [***], with each Party's representatives collectively having [***] vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JDC, JCC or another subcommittee of the JSC, the representatives of the Parties cannot reach an agreement as to such matter within [***] after such matter was brought to such Committee for resolution, such disagreement shall be referred to the JSC for resolution. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as to such matter within [***] after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, such disagreement shall be referred to the Chief Executive Officer of ARS and the Chief Executive Officer of ALFRESA or its designee (collectively, the "*Executive Officers*") for resolution as follows:

(a) If such matter relates to [***], then the Executive Officers shall discuss in good faith a resolution of the matter that addresses both [***], and if the Executive Officers cannot resolve such matter within [***] after such matter has been referred to them, the [***] shall be entitled to make the final decision regarding such matter; provided that such decision shall be made in good faith consideration of the other Party's views on the matter, that such decision is not reasonably expected to directly affect [***], and that such decision shall be consistent with the terms and conditions of this Agreement.

(b) If such matter relates to [***], then the Executive Officers shall discuss in good faith a resolution of the matter, and if the Executive Officers cannot resolve such matter within [***] after such matter has been referred to them, the [***] shall be entitled to make the final decision regarding such matter; provided that such decision shall be made in good faith consideration of the other Party's views on the matter, that such decision is not reasonably expected to directly affect [***], and that such decision shall be consistent with the terms and conditions of this Agreement.

3.6 Limitations on Authority. Each Committee shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, no Committee will have the power to amend this Agreement, and no decision of a Committee may be in contravention of any terms and conditions of this Agreement.

3.7 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (the “*Alliance Manager*”). Each Alliance Manager shall be responsible for alliance management between the Parties on a day-to-day basis throughout the Term. Each Alliance Manager shall be permitted to attend meetings of the JSC and other Committees as appropriate as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the day-to-day activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JSC and its subcommittees.

4. DEVELOPMENT

4.1 Development Responsibilities.

(a) Development in the ALFRESA Territory. Subject to the terms and conditions of this Agreement, ARS (itself and with ARS Collaborators, as applicable) shall be responsible for all clinical trials that are necessary for or otherwise support Regulatory Approval in the ALFRESA Territory two Products: i) a [***], or equivalent, Product corresponding to a [***], and ii) a [***], or equivalent, Product corresponding to a [***]. [***] shall be responsible for the costs of the EPI-JP-01 Study and any duplication of the EPI-JP-01 Study if the EPI-JP-01 Study does not meet its objectives. [***] agree to [***] the Development Costs of any additional Development activities beyond the EPI-JP-01 Study that are required specifically for approval of these two Products in the ALFRESA Territory. Such additional Development activities required specifically for approval in the ALFRESA Territory and the Development Cost thereto shall be agreed to in writing by both ARS and ALFRESA, and [***] shall be responsible for conducting these activities unless agreed to otherwise. [***] shall provide [***] an invoice and reasonable documentation for the costs incurred by [***] for such Development Activities, on a [***] basis, and [***] shall pay [***] such costs as set forth in the invoice within [***] after receipt thereof, unless subject to a bona fide dispute. For clarity, [***] shall be responsible, at its sole cost and expense, for all clinical trials and activities related to post-approval marketing and commercialization tests in the ALFRESA Territory. ALFRESA may reasonably request that [***] conduct or assist [***] with other Development activities in the ALFRESA Territory on [***]’s behalf, at [***]’s expense. If [***] agrees to conduct or assist with any such activities (which [***] may accept or decline to do, in [***]’ sole discretion), the Parties shall amend the Development Plan accordingly, and [***] shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by [***] to conduct such activities in accordance with the Development Plan; provided that items and costs of such Development activities shall be discussed and agreed upon in advance between the Parties.

(b) Development Outside the ALFRESA Territory. Subject to Section 4.3, ARS (itself and with ARS Collaborators, as applicable) shall be responsible, at its sole cost and expense, for all Development of Compositions and Products that support obtaining and maintaining Regulatory Approval outside the ALFRESA Territory. ARS, itself or through ARS Collaborators, may conduct all such activities in its sole discretion.

4.2 Development Plan. Subject to **Section 4.1(a)** ARS shall conduct only such clinical trials that are necessary for or otherwise support Regulatory Approval solely in the ALFRESA Territory for: i) a [***], or equivalent, Product corresponding to a [***], and ii) [***], or equivalent, Product corresponding to a [***]. Any other Development activities for the ALFRESA Territory are the sole responsibility of [***], unless otherwise agreed to in writing by both Parties. The Parties intend that the plan for Development of Product in the ALFRESA Territory (as

such plan may be amended by the JSC, the “**Development Plan**”) will include detailed descriptions of each clinical trial described therein; including the design, enrollment criteria, endpoints and protocols thereof, as well as the regulatory strategy for Products throughout the ALFRESA Territory, and ARS will include all such information in the Development Plan when available. From time to time, but at least every [***], ARS will update the Development Plan and submit such updated plan to the JDC for review and discussion. The JDC will then submit the Development Plan to the JSC for review, discussion and approval.

4.3 Global Trials. If the Parties agree to conduct a Global Trial, then the Parties and, if applicable, the relevant ARS Collaborators shall discuss in good faith and determine the terms under which the Parties will conduct such Global Trial, including the allocation between the Parties of costs and expenses, decision-making process and authority for trial design and protocols, management of budget overages, allocation of Development activities and responsibilities and data sharing procedures. ALFRESA shall determine, in its sole discretion, whether and to what extent it participates in any cost-sharing or other activities related to Global Trials. ARS shall also determine, in its sole discretion, whether and to what extent it participates, and any of its ARS Collaborators participate, in any cost-sharing or other activities related to Global Trials. Upon agreement to conduct a Global Trial, the Parties shall enter into a written agreement setting forth all such agreed terms.

4.4 Conduct of Development Activities. ARS shall perform its obligations under this Agreement, in compliance with all Applicable Laws, including the FCPA and good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted. ALFRESA shall perform its obligations under this Agreement in compliance with all Applicable Laws, including the FCPA and good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

4.5 Records and Updates. ARS shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of ARS in the performance of Development activities pursuant to this Agreement. ARS shall keep the JSC regularly informed of the status of all Development activities with respect to Compositions and Products in the Field in the ALFRESA Territory conducted by it or on its behalf pursuant to this Agreement. Without limiting the foregoing, at least every [***], ARS shall provide the JSC with summaries in reasonable detail of all data and results generated or obtained in the course of ARS’ performance of activities with respect to Compositions and Products in the Field in the ALFRESA Territory. ALFRESA shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of ALFRESA in the performance of Development activities which ALFRESA agrees to perform pursuant to this Agreement. In addition, ALFRESA shall keep the JSC regularly informed of the status of all Development activities with respect to Compositions and Products conducted by it or on its behalf pursuant to this Agreement. Without limiting the foregoing, at least every [***], ALFRESA shall provide the JSC with summaries in reasonable detail of all data and results generated or obtained by or on behalf of ALFRESA in the performance of Development activities which ALFRESA agrees to perform pursuant to this Agreement.

4.6 Development Diligence. Both Parties shall use Commercially Reasonable Efforts to Develop Product in the Field throughout the ALFRESA Territory. Both Parties shall conduct all such activities in accordance with the Development Plan and Applicable Laws.

4.7 Materials Transfer. In order to facilitate the Development activities contemplated by this Agreement, either Party may provide to the other Party certain materials, including but not limited to, the drug substance and its related compounds including impurities, metabolites, references, standards and internal standards Controlled by the supplying Party (collectively, “**Materials**”) free of charge for use by the other Party solely for the purpose of performing its Development activities. For avoidance of doubt, ARS is obliged to supply Drug Product in accordance with Section 7.1 hereof. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the other Party’s Development activities conducted in accordance

with this Agreement, will not be used or delivered to or for the benefit of any Third Party, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used by the recipient Party with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. ARS shall provide the certificate of analysis for the Materials and represent and warrant that the qualities and standards of the Materials meet the specifications specified in the certificate of analysis. Except as expressly set forth in the preceding sentence, THE MATERIALS ARE PROVIDED “AS IS” AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

5. REGULATORY ACTIVITIES

5.1 Conduct of Regulatory Activities. ALFRESA shall be solely responsible for formulating regulatory strategy and for preparing, filing, obtaining and maintaining Regulatory Approvals for Products in the Field in the ALFRESA Territory. If the Regulatory Authority in the ALFRESA Territory requires reanalysis of any Product used in a clinical trial, ARS shall assist with such reanalysis subject to reimbursement by ALFRESA of costs incurred by ARS for such reanalysis. ALFRESA shall be the holder of all Regulatory Approvals for Products in the Field in the ALFRESA Territory and shall have responsibility for interactions with Regulatory Authorities with respect to Products in the Field in the ALFRESA Territory. ALFRESA shall use Commercially Reasonable Efforts to file MAAs and, as applicable, seek Pricing and Reimbursement Approval for and seek and maintain Regulatory Approval for Products in the Field throughout the ALFRESA Territory. ALFRESA shall conduct all such activities in accordance with Applicable Laws. ALFRESA shall consult with ARS either directly or through the JDC regarding, and keep ARS regularly informed of, the preparation, Regulatory Authority review and approval of submissions and communications with Regulatory Authorities with respect to Products in the Field in the ALFRESA Territory. In addition, ALFRESA shall promptly provide ARS with copies of any material documents, information and correspondence received from a Regulatory Authority with an English translation thereof and, upon reasonable request by ARS, with copies of any other documents, reports and communications from or to any Regulatory Authority relating to Compositions, Products or activities under this Agreement. Except as agreed otherwise by the Parties under **Section 4.3**, ALFRESA shall bear all expenses it incurs to conduct all regulatory activities in the ALFRESA Territory under this Agreement.

5.2 ARS Activities. ARS agrees to keep ALFRESA informed of the preparation, Regulatory Authority review and approval of submissions and communications with Regulatory Authorities with respect to Products in the Field outside the ALFRESA Territory. In addition, ARS shall, upon reasonable request by ALFRESA, promptly provide ALFRESA with copies of any material documents, information and correspondence received from a Regulatory Authority outside the ALFRESA Territory, to the extent the requested items are in ARS’s possession and for which ARS has the legal right to disclose and transfer. In the event that ARS Data shall be incorporated in the Regulatory Filing to obtain Regulatory Approvals in ALFRESA Territory, and ARS has been informed in writing of such ARS Data that have been so incorporated, ARS shall, to the extent the requested items are in ARS’s possession and for which ARS has the legal right to disclose and transfer, promptly provide ALFRESA copies of any modification, correction and revision of such ARS Data to fulfill ALFRESA’s obligation in Development and Regulatory Approval in the ALFRESA Territory. ALFRESA must fully disclose all such ARS Data that has been incorporated into the Regulatory Filing. Upon ALFRESA’s reasonable request and expense, ARS shall assist ALFRESA to fulfill the requirements of any Regulatory Agency in the ALFRESA Territory related to ARS Data incorporated in the Regulatory Filing in the ALFRESA Territory, and ALFRESA shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by ARS to conduct such activities, provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

5.3 Inspections and Audits.

(a) By Regulatory Authorities. In the event ALFRESA receives any correspondence, inquiry or request for an inspection or audit from a Regulatory Authority which relates to ARS Data or Product, ALFRESA shall promptly notify ARS in writing of such correspondence, inquiry or request of any inspection or audit. ARS shall cooperate with ALFRESA, at ALFRESA's expense, in responding to such correspondence, inquiry or any inspection or audit concerning such ARS Data, and ALFRESA shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by ARS to conduct such activities; provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

(b) By ALFRESA. In the event that ARS Data shall be incorporated in the Regulatory Filing to obtain Regulatory Approvals in ALFRESA Territory, ARS shall permit ALFRESA or its authorized representatives, which are subject to ARS' reasonable prior approval, to conduct a reasonable examination or quality inspection of such ARS Data (but no more than [***]).

5.4 Adverse Event Reporting; Pharmacovigilance Agreement. As between the Parties: (a) ARS shall be responsible for the timely reporting of all quality issues, complaints and Safety Data relating to Products to the appropriate Regulatory Authorities outside the ALFRESA Territory and shall timely report to ALFRESA the content of the report made to the Regulatory Authorities; and (b) except as otherwise agreed in writing by the Parties, ALFRESA shall be responsible for the timely reporting of all quality issues, complaints and Safety Data relating to Products to the relevant Regulatory Authorities in the ALFRESA Territory, in each case in accordance with Applicable Laws of the relevant countries and Regulatory Authorities. The Parties shall cooperate with each other with respect to their respective pharmacovigilance responsibilities, and each Party shall be solely responsible for its costs relating to its respective pharmacovigilance responsibilities, unless agreed otherwise by the Parties in writing. The Parties shall negotiate in good faith and enter into, in timely manner, a mutually acceptable pharmacovigilance agreement with respect to the Products. Until such pharmacovigilance agreement is established, ARS shall report quality issues, complaints and Safety Data relating to clinical trials in the ALFRESA Territory up until the submission of the application to regulatory authorities in the ALFRESA Territory. Unless otherwise mutually agreed, such pharmacovigilance agreement shall cover the exchange of safety information and appropriate management of pharmacovigilance activities to fulfill all legal and regulatory requirements both inside and outside of the ALFRESA Territory.

6. COMMERCIALIZATION

6.1 Commercialization. ALFRESA shall Commercialize Products in the Field in the ALFRESA Territory during the Term, subject to the terms and conditions of this Agreement. ALFRESA will perform all Product Commercialization activities, and [***] regarding such Product Commercialization, all at [***] cost. [***]: (a) establishing [***]; (b) establishing Product [***]; (c) [***] orders; (d) [***]; (e) [***]; and (f) [***].

6.2 Commercialization Plan. No later than [***] after the submission of the MAA for Product approval to Regulatory Authorities in the ALFRESA Territory, ALFRESA shall prepare a preliminary, non-binding commercialization plan for the marketing, promotion and pricing of Products in the Field in the ALFRESA Territory during the first [***] after First Commercial Sale in the ALFRESA Territory, which plan shall be reasonable in scope and detail and may be amended by ALFRESA (the "**Commercialization Plan**"). ALFRESA shall update the Commercialization Plan on a yearly basis and shall promptly provide each such update and any material amendments to each Commercialization Plan to ARS through the JCC. Without limiting the provisions of this **Section 6.2**, through the JCC, ALFRESA shall regularly consult with and provide updates to ARS regarding the Commercial Strategy and Commercialization of Products in the Field in the ALFRESA Territory.

6.3 Diligence. During the Term, ALFRESA shall use Commercially Reasonable Efforts to market, promote and otherwise Commercialize Products in the Field throughout the ALFRESA Territory. Without limiting the foregoing, ALFRESA shall use Commercially Reasonable Efforts to achieve First Commercial Sale of a Product in the ALFRESA Territory within a reasonable time, generally within [***] after the date on which ALFRESA is notified that the Product has received Regulatory Approval in the ALFRESA Territory.

6.4 Mutual Agreement. Subject to Applicable Laws, (a) neither ALFRESA nor its Affiliates or Sublicensees will engage in any advertising or promotional activities relating to any Product directed primarily to customers or other buyers or users of any Product located outside of the ALFRESA Territory or accept orders for Products from or sell Products into any country or jurisdiction outside the ALFRESA Territory for its own account, and, if ALFRESA receives any order for any Product for any country or jurisdiction outside the ALFRESA Territory, it shall refer such orders to ARS, and (b) neither ARS, its Affiliates, Licensees nor Sublicensees will engage in any advertising or promotional activities relating to any Product directed primarily to customers or other buyers or users of any Product located in the ALFRESA Territory or accept orders for Products from or sell Products into the ALFRESA Territory for its own account, and, if ARS receives any order for any Product for the ALFRESA Territory, it shall refer such orders to ALFRESA. Each Party will use reasonable efforts to monitor and prevent exports of Products from its own territory (the ALFRESA Territory as to ALFRESA, or outside the ALFRESA Territory as to ARS) for Commercialization in the other Party's territory using methods permitted under Applicable Laws that are commonly used in the industry for such purpose (if any).

7. MANUFACTURE AND SUPPLY

7.1 Development Supply.

(a) Obligations. Subject to the terms and conditions of the Development Supply Agreement, ARS, itself or through any Affiliate or CMO, shall supply all Products, in the form of drug product, which is the vial containing the active substance and the sprayer delivery device ("**Drug Product**") for all Development of Compositions and Products in the Field in the ALFRESA Territory to be conducted by ALFRESA or its Affiliate in accordance with this Agreement. The Parties will negotiate in good faith and enter into a separate Drug Product supply agreement (the "**Development Supply Agreement**"), along with a quality agreement, reasonably in advance of anticipated first Development supply of Drug Product to ALFRESA in the ALFRESA Territory. Unless agreed otherwise by the Parties in writing, all Drug Product supplied by ARS under this **Section 7.1** or the Development Supply Agreement shall be used solely to conduct Development in the Field in the ALFRESA Territory in accordance with the terms of this Agreement.

(b) Price. All Drug Product supplied by ARS for Development use will be supplied at a price of [***]. ARS will invoice ALFRESA within [***] after each shipment of Drug Product pursuant to **this Section 7.1**, and ALFRESA will pay each such invoice within [***] after receipt of the respective corresponding [***]. The price of such Drug Product may be changed due to an unexpected cost increase, such as a substantial increase of the raw materials costs, labor costs or subcontractor costs, or to adjust for inflation. In such case, ARS shall notify ALFRESA of the [***] changed price and reason for such change [***].

7.2 Commercial Supply.

(a) Commercial Supply Agreement. Unless and until elected otherwise by ALFRESA and the Manufacturing License Conditions have been satisfied, ARS, itself or through its Affiliate or CMO, shall manufacture and supply ALFRESA's and its Affiliates' and Sublicensees' requirements for Drug Product for commercial use in the ALFRESA Territory, pursuant to a separate commercial supply

agreement to be negotiated in good faith and entered into between the Parties (the “**Commercial Supply Agreement**”), along with a quality agreement, reasonably in advance of anticipated First Commercial Sale of Product in the ALFRESA Territory. In accordance with the terms of the Commercial Supply Agreement, ARS will supply Drug Product at a [***] of either (i) [***] of the NHI price for the Product, if the [***], or (ii) if the [***], then [***] to a fixed unit price for each Product at such time instead of [***] (as may be adjusted as described below, the “**Transfer Price**”). ARS will invoice ALFRESA within [***] after each shipment of Drug Product to ALFRESA pursuant to the Commercial Supply Agreement, and the payment terms for such invoice shall be determined in the Commercial Supply Agreement. Upon the mutual written agreement by both Parties (not to be unreasonably withheld or delayed), the Transfer Price of the Drug Product may be changed due to unexpected cost increase, such as [***]. In such case, ARS shall notify ALFRESA of the [***] changed Transfer Price and reason for such change [***]. For avoidance of doubt, ALFRESA is not obliged to agree on the [***] changed transfer price. Such notification of a changed Transfer Price shall be made in writing and made within a reasonable time after ARS became aware that an adjustment would be needed, and then the Parties shall negotiate in good faith to agree on the revision of the Transfer Price. [***].

(b) ALFRESA’s Manufacture and Transition. At any time, ALFRESA may elect to assume responsibility for manufacturing and supplying all of the Drug Product requirements for ALFRESA’s and its Affiliates’ and Sublicensees’ commercial use in the ALFRESA Territory; provided that (i) ALFRESA shall notify ARS in writing at least [***] prior to its anticipated establishment of such Drug Product supply, (ii) ARS shall have the right to reasonably evaluate the manufacturing capabilities and plan of ALFRESA, (iii) ALFRESA shall keep ARS reasonably informed of its progress in establishing such supply, and (iv) such assumption of responsibility for manufacture and supply shall not take place unless and until the Manufacturing Licensed Conditions have been met. Upon ARS’s receipt of such notice and satisfaction of the conditions in the proviso of the preceding sentence, ARS and ALFRESA will in good faith prepare and agree on a schedule and plan (including manufacturing technology transfer expenses, which will be borne solely by ALFRESA) pursuant to which ALFRESA (directly or through its Affiliate or CMOs) will assume all of such Drug Product manufacturing responsibility for commercial use in the ALFRESA Territory.

For clarity, in case ALFRESA assumes full responsibility for the manufacturing and supplying of Drug Product as described in the foregoing subsection (b), ARS shall not unreasonably refuse ALFRESA the right to use the CMO (including the CMO for the manufacturing of the starting material) that is the same as the one ARS used to manufacture Drug Product. The Parties agree to discuss in good faith a joint purchasing arrangement, to the extent permitted by Applicable Law.

If ALFRESA assumes responsibility for manufacturing and supplying Drug Product requirements per this **Section 7.2(b)**, then ARS and ALFRESA agree that ARS will receive royalties on Product net sales in the ALFRESA Territory equivalent to the monetary value ARS would have received by supplying Drug Product to ALFRESA at the Transfer Price on terms agreed in writing by ALFRESA and ARS.

7.3 Technical Transfer. If ALFRESA assumes responsibility for manufacturing and supplying Drug Product requirements pursuant to **Section 7.2(b)**, then upon reasonable written request from ALFRESA and at ALFRESA’s expense, ARS shall reasonably cooperate with ALFRESA or its designated Drug Product manufacturer, and provide ALFRESA or its designated Drug Product manufacturer, with technical assistance, and with respect to ARS Know-How for manufacturing, that is necessary in order to

enable ALFRESA to use such ARS Technology to manufacture and produce the Composition and Drug Product. ARS shall use Commercially Reasonable Efforts to complete such technical transfer within [***] after ARS's receipt such request. If ALFRESA assumes responsibility for manufacturing and supplying Drug Product requirements pursuant to **Section 7.2(b)**, upon reasonable written request from ALFRESA and at ALFRESA's expense, ARS shall reasonably cooperate with ALFRESA or its designated analytical testing facility, and provide ALFRESA or its designated analytical testing facility, with technical assistance, with respect to ARS Know-How for manufacturing in order to enable ALFRESA to use such ARS Technology to analyze the Drug Product manufactured by ALFRESA or its designated Drug Product manufacturer. ARS shall use Commercially Reasonable Efforts to complete such technical transfer within [***] after such request. ALFRESA shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by ARS to conduct such activities under this **Section 7.3**, provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

7.4 Information on Manufacture. To the extent ARS, itself or through any Affiliate or CMO, supplies Composition and Drug Product to ALFRESA for Development and Commercialization under this Agreement, ARS shall make available to ALFRESA all information, in its possession and that ARS has the legal right to transfer, that is relevant and necessary to the Manufacture of Composition and Drug Product, to enable ALFRESA to maintain or obtain the Regulatory Approval in the ALFRESA Territory. [***] shall use [***] to [***] that its [***] provide [***] access to and the right to use [***], to the extent that such information is [***] for Development or Commercialization of Products in the Field for the ALFRESA Territory, including preparation and filing of MAAs for a Product with the applicable Regulatory Authorities in the ALFRESA Territory, in accordance with this Agreement. ALFRESA shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by ARS to conduct such activities under this **Section 7.4**, provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

8. FEES AND PAYMENTS

8.1 Definitive Agreement Upfront Payment. ALFRESA shall make a one-time, non-refundable, non-creditable payment to ARS of two million U.S. dollars (\$2,000,000) within [***] after the Effective Date. ALFRESA may use dollar for dollar credit it receives for the payment of the Upfront Payment paid pursuant to the Letter of Intent entered into between the Parties on [***] that is worth [***] against the Definitive Agreement Upfront Payment in this **Section 8.1**.

8.2 Milestone Payments.

(a) Regulatory and Commercialization Milestone Payments.

(i) Within [***] after the first achievement of each Milestone Event below (whether by ALFRESA or any of its Sublicensees), ALFRESA shall pay to ARS the non-refundable, non-creditable Milestone Payment corresponding to such Milestone Event as shown below.

Regulatory and Commercialization Milestone Events	Milestone Payments (in U.S. Dollars)
[***]	[***]
[***]	[***]
[***]	[***]

(ii) For clarity, the Milestone Payments set forth in this **Section 8.2(a)** shall be payable only once, upon the first achievement of the applicable Milestone Event for the first Product in the Field in the ALFRESA Territory. Therefore, the maximum total amount payable under this **Section 8.2(a)** is \$13,000,000.

9. PAYMENT; RECORDS; AUDITS

9.1 Exchange Rate; Manner and Place of Payment. All references to dollars and “\$” herein shall refer to U.S. dollars. All references to yen and “¥” herein shall refer to the Japanese yen. All payments hereunder shall be payable in U.S. dollars. When conversion of payments from any currency other than U.S. dollars is required, Parties shall use the average rate of exchange for Japanese yen prevailing on the last day of each of the four calendar quarters during each year hereunder as published in The Wall Street Journal under the heading “Foreign Exchange,” unless otherwise agreed upon in writing by the Parties. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by ARS, unless otherwise specified in writing by ARS.

9.2 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible and in compliance with Applicable Laws, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective and intent. As such, ALFRESA shall not change the country from which its payments to ARS originate (which the Parties agree is Japan) without the prior written consent of ARS. The Parties shall cooperate to help ARS obtain benefits under any applicable tax treaty, including the reduction or exemption from any withholding tax and the procurement of any available tax refunds. ARS represents that it is a US tax resident and accordingly, is exempt from withholding on this payment under Article 12 of the Japan/US income tax treaty. ARS may extend the due date of the Upfront Payment to comply with applicable tax regulations.

(b) Payment of Tax. ARS will pay any and all taxes levied on its income on account of any payments made to it under this Agreement. If any taxes are required to be withheld by ALFRESA from any payment made to ARS under this Agreement, ARS will provide the Tax Withholding Avoidance Documents to ALFRESA prior to such payment to ARS for avoiding withholding taxes. Provided, that ALFRESA does not guarantee that the tax withholding is available and applicable. In case the Tax Withholding Avoidance Documents are not available to ALFRESA at the due date of such payments to ARS, ALFRESA will (i) deduct such taxes from the payment made to ARS, (ii) timely pay the taxes to the proper taxing authority, and (iii) send proof of such withholding tax payment to ARS and certify its receipt by the taxing authority within thirty (30) days following such payment. ALFRESA shall file for the refund of any withholding taxes paid within (30) days following the receipt of the Tax Withholding Avoidance Documents from ARS. The ALFRESA refund filing shall request that the amount of the refund be wired directly to an ARS authorized bank account.

9.3 Records; Audit. ALFRESA shall keep, and shall [***] its Sublicensees to keep, complete and accurate records pertaining to the sale or other transfer or disposition for value of Products in sufficient detail to permit ARS to confirm the accuracy of all payments due hereunder. Such records shall be kept for such period of time required by Applicable Laws, but no less than [***] following the end of the Calendar Year to which they pertain. ARS shall have the right to cause an independent, international, certified public accounting firm reasonably acceptable to ALFRESA to audit such records to confirm payments for a period covering not more than [***] Calendar Years following the Calendar Year containing the Calendar Quarter to which they pertain. Such audits may be exercised during normal business hours upon reasonable prior written notice to ALFRESA. Prompt adjustments shall be made by the Parties to reflect the results of such audit. ARS shall bear the full cost of such audit unless such audit discloses an underpayment by ALFRESA of more than [***] of the amount of payments due under this Agreement for any applicable Calendar Quarter, in which case, ALFRESA shall bear the cost of such audit and shall promptly remit to ARS the amount of any underpayment plus such audit costs. [***].

9.4 Late Payments. In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at the rate of [***] per annum; *provided, however*, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights and/or remedies it may have as a consequence of the lateness of any payment.

10. INTELLECTUAL PROPERTY

10.1 Ownership.

(a) Data. All Data generated in connection with any Development, regulatory, manufacturing or Commercialization activities with respect to any Composition or Product conducted by or on behalf of ALFRESA or its Affiliates or Sublicensees (the "**ALFRESA Data**") shall be the sole and exclusive property of ALFRESA or its Affiliates or Sublicensees, as applicable; *provided, however*, ALFRESA is obligated to provide and shall provide all ALFRESA Data to ARS upon ARS's reasonable request. For avoidance of doubt, ALFRESA shall remain the holder of all the rights and titles in and to the ALFRESA Data provided pursuant to the immediately preceding sentence. All Data generated in connection with any Development, regulatory, manufacturing or Commercialization activities with respect to any Composition or Product conducted by or on behalf of ARS and its Affiliates and ARS Collaborators (the "**ARS Data**"), shall be the sole and exclusive property of ARS or its Affiliates or ARS Collaborators, as applicable.

(b) Inventions. Inventorship of any Inventions will be determined in accordance with the standards of inventorship and conception under U.S. patent laws. The Parties will work together to resolve any issues regarding inventorship or ownership of Inventions. Ownership of Inventions will be allocated as follows:

(i) Inventions discovered, made, or conceived as a result of performance under this Agreement solely by one (1) or more employees or contractors of ARS or its Affiliates, and Patents claiming such Inventions, after the Effective Date and during the Term of this Agreement, shall be solely owned by ARS, and Inventions discovered, made, or conceived as a result of performance under this Agreement solely by one (1) or more employees or contractors of ALFRESA or its Affiliates, and Patents claiming such Inventions, after the Effective Date and during the Term of this Agreement, shall be solely owned by ALFRESA.

(ii) Joint Inventions and Joint Patents shall be jointly owned by ARS and ALFRESA. The proportional ratio in the ownership of the Joint Invention shall be fifty percent to fifty percent (50%: 50%) in principle, provided, that such proportional ratio may be amended by mutual agreement between ARS and ALFRESA. Subject to the rights and licenses granted under this Agreement, each Party shall have the right to use, and to grant licenses to use, any Joint Invention and Joint Patents in its own territory (ALFRESA in the ALFRESA Territory and ARS outside of the ALFRESA Territory) without the other Party's written consent, and without a duty to account to the other Party for such use or license, provided however, that each Party shall notify the other Party in writing on each such license granted to the Third Party, and each Party hereby waives any right it may have under the laws of any country to require any such consent or accounting.

10.2 Patent Prosecution and Maintenance.

(a) ARS Patents.

(i) Subject to this **Section 10.2(a)**, ARS shall have the sole right, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all ARS Patents worldwide, at its sole cost and expense and by counsel of its own choice, provided, that as for ALFRESA Territory, ARS shall be obliged to prepare, file, prosecute (including any interferences, reissue proceedings and re-examinations) and maintain all of ARS Patents at ARS's cost. ARS shall keep ALFRESA reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of ARS Patents, including content, timing and jurisdiction of the filing of such ARS Patents, and shall consult with, and consider in good faith the requests and suggestions of, ALFRESA with respect to strategies for filing and prosecuting ARS Patents in the ALFRESA Territory; provided that ARS will make all final decisions regarding the ARS Patents.

(ii) In the event that ARS desires to abandon or cease prosecution or maintenance of any ARS Patent in the ALFRESA Territory (“*Discontinued ARS Patent*”), ARS shall provide reasonable prior written notice to ALFRESA of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such ARS Patent in the relevant patent office). In such case, upon ALFRESA’s written election provided to ARS no later than [***] after such notice from ARS, ALFRESA shall have the right to assume prosecution and maintenance of such Discontinued ARS Patent at ALFRESA’s expense. When ALFRESA assumes prosecution and maintenance of such Discontinued ARS Patent and requires assistance or approval from joint patent holder of ARS Patents in such prosecution and maintenance procedure, ARS shall procure that such joint patent holder of ARS Patents provides necessary assistance and approval. In such case, ALFRESA shall keep ARS regularly and reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of each of such Discontinued ARS Patents, including content, timing and jurisdiction of the filing of such Discontinued ARS Patents, and shall consult with, and consider in good faith the requests and suggestions of, ARS with respect to strategies for filing and prosecuting such Discontinued ARS Patents (particularly to avoid prosecution inconsistencies with ARS Patents in and outside the ALFRESA Territory that ARS has not abandoned). If ALFRESA does not provide such election within such [***] after such notice from ARS, ARS may, in its sole discretion, continue prosecution and maintenance of such ARS Patent or discontinue prosecution and maintenance of such ARS Patent. For avoidance of doubt, when ALFRESA assumes prosecution and maintenance procedure of Discontinued ARS Patent and such Discontinued ARS Patent is registered in Japan Patent Office, as a result of abandonment of Discontinued ARS Patent, ALFRESA shall become the owner and patent holder of such Discontinued ARS Patent (co-owner if there is joint patent holder in such Discontinued ARS Patent), and for the purpose of this Agreement such Discontinued ARS Patent shall be treated and regarded as ARS Patent, provided, that in such case, ARS and ALFRESA shall negotiate in good faith to amend the amount of Milestone Payments and/or transfer price of the Drug Products in the Commercial Supply Agreement.

(b) ALFRESA Patents.

(i) Subject to this **Section 10.2(b)**, ALFRESA shall have the sole right, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all ALFRESA Patents worldwide, at its sole cost and expense and by counsel of its own choice. ALFRESA shall keep ARS reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of the ALFRESA Patents, including content, timing and jurisdiction of the filing of such ALFRESA Patents, and shall consult with, and consider in good faith the requests and suggestions of, ARS with respect to strategies for filing and prosecuting ALFRESA Patents; provided that ALFRESA will make all final decisions regarding the ALFRESA Patents. If ALFRESA desires to not prepare, file or prosecute ALFRESA Patents in countries outside the ALFRESA Territory, ALFRESA shall provide reasonable prior written notice to ARS of such intention (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such ALFRESA Patent in the relevant patent office). In such case, upon ARS’ written election provided to ALFRESA no later than [***] after such notice from ALFRESA, ARS may, in its sole discretion and at its own expense, continue prosecution and maintenance of such ALFRESA Patent or discontinue prosecution and maintenance of such ALFRESA Patent outside of the ALFRESA Territory.

(ii) In the event that ALFRESA desires to abandon or cease prosecution or maintenance of any ALFRESA Patent (“**Discontinued ALFRESA Patent**”), ALFRESA shall provide reasonable prior written notice to ARS of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such ALFRESA Patent in the relevant patent office). In such case, upon ARS’s written election provided to ALFRESA no later than [***] after such notice from ALFRESA, ARS shall have the right to assume prosecution and maintenance of such Discontinued ALFRESA Patent at ARS’s expense. In such case, ARS shall keep ALFRESA regularly and reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of each of such Discontinued ALFRESA Patents, including content, timing and jurisdiction of the filing of such Discontinued ALFRESA Patents, and shall consult with, and consider in good faith the requests and suggestions of, ALFRESA with respect to strategies for filing and prosecuting such Discontinued ALFRESA Patents (particularly to avoid prosecution inconsistencies with ALFRESA Patents that ALFRESA has not abandoned). If ARS does not provide such election within [***] after such notice from ALFRESA, ALFRESA may, in its sole discretion, continue prosecution and maintenance of such ALFRESA Patent or discontinue prosecution and maintenance of such ALFRESA Patent.

(c) Joint Patents.

(i) ARS shall have the first right, to prepare, file, prosecute (including any interferences, reissue proceedings and re-examinations) and maintain Joint Patents using a patent counsel selected by ARS and reasonably acceptable to ALFRESA. ALFRESA shall reimburse ARS for all external patent fees and costs incurred with respect to the preparation, filing, prosecution and maintenance of Joint Patents in the ALFRESA Territory within [***] from the date of invoice for such costs and expenses provided by ARS. In the event that ALFRESA does not reimburse ARS for such external patent fees and costs for any Joint Patent in the ALFRESA Territory, or ALFRESA notifies ARS in writing that it elects to cease reimbursing ARS for such external patent fees and costs for any Joint Patent in the ALFRESA Territory, ALFRESA shall promptly execute such documents and perform such acts, at ALFRESA’s expense, as may be reasonably necessary to effect an assignment of ALFRESA’s entire right, title, and interest in and to such Joint Patent to ARS, and such Patent shall cease to be either a Joint Patent or an ARS Patent and shall no longer be subject to the licenses and other rights granted by ARS to ALFRESA under this Agreement. ARS shall keep ALFRESA reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Joint Patent (assigned to ARS) in the ALFRESA Territory; provided that ARS will make all final decisions regarding such Joint Patents that are assigned to ARS.

(ii) In the event that ARS desires to abandon or cease prosecution or maintenance of any Joint Patent in the ALFRESA Territory (except in the event the Parties mutually decide to abandon or cease prosecution, maintenance or enforcement of such Joint Patent) (“**Discontinued Joint Patent**”), ARS shall provide reasonable prior written notice to ALFRESA of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Discontinued Joint Patent in the relevant patent office). In such case, ALFRESA may elect to continue prosecution or maintenance of such Joint Patent in the ALFRESA Territory at its sole discretion and own expense, in which case, all of ARS’s rights in such Joint Patent in the ALFRESA Territory shall be assigned to ALFRESA. ARS shall promptly execute such documents and perform such acts, at its own expense, as may be reasonably necessary to effect an assignment of its entire right, title, and interest in and to such Joint Patent in the ALFRESA Territory to ALFRESA. Any such assignment shall be completed in a timely manner to allow ALFRESA to continue prosecution and maintenance of such Discontinued Joint Patent and such Discontinued Joint Patent so assigned and shall no longer be subject to the licenses and other rights granted by ARS to ALFRESA under

this Agreement. ALFRESA shall keep ARS reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Discontinued Joint Patent in the ALFRESA Territory (particularly to avoid prosecution inconsistencies with ARS Patents and Joint Patents that ARS has not abandoned); provided that ALFRESA will make all final decisions regarding such Discontinued Joint Patents in the ALFRESA Territory that are assigned to ALFRESA.

10.3 Cooperation of the Parties. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Patents under **Section 10.2** and in the obtaining and maintenance of any extensions, supplementary protection certificates and their equivalent with respect thereto respectively, at its own cost (except as expressly set forth otherwise in this **Article 10**). Such cooperation includes: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, reasonably requested by the other Party so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by **Section 10.2**; and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

10.4 Infringement by Third Parties.

(a) Notice. In the event that either ARS or ALFRESA becomes aware of any infringement or threatened infringement by a Third Party of any ARS Patent, ALFRESA Patent or Joint Patent, or any declaratory judgment or equivalent action challenging any ARS Patent, ALFRESA Patent or Joint Patent in connection with any such infringement, it will promptly notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, filed by such Third Party.

(b) ARS Patents.

(i) Subject to this **Section 10.4(b)**, ARS shall have the sole right, but not the obligation, as between ARS and ALFRESA, to bring and control any action or proceeding with respect to infringement or challenge of any ARS Patent outside the ALFRESA Territory at its own expense and by counsel of its own choice. Subject to **Section 10.4 (b)**, and to the extent stipulated under the Provisional Exclusive License or Exclusive License, ALFRESA shall have the first right, as between ARS and ALFRESA, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any ARS Patent in the ALFRESA Territory, at its own expense and by counsel of its own choice. In such case, ARS's counsel will reasonably cooperate with ALFRESA and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the ALFRESA Territory. When ARS becomes a party to such action in the ALFRESA Territory, ARS shall have the right, at its own expense, to be represented in any such action, by counsel of ARS's own choice, and ALFRESA and its counsel will reasonably cooperate with ARS and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the ALFRESA Territory. If ALFRESA fails to bring an action or proceeding with respect to infringement of any ARS Patent in the ALFRESA Territory within (A) [***] following receipt or delivery (as applicable) of the notice of alleged infringement or (B) [***] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then following a discussion with ARS regarding the reasons why ALFRESA did not bring such action or proceeding, which reasons ARS shall consider in good faith, ARS shall have the right, but not the obligation, to bring and control such action or proceeding in the ALFRESA Territory at its own expense and by counsel of its own choice, and ALFRESA shall have the right, at its own expense, to be represented in any such action or proceeding by counsel of its own choice. ARS and its counsel will reasonably cooperate with ALFRESA and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the ALFRESA Territory.

(ii) Except as otherwise agreed by the Parties in writing as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to ARS Patents shall be used first to reimburse the Parties' documented out-of-pocket legal expenses incurred in such action or proceeding on a pro rata basis, and any remaining compensatory, punitive, or other damages that were awarded in respect of Products (including awards made in respect of lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding.

(c) ALFRESA Patents.

(i) ALFRESA shall have the sole right, as between ARS and ALFRESA, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any ALFRESA Patent in the ALFRESA Territory at its own expense and by counsel of its own choice, subject to this **Section 10.4(c)(i)**. Any recovery or damages realized as a result of such action or proceeding by ALFRESA with respect to ALFRESA Patents in the ALFRESA Territory shall be used first to reimburse the Parties' documented out-of-pocket legal expenses incurred in such action or proceeding on a pro rata basis, and any remaining compensatory, punitive, or other damages that were awarded in respect of Products (including awards made in respect of lost sales or lost profits with respect to Products) shall be retained by ALFRESA.

(ii) Subject to this **Section 10.4(c)(ii)**, ARS shall have the first right, as between ARS and ALFRESA, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any ALFRESA Patent outside the ALFRESA Territory, at its own expense and by counsel of its own choice. ALFRESA shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and ARS and its counsel will reasonably cooperate with ALFRESA and its counsel in strategizing, preparing and prosecuting any such action or proceeding outside the ALFRESA Territory. If ARS fails to bring an action or proceeding with respect to infringement of any ALFRESA Patent outside the ALFRESA Territory within (A) [***] following receipt or delivery (as applicable) of the notice of alleged infringement or (B) [***] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then following a discussion with ARS regarding the reasons why ARS did not bring such action or proceeding, which reasons ALFRESA shall consider in good faith, ALFRESA shall have the right, but not the obligation, to bring and control any such action outside the ALFRESA Territory at its own expense and by counsel of its own choice, and ARS shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. ALFRESA and its counsel will reasonably cooperate with ARS and its counsel in strategizing, preparing and prosecuting any such action or proceeding outside the ALFRESA Territory. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to ALFRESA Patents outside the ALFRESA Territory shall be used first to reimburse the Parties' documented out-of-pocket legal expenses incurred in such action or proceeding on a pro rata basis, and any remaining compensatory, punitive, or other damages that were awarded in respect of Products (including awards made in respect of lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding.

(d) Joint Patents.

(i) Subject to this **Section 10.4(d)(i)**, ALFRESA shall have the first right, as between ALFRESA and ARS, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any Joint Patent in the ALFRESA Territory, at its own expense and by counsel of its own choice, and ARS shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. ALFRESA and its counsel will reasonably cooperate with ARS and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the ALFRESA Territory. If ALFRESA fails to bring an action or proceeding with respect to infringement or challenge of any Joint Patent in the ALFRESA Territory within (A) [***] following the notice of alleged infringement or (B) [***] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then following a discussion with ALFRESA regarding the reasons why ALFRESA did not bring such action or proceeding, which reasons ARS shall consider in good faith, ARS shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and ALFRESA shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. ALFRESA and its counsel will reasonably cooperate with

ARS and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the ALFRESA Territory. Except as otherwise agreed by the Parties in writing as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Joint Patents in the ALFRESA Territory shall be used first to reimburse the Parties' documented out-of-pocket legal expenses incurred in such action or proceeding on a pro rata basis, and any remaining compensatory, punitive, or other damages were awarded in respect of Products (including awards made in respect of lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding.

(ii) Subject to this **Section 10.4(d)(ii)**, ARS shall have the sole right, as between ARS and ALFRESA, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any Joint Patent outside the ALFRESA Territory, at its own expense and by counsel of its own choice, and ALFRESA shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed by the Parties in writing as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Joint Patents outside the ALFRESA Territory shall be used first to reimburse the Parties' documented out-of-pocket legal expenses incurred in such action or proceeding on a pro rata basis, and any remaining compensatory, punitive, or other damages awarded in respect of Products (including awards made in respect of lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding.

(e) Cooperation. In the event a Party brings an action in accordance with this **Section 10.4**, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party to such action.

10.5 Infringement of Third Party Rights. Each Party shall promptly notify the other Party in writing of any allegation by a Third Party that the manufacture, Development, importation, use, marketing, offer for sale or sale of any Composition or Product in the ALFRESA Territory infringes or may infringe the intellectual property rights of a Third Party (each an "**Infringement Claim**"). The notice shall set forth the facts of the Infringement Claim in reasonable detail, to the extent such notifying Party has the right to disclose them. ALFRESA shall have the first right to control any defense of any such Infringement Claim at its own expense and by counsel of its own choice, and ARS shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If ALFRESA fails to defend against such Infringement Claim action, or notifies ARS that it does not intend to defend against such Infringement Claim action, within (A) [***] following the notice of alleged infringement or (B) [***] before the time limit, if any, set forth in the appropriate laws and regulations for the response to such action, whichever comes first, ARS shall have the right, but not the obligation, to defend any such Infringement Claim action at its own expense and by counsel of its own choice, and ALFRESA shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

10.6 Consent for Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any action or proceeding under this **Article 10** that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld, conditioned or delayed.

10.7 Trademarks. ALFRESA shall own and be responsible for all trademarks, trade names, branding or logos related to Commercialization of Products in the Field in the ALFRESA Territory. Subject to consultation with ARS through the JDC, ALFRESA shall be responsible for selecting, registering, prosecuting, defending, and maintaining all such marks at ALFRESA's sole discretion, cost and expense. ARS shall not own all trademarks, trade names, branding or logos related to Commercialization of Products in the Field in the ALFRESA Territory and shall not, directly or indirectly through any Third Parties, register or prosecute any trademarks, trade names, branding or logos related to Commercialization of Products in the Field in the ALFRESA Territory, without obtaining prior written approval by ALFRESA.

10.8 ARS Controlled Patents Outside the ALFRESA Territory. For clarity, ARS reserves all rights to prepare, file, prosecute (including any interferences, reissue proceedings and re-examinations), maintain, defend and enforce all Patents owned or controlled by ARS related to Compositions and Products outside the ALFRESA Territory (other than Joint Patents, which are subject to this **Article 10**). In the event that ARS becomes aware of any infringement or threatened infringement by a Third Party of any ARS Patent outside the ALFRESA Territory, or any declaratory judgment or equivalent action challenging any ARS Patent in connection with any such infringement outside the ALFRESA Territory, ARS shall notify ALFRESA in writing to that effect.

11. REPRESENTATIONS AND WARRANTIES

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it, and (d) it has the right to grant the licenses granted by it under this Agreement.

11.2 Mutual Covenants. Each Party hereby covenants to the other Party as follows:

(a) Each Party shall conduct, and shall use Commercially Reasonable Efforts to cause its Sublicensees, contractors, and consultants to conduct, all of its activities contemplated under this Agreement in accordance with all applicable laws and regulations.

(b) Neither Party will use in any capacity, in connection with the Development, manufacture or Commercialization of any Product, any individual or entity who has been Debarred. Each Party shall inform the other Party in writing immediately upon becoming aware that any individual or entity who is performing hereunder is Debarred, or if any claim is pending or, to the best of such Party's knowledge, is threatened, relating to the Debarment of such Party or any individual or entity used in any capacity by such Party in connection with the Development, manufacture or Commercialization of any Product. "**Debarred**" means, with respect to an individual or entity, that such an individual or entity (a) is debarred by the FDA pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act ("**FDCA**"), or is the subject of a conviction described in such section (or subject to a similar sanction of any other applicable Regulatory Authority), (b) is the subject of an FDA debarment investigation or proceeding (or similar proceeding of any other applicable Regulatory Authority), or (c) has been charged with or convicted under U.S. Law for conduct relating to the development or approval, or otherwise relating to the regulation, of any product under the Generic Drug Enforcement Act of 1992.

11.3 Additional ARS Representations and Warranties. ARS represents and warrants to ALFRESA that, as of the Effective Date:

(a) Exhibit 1 is a complete and correct list of all ARS Patent Rights in the ALFRESA Territory that are being licensed to ALFRESA under Section 2.1;

(b) ARS is the owner or co-owner, as the case may be, of all ARS Patents listed in Exhibit 1;

(c) ARS has obtained from all individuals and entities that participated with ARS in the invention of any ARS Patents effective assignments of all ownership rights of such individuals and entities in such ARS Patents either pursuant to written agreements or by operation of law;

(d) ARS has filed and prosecuted patent applications within the ARS Patents in Alfresa Territory and has complied with all duties of disclosure with respect thereto under Applicable Laws;

(e) all application, registration, maintenance and renewal fees in respect of the ARS Patents have been paid and to ARS's knowledge, all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining such ARS Patents;

(f) ARS has not received any written notice or does not otherwise have knowledge prior to Effective Date that ARS Patent or Product has infringed or would infringe any Third Party Patents;

(g) ARS has not, of the Effective Date, granted any Third Party rights under the ARS Technology or to Develop, Manufacture, register, use or Commercialize the Product in the Alfresa Territory that would interfere or be inconsistent with Alfresa's rights hereunder, and there are no agreements or arrangements to which ARS or any of its Affiliates is a party relating to the Product, ARS Patents or ARS Know-How that would limit the rights granted to Alfresa under this Agreement, except for the terms of License Agreement dated as of [***] between ARS and [***] under which ARS licensed or acquired any ARS Patents or ARS Know-How from [***], as disclosed by ARS to ALFRESA; and no rights granted to Alfresa pursuant to this Agreement are in violation of any agreement between ARS or any of its Affiliates and any Third Party;

(h) ARS does not own or Control any Patent or other intellectual property right that dominates the subject matter of the claims set forth in the ARS Patents or that would otherwise prevent Alfresa from exploiting the license granted to it under the ARS Technology to Develop, Manufacture, register, use or Commercialize the Product in the ALFRESA Territory under this Agreement;

(i) ARS has not received any written notice and does not otherwise have knowledge that ARS Know-How would misappropriate the know-how of any Third Party;

(j) ARS has not initiated or been involved in any proceedings or claims in which it alleges that any Third Party is or was infringing or misappropriating any ARS Patents and ARS Know-how;

(k) To the best knowledge of ARS, no officer or employee of ARS is subject to any agreement with any other Third Party which requires such officer or employee to assign any interest in any ARS Patent or ARS Know-how relating to the Product in the Field and in the Alfresa Territory to any Third Party;

(l) ARS has taken all reasonable precautions to preserve the confidentiality of the ARS Know-How that is existing and documented as of the Effective Date;

(m) The documents containing ARS Patents, ARS Data and ARS Know-How disclosed or made available by ARS to Alfresa are true and accurate copies of what they purport to be. ARS has made available to Alfresa all ARS Patent, ARS Data and ARS Know-How and other relevant information in ARS' possession or control relating to the Development, Manufacture and Commercialization of the Product. Without limiting the foregoing, ARS has disclosed to Alfresa any information known to ARS with respect to (i) the safety of the Product, and (ii) the efficacy of the Product, and (iii) any then existing circumstance which would be, to the best knowledge of ARS, likely to prevent or restrict the Development, Manufacturing and/or Commercialization of the Products and Compositions in the ALFRESA Territory;

(n) joint patent holder of ARS Patent acknowledges, agrees and approves to the grant of license pursuant to this Agreement to ALFRESA and ALFRESA's application for the registration of Provisional Exclusive License and Exclusive License to Japan Patent Office pursuant to this Agreement.

11.4 Disclaimer. Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing, (a) neither Party represents or warrants that any data obtained from conducting clinical trials in one country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted by pursuant to this Agreement or the safety or usefulness for any purpose of the technology it provides hereunder.

12. INDEMNIFICATION

12.1 Indemnification by ARS. ARS hereby agrees to defend, indemnify and hold harmless ALFRESA, its Sublicensees and their respective directors, officers, employees and agents (each, an “**ALFRESA Indemnitee**”) from and against any and all liabilities, expenses and losses, including reasonable legal expenses and attorneys’ fees (collectively, “**Losses**”), to which any ALFRESA Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, sale or other disposition of any Composition or Product by ARS or its Affiliates or ARS Collaborators (excluding any activities by or on behalf of ALFRESA or its Affiliates or Sublicensees), (b) the negligence or willful misconduct of any ARS Indemnitee, or (c) the breach by ARS of any warranty, representation, covenant or agreement made by ARS in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of the negligence or willful misconduct of any ALFRESA Indemnitee or the breach by ALFRESA of any warranty, representation, covenant or agreement made by ALFRESA in this Agreement.

12.2 Indemnification by ALFRESA. ALFRESA hereby agrees to defend, indemnify and hold harmless ARS, its Affiliates and the ARS Collaborators and their respective directors, officers, employees and agents (each, an “**ARS Indemnitee**”) from and against any and all Losses to which any ARS Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, sale or other disposition of any Composition or Product by ALFRESA or its Affiliates or Sublicensees (excluding any activities by or on behalf of ARS or its Affiliates or ARS Collaborators), (b) the negligence or willful misconduct of any ALFRESA Indemnitee, or (c) the breach by ALFRESA of any warranty, representation, covenant or agreement made by ALFRESA in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of the negligence or willful misconduct of any ARS Indemnitee or the breach by ARS of any warranty, representation, covenant or agreement made by ARS in this Agreement.

12.3 Procedure. A Party that intends to claim indemnification under this **Article 12** (the “**Indemnitee**”) shall promptly notify the indemnifying Party (the “**Indemnitor**”) in writing of any Third Party claim, demand, action or other proceeding (each, a “**Claim**”) in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate at its expense in the Indemnitor’s defense of and settlement negotiations for any Claim with counsel of the Indemnitee’s own selection. The indemnity arrangement in this **Article 12** shall not apply to amounts paid in settlement of any action with respect to a Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this **Article 12** if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

12.4 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

12.5 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF **ARTICLE 13** AND UNLESS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *PROVIDED, HOWEVER, THAT THIS SECTION 12.5 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY’S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 12.*

13. CONFIDENTIALITY

13.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other (disclosing) Party under this Agreement, and both receiving Parties shall keep confidential and, subject to **Sections 13.2, 13.3 and 13.5**, shall not publish or otherwise disclose the terms of this Agreement. Each receiving Party may use the disclosing Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations. Each receiving Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors and other representatives do not disclose or make any unauthorized use of the disclosing Party's Confidential Information. Each receiving Party will promptly notify the disclosing Party upon discovery of any unauthorized use or disclosure of the disclosing Party's Confidential Information.

13.2 Exceptions. The obligations of confidentiality and restriction on use under **Section 13.1** will not apply to any information that the receiving Party can demonstrate through contemporaneous written records: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party or its representatives, generally known or available to the public; (b) is known by the receiving Party at the time of receiving such information, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, or contractors; (c) is hereafter furnished to the receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the receiving Party without the use of Confidential Information belonging to the disclosing Party.

13.3 Authorized Disclosure. Each receiving Party may disclose Confidential Information belonging to the disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;

(b) regulatory filings for Products (for ALFRESA, only in the ALFRESA Territory) that such Party has a license or right to Develop hereunder in a given country or jurisdiction;

(c) prosecuting or defending litigation arising under this Agreement;

(d) complying with applicable court orders or governmental regulations; and

(e) disclosure to its and its Affiliates' employees, contractors and agents, to ARS Collaborators (in the case of ARS) and to Sublicensees (in the case of ALFRESA), in each case on a need-to-know basis in connection with the Development and manufacture of Compositions, and Development, manufacture and Commercialization of Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and

(f) disclosure to potential and actual investors, acquirers, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration in such receiving Party, in each case under written or professional obligations of confidentiality and non-use at least as stringent as those herein.

Notwithstanding the foregoing, in the event a receiving Party is required to make a disclosure of the disclosing Party's Confidential Information pursuant to **Section 12.3(c)** or **(d)**, and before making any such disclosure, it will, except where impracticable or prohibited, give prompt advance written notice to the disclosing Party of such requirement and its intended disclosure, and shall cooperate with the disclosing Party's efforts to limit or avoid such disclosure and/or to seek a protective order, confidential treatment of such Confidential Information or other available remedy. In any event, the Parties agree to take all reasonable action to avoid disclosure of a disclosing Party's Confidential Information hereunder. Any information disclosed pursuant to **Section 12.3(c)** or **(d)** shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this **Article 13**.

13.4 Publications. Each Party shall have the right to review and comment on any material proposed for public disclosure or publication by the other Party regarding results of and other information regarding the other Party's Development or Commercialization activities with respect to Products, whether by oral presentation, manuscript or abstract, or other means of public disclosure, and including disclosures to the investment community, if such proposed public disclosure or publication might negatively affect Development and/or Commercialization of Products in the ALFRESA Territory (for ARS publications) or outside the ALFRESA Territory (for ALFRESA publications), as the case may be. For the sake of clarity, any press release by a Party shall follow the process set forth in **Section 13.5** below, and not the process contained in this **Section 13.4**. Before any such material described in this Section 13.4 is submitted for publication or presentation of any such material is made, the receiving Party that proposed to publish or publicly disclose such material shall deliver a complete copy to the disclosing Party prior to submitting the material to a publisher or initiating any other public disclosure. Each disclosing Party shall review any such material and give its comments to the receiving Party as soon as practicable. With respect to oral presentation materials and abstracts, each disclosing Party shall make reasonable efforts to expedite review of such oral presentation materials and abstracts, and shall return its comments if any, on such items as soon as practicable to the receiving Party. Each receiving Party shall comply with the disclosing Party's request to delete references to the disclosing Party's Confidential Information in any such material and will delay any submission for publication or other public disclosure for a period of up to an additional ninety (90) days for the purpose of preparing and filing appropriate patent applications.

13.5 Publicity; Public Disclosures. The Parties will issue an initial press release substantially in the form agreed to prior to the Effective Date, on or as promptly as practicable following, the application for Regulatory Approval to PMDA. It is understood that each Party may desire or be required to issue subsequent press releases relating to this Agreement or activities hereunder. The Parties will consult with each other reasonably and in good faith with respect to the text and timing of all press releases prior to the issuance thereof, to the extent practicable, provided that a Party may not unreasonably withhold, condition or delay consent to such press releases, and that either Party may issue such press releases or make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following the initial press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

13.6 Prior Confidentiality Agreement. As of the Effective Date, the terms of this **Article 13** shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

13.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party may suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this **Article 13**. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this **Article 13**.

14. TERM AND TERMINATION

14.1 Term. This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this **Article 14** or by mutual written agreement of the Parties, shall continue until the latest of (i) expiration of the last-to-expire Valid Claim of the ARS Patents and Joint Patents covering the composition, method of manufacture or method of use in the Field of any Product in the ALFRESA Territory; or (ii) [***] after the First Commercial Sale of any Product in the ALFRESA Territory (the “**Term**”). Upon expiration (but not termination) of this Agreement, ALFRESA’s licenses under **Section 2.1** will become perpetual, irrevocable, non-exclusive, fully paid-up and royalty free.

14.2 Termination for Cause.

(a) Material Breach. Each Party shall have the right to terminate this Agreement in its entirety upon written notice of termination delivered to the other Party, if such other Party materially breaches this Agreement and has not cured such breach within [***] ([***] with respect to any payment breach) after receipt of written notice from the non-breaching Party describing such breach and demanding its cure.

(b) Bankruptcy. Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files a voluntary insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within [***] after the commencement thereof.

14.3 Termination for Patent Challenge. ARS shall have the right to terminate this Agreement in its entirety upon written notice to ALFRESA if ALFRESA or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, (a) commences any interference or opposition proceeding with respect to, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any ARS Patent, or (b) institutes, actively participates as an adverse party in, or otherwise provides material support to, any action, suit or other proceeding to invalidate any ARS Patent or to obtain a ruling that any claim within any ARS Patent is unenforceable or not patentable.

14.4 Termination by ALFRESA. (a) Invalidity of ARS Patents. ALFRESA shall have the right to terminate this Agreement upon written notice to ARS when an examiner or trial makes final and binding decision to refuse to grant any ARS Patent to ARS or when a trial decision to the effect that the ARS Patent is to be invalidated has become final and binding by giving notice to ARS with the immediate effect. **(b) Termination without Cause.** ALFRESA shall have the right to terminate this Agreement at any time for any reason or for no reason upon [***] written notice to ARS.

14.5 Effects of Termination for in Certain Situations. Upon any termination of this Agreement by ARS pursuant to **Section 14.2, 14.3** or the termination of this Agreement by ALFRESA pursuant to **14.4**, the following will apply:

(a) Termination of Licenses and Other Rights. All licenses granted to ALFRESA will automatically terminate, all other rights and obligations of the Parties under this Agreement will terminate, and all sublicenses under the ARS Technology granted from ALFRESA to any Sublicensee will automatically terminate, in each case on the effective date of termination.

(b) Assignments. ARS shall notify ALFRESA within [***] after the effective date of termination whether it wishes to obtain the assignments set forth in **Sections 14.5(b)(i)-(iii)**. All such assignments under **Sections 14.5(b)(i)-(iii)** will be without cost to ARS.

(i) Regulatory Filings. As promptly as practicable (and in any event within [***]) after such notice, ALFRESA shall: (A) to the extent not previously provided to ARS, deliver to ARS true, correct and complete copies of all Regulatory Filings (including Regulatory Approvals) for Products in the Field in the ALFRESA Territory, and provide to ARS all ALFRESA Know-How not previously disclosed to ARS; (B) and hereby does, effective upon such termination, transfer and assign, or cause to be transferred or assigned, to ARS or its designee (or to the extent not so assignable, take all reasonable actions to make available to ARS or its designee all of the benefits of) all Regulatory Filings (including Regulatory Approvals) for Products in the Field in the ALFRESA Territory, whether held in the name of ALFRESA or its Affiliate or Sublicensee; and (C) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this **Section 14.5(b)(i)** to ARS;

(ii) ALFRESA Technology. ALFRESA shall, and hereby does, effective upon such termination, assign to ARS all of ALFRESA's and its Affiliates' right, title and interest in and to the ALFRESA Technology, and ALFRESA shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment, at ARS's cost;

(iii) Marks. ALFRESA shall, and hereby does, effective on such termination that occurs during the period until the latest of (i) expiration of the last-to-expire Valid Claim of the ARS Patents and Joint Patents covering the composition, method of manufacture or method of use in the Field of any Product in the ALFRESA Territory; or (ii) 10 years after the First Commercial Sale of any Product in the ALFRESA Territory, assign to ARS all of ALFRESA's and its Affiliates' right, title and interest in and to any and all Product-specific trademarks used by ALFRESA and its Affiliates in the ALFRESA Territory, including all goodwill therein, and ALFRESA shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment, at ARS's cost;

(c) Wind-Down. ALFRESA shall, as directed by ARS, either wind-down any ongoing Development activities of ALFRESA and its Sublicensees with respect to any Compositions or Products in the Field in the ALFRESA Territory in an orderly fashion or promptly transfer such Development activities to ARS or its designee, in compliance with all Applicable Laws;

(d) Transition Assistance. ALFRESA shall, at ARS's cost, provide reasonable consultation and assistance for a period of no more than [***] for the purpose of transferring or transitioning to ARS all ALFRESA Know-How not already in ARS's possession and, at ARS's request, all then-existing commercial arrangements relating specifically to Compositions and Products that ALFRESA is able, using Commercially Reasonable Efforts, to transfer or transition to ARS, in each case, to the extent reasonably necessary or useful for ARS to commence Developing, manufacturing, or Commercializing Products in the ALFRESA Territory. The foregoing shall include transferring, upon request of ARS, any agreements with Third Party suppliers or vendors that specifically cover the supply or sale of Compositions or Products in the ALFRESA Territory. If any such contract between ALFRESA and a Third Party is not assignable to ARS (whether by such contract's terms or because such contract does not relate specifically to Compositions or Products) but is otherwise reasonably necessary or useful for ARS to commence Developing, manufacturing, or Commercializing Products in the ALFRESA Territory, or if ALFRESA manufactures the Product itself (and thus there is no contract to assign), then ALFRESA shall reasonably cooperate with ARS to negotiate for the continuation of services or supply from such entity, or ALFRESA shall supply such Composition or Product, as applicable, to ARS for a reasonable period (not to exceed [***]) until ARS establishes an alternate, validated source of such services or supply of finished, packaged, labeled Product for the ALFRESA Territory. The cost to ARS for such supply from ALFRESA shall be negotiated and agreed with each other, but no greater than the cost to ALFRESA for such supply.

(e) Remaining Inventories. ALFRESA shall promptly deliver, at no charge, to ARS all of the inventory of Compositions and Products held by ALFRESA as of the date of termination at a price equal to ALFRESA's actual cost to acquire or manufacture such inventory.

14.6 Effects of Material Breach by ARS. If ARS materially breaches this Agreement and has not cured such breach within [***] after notice of such breach from ALFRESA (or, in the event the breach is not one that can be cured within [***], has not implemented a plan to cure such breach within [***]) ALFRESA shall have the right to seek the following remedies;

(a) In the case that ALFRESA will exercise its right to terminate this Agreement pursuant to **Section 14.2(a)**, **Section 14.5 (a)-(e)** will apply, provided that, ARS shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by ALFRESA to conduct ARS-requested activities under **Section 14.5(b)-(e)**, notwithstanding anything to the contrary in **Section 14.5(b)-(e)**.

(b) In the case that ALFRESA will not exercise its right to terminate this Agreement pursuant to **Section 14.2(a)**, this Agreement shall survive and remain in full force and effect.

14.7 Confidential Information. Upon termination of this Agreement in its entirety, except to the extent that a receiving Party obtains or retains the right to use the disclosing Party's Confidential Information, each receiving Party shall promptly return to the disclosing Party, or delete or destroy, all relevant records and materials in such receiving Party's possession or control containing Confidential Information of the disclosing Party; provided that such receiving Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations. All ALFRESA Know-How assigned to ARS after the termination of this Agreement as set forth in **Section 14.5** and **14.6(a)** will be deemed ARS's Confidential Information and no longer ALFRESA's Confidential Information.

14.8 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: [To be populated]

14.9 Exercise of Right to Terminate. The use by either Party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto; *provided, however*, that termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

14.10 Damages; Relief. Subject to **Section 14.8**, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

14.11 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "**intellectual property**" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. A Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. In the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete

duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property that are necessary for use and exploitation of such other Party's licenses and rights hereunder, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party. In the event where any Third Party other than the bankrupt Party (including but not limited to CMO) owns or possesses a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property that are necessary for use and exploitation of such other Party's licenses and rights hereunder, and same, the bankrupt Party shall procure such Third Party to deliver such complete duplicate to the other Party, upon such other Party's written request.

15. DISPUTE RESOLUTION

15.1 Objective. The Parties recognize that disputes as to matters (i) arising under, or relating to, this Agreement or (ii) either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this **Article 15** to resolve any such dispute if and when it arises.

15.2 Resolution by Executive Officers. Except as otherwise provided in **Article 3**, if an unresolved dispute as to matters arising under or relating to this Agreement or either Party's rights and obligations hereunder arises, either Party may refer such dispute to the Executive Officers, who shall meet in person or by telephone within [***] after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of such Executive Officers within such [***] period (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with **Section 15.3**.

15.3 Arbitration.

(a) If the Parties do not resolve a dispute as provided in **Section 15.2**, and a Party wishes to pursue the matter, each such dispute that is not an Excluded Claim (defined below) shall be resolved by binding arbitration administered by [***] in accordance with the Arbitration Rules of [***] for the time being in force, which rules are deemed to be incorporated by reference in this clause. The arbitration award rendered in any such arbitration will be final and not appealable and may be executed by any court of competent jurisdiction. If either Party intends to commence binding arbitration of such dispute, such Party will provide written notice to the other Party informing the other Party of such intention and the issues to be resolved. Within [***] after the receipt of such notice, the other Party may, by written notice to the Party initiating binding arbitration, add additional issues to be resolved.

(b) The arbitration shall be conducted by a [***] appointed in accordance with the SIAC Rules, none of whom shall be a current or former employee or director, or a then-current stockholder, of either Party, their respective Affiliates or any Sublicensee. The place of arbitration shall be [***] and all proceedings and communications shall be in English.

(c) It is the intention of the Parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than [***] after selection of the arbitrators, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within [***] from such meeting. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

(d) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages. The award shall be in writing and shall describe the basis for the award and the arbitrators' decision(s). The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a Party in connection with the arbitration be paid by the other Party. Each Party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.

(e) Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable [***] of limitations.

(f) As used in this Section, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns (i) the validity, enforceability or infringement of a patent, trademark or copyright or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

16. GENERAL PROVISIONS

16.1 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded.

16.2 Entire Agreement; Modification. This Agreement is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

16.3 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

16.4 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

16.5 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations of a Party hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed); *provided, however*, that either Party may, upon the prior notice to the other Party, assign or otherwise transfer this Agreement in its entirety without the other Party's consent:

(a) in connection with the transfer or sale to a Third Party of all or substantially all of the business or assets of such Party relating to Products, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise, provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder; or

(b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this **Section 16.5** shall be null and void.

16.6 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

16.7 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, or by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, or (c) facsimile or electronic mail (with written confirmation of the recipient) thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this **Section 16.7**. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt; (ii) if air mailed, [***] after the date of postmark; (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries, (iv) if sent by facsimile, the date of confirmation of receipt if during the recipient Party's normal business hours, otherwise the next business day, (v) if notice is given by electronic mail, a hard copy shall be provided via air mail (postage prepaid) requiring return receipt, or courier service; the receipt of such hard copy by the receiving Party shall constitute notice here under.

If to ALFRESA, notices must be addressed to:

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku,
Osaka 540-8575, Japan

with a copy to:

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku,
Osaka 540-8575, Japan

If to ARS, notices must be addressed to:

ARS Pharmaceuticals, Inc.
3525 Del Mar Heights Rd., #855
San Diego, CA 92130, USA
Attention: Chief Executive Officer Facsimile:

with a copy to:

ARS Pharmaceuticals, Inc.
3525 Del Mar Heights Rd., #855
San Diego, CA 92130, USA
Attention: Chief Business Officer Facsimile:

16.8 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement or delay or failure of transportation or supply of raw materials (other than failure to make payment when due) by reason of any event beyond such Party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, epidemic, pandemic, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, , or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not directly or indirectly caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given in writing to the other Party within [***] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

16.9 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein," "hereof" and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

16.10 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or be executed by facsimile or PDF signature or other electronic signature means, and upon such delivery such electronic delivery or facsimile, PDF or electronic signature(s) will be deemed to have the same effect as if the original signature had been delivered to the other Party.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties hereto have caused this **COLLABORATION AND LICENSE AGREEMENT** to be executed and entered into by their duly authorized representatives as of the Effective Date.

ARS PHARMACEUTICALS, INC.

ALFRESA PHARMA CORPORATION

By: /s/ Richard Lowenthal
Name: Richard Lowenthal
Title: President & Chief Executive Officer
Date: 4/30/2020

By: /s/ Koichi Shimada
Name: Koichi Shimada
Title: President & CEO
Date: 4/29/2020

SIGNATURE PAGE TO COLLABORATION AND LICENSE AGREEMENT

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED
BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND
CONFIDENTIAL.**

Confidential

COLLABORATION AND DISTRIBUTION AGREEMENT

THIS COLLABORATION AND DISTRIBUTION AGREEMENT (the “*Agreement*”) is entered into as of March 1st, 2021 (the “*Effective Date*”), by and between **ARS PHARMACEUTICALS, INC.**, a Delaware corporation (“*ARS*”), having an address of 3525 Del Mar Heights Rd., #855, San Diego, CA 92130, U.S., and **Pediatrix Therapeutics**, a Cayman corporation (“*Pediatrix*”), having a registered office at Aequitas International Management Ltd., Grand Pavilion Commercial Center, Suite 24, 802 West Bay Road, P.O. Box 10281, Grand Cayman KY1-1003, Cayman Island. ARS and Pediatrix may be referred to herein individually as a “*Party*” or collectively as the “*Parties*”.

RECITALS

WHEREAS, ARS is developing its proprietary Composition referred to as ARS-1, and owns or Controls certain ARS Technology (as each of these capitalized terms is defined below) relating to such Composition;

WHEREAS, Pediatrix is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, ARS and Pediatrix desire that Pediatrix exclusively collaborate and distribute products containing ARS-1 in the Pediatrix Territory (as defined below), all subject to the terms and conditions of this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, ARS and Pediatrix hereby agree as follows:

1. DEFINITIONS

- 1.1** “*Aegis Agreement*” means the License Agreement dated as of June 18, 2018 between ARS and Aegis Therapeutics, LLC (“*Aegis*”) and the Supply Agreement dated as of June 18, 2018 between ARS and Aegis.
- 1.2** “*Affiliate*” means, with respect to a Party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party, but for only so long as such control exists. As used in this **Section 1.2**, “*control*” means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital or other equity interest in such entity.
- 1.3** “*Aggregate Annual Net Sales*” means, the aggregate Net Sales of all Products by Pediatrix and its Affiliates and Sublicensee in the Pediatrix Territory in a given Calendar Year.
- 1.4** “*Aggregate Annual Net Sales Milestone Events*” has the meaning set forth in **Section 8.2(b)(i)**.
- 1.5** “*Alliance Manager*” has the meaning set forth in **Section 3.5**.
- 1.6** “*Applicable Laws*” means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including NDAs) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item, including, without limitations, (a) relevant implementing laws in the Pediatrix Territory, (b) U.S. Export Control Laws, (c) FCPA and all applicable anti-corruption laws and trade control laws, (d) applicable regulations and guidelines of the NMPA and other Regulatory Authorities and the ICH guidelines, (e) applicable Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and current Good Manufacturing Practices (cGMP) promulgated by NMPA and other Regulatory Authorities or the ICH; (f) all applicable industry and trade standards, including applicable standards of the ISO with, at a minimum, the ISO 9001/9002 quality standards.

- 1.7 “**ARS Collaborator**” means any Third Party licensee of ARS with respect to the Development and Commercialization of Compositions and Products in any country outside the Pediatrix Territory.
- 1.8 “**ARS Indemnitee**” has the meaning set forth in **Section 12.2**.
- 1.9 “**ARS Know-How**” means all Know-How that is Controlled by ARS or its Affiliates as of the Effective Date or during the Term (including Know-How constituting New IP), that is (i) necessary for the development, manufacture, sale, offering for sale, importation, or otherwise commercialization of the Product in the Field in the Pediatrix Territory; or (ii) arising out of activities related to the development, manufacture, sale, offering for sale, importation, or otherwise commercialization of the Product in the Field in and outside the Pediatrix Territory; *provided* that, if a Third Party becomes an Affiliate of ARS after the Effective Date as a result of a Change of Control of ARS, then ARS Know-How shall exclude the Know-How owned or controlled by such Third Party before the closing of such Change of Control transaction, unless such Know-How is already Controlled by ARS or its Affiliates before the closing of such Change of Control transaction. For clarity, the ARS Know-How includes the Know-How of ARS’s CMO to the extent that these are necessary or reasonably useful for the Manufacture of any Composition or Product; *provided* such Know-How is in ARS’s possession and ARS has the legal right to transfer such Know-How.
- 1.10 “**ARS Patents**” means all Patents in the Pediatrix Territory that are Controlled by ARS or its Affiliates as of the Effective Date or during the Term (including any Patents constituting New IP) that are (i) necessary for the development, manufacture, sale, offering for sale, importation, or otherwise commercialization of the Product in the Field in the Pediatrix Territory; or (ii) arising out of activities related to the development, manufacture, sale, offering for sale, importation, or otherwise commercialization of the Product in the Field in and outside the Pediatrix Territory; and that would be infringed, absent a license or other right to practice granted to Pediatrix under such Patents, by the research, Development, manufacture, use, or importation of any Composition, or research, Development, Manufacture, use, importation, offer for sale or sale of any Product, in the Field in the Pediatrix Territory (considering patent applications to be issued with the then-pending claims); *provided* that, if a Third Party becomes an Affiliate of ARS after the Effective Date as a result of a Change of Control of ARS, then ARS Patents shall exclude the Patents owned or controlled by such Third Party before the closing of such Change of Control transaction, unless such Patent is already Controlled by ARS or its Affiliates before the closing of such Change of Control transaction. The ARS Patents existing as of the Effective Date are set forth in **Exhibit 1** hereof.
- 1.11 “**ARS Product Marks**” has the meaning set forth in **Section 10.7**.
- 1.12 “**ARS Technology**” means the ARS Know-How and the ARS Patents.
- 1.13 “**Business Day**” means a day other than a Saturday, Sunday or any day on which banks located in California, United States, Cayman Islands or Beijing, China are authorized or obligated to close. Whenever the agreement refers to number of days, such number shall refer to calendar days unless Business Days are specified.
- 1.14 “**Calendar Quarter**” means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, or December 31.
- 1.15 “**Calendar Year**” means each respective period of twelve (12) consecutive months ending on December 31.

- 1.16 “**cGMP**” means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, and (c) the principles detailed in the ICH Q7 guidelines, each as may be amended from time to time
- 1.17 “**Change of Control**” means, with respect to a Party, (a) a merger, reorganization, consolidation or other transaction involving such Party and any entity that is not an Affiliate of such Party as of the Effective Date, which results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or other transaction, (b) any entity that is not an Affiliate of such Party as of the Effective Date becoming the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party or otherwise acquiring the power (whether through ownership interest, contractual right or otherwise) to direct or cause the direction of the management or policies of such Party.
- 1.18 “**Claim**” has the meaning set forth in **Section 12.3**.
- 1.19 “**CMC**” means chemistry, manufacturing, and control.
- 1.20 “**CMO**” means a Third-Party company who has contracted with either Party to Manufacture, or engage in Manufacturing activities, of Composition or the Product.
- 1.21 “**Commercial Supply Agreement**” has the meaning set forth in **Section 7.2(a)**.
- 1.22 “**Commercialization**” means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Products to customers) of Products in the Field in or outside of the Pediatrix Territory, including: (i) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training, and sales and distribution; (ii) scientific and medical affairs; and (iii) post- approval clinical trials. “**Commercialize**” and “**Commercializing**” have correlative meanings.
- 1.23 “**Commercialization Plan**” has the meaning set forth in **Section 6.2**.
- 1.24 “**Commercially Reasonable Efforts**” (a) with respect to a Party’s obligations or activities under this Agreement [***].

- 1.25 “**Competitive Product**” shall mean any pharmaceutical product (other than the Product) in the Field to which all of the following conditions apply: (i) contains epinephrine and (ii) delivered via a nasal spray.
- 1.26 “**Composition**” means (a) the combination of epinephrine and [***] (“**ARS-1**”), or (b) any other composition or derivative or improvement of ARS-1 that (i) is claimed in a Patent Controlled by ARS or its Affiliates existing on the Effective Date or during the Term or (ii) is otherwise Controlled by ARS or its Affiliates.
- 1.27 “**Confidential Disclosure Agreement**” means that certain Confidential Disclosure Agreement between ARS and Pediatrix dated as of September 3, 2020.
- 1.28 “**Confidential Information**” means all Know-How and other proprietary scientific, marketing, financial or commercial information or data that is not publicly available, and that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic or visual form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement. All ARS Technology shall be ARS’s Confidential Information.
- 1.29 “**Control**” or “**Controlled**” means, with respect to any Know-How, Patents or other intellectual property rights, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license or a sublicense of or under such Know-How, Patents or other intellectual property rights to the other Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.
- 1.30 “**Cost of Goods**” means, with respect to any Product supplied by ARS or its Affiliate to Pediatrix under **Article 7** (or the Development Supply Agreement and the Commercial Supply Agreement): (i) in the case of products and services acquired from Third Parties relating directly to the manufacture of such Product, [***] the amount [***] by ARS or its Affiliate for such Product manufacture; and (ii) in the case of manufacturing services performed by a ARS or its Affiliate, [***] (i), the Actual Unit Costs of such manufacture. “Actual Unit Costs” shall mean with respect to a Product, Direct Material Costs, Direct Labor Costs, and Manufacturing Overhead [***] in accordance with GAAP. “Direct Material Costs” shall mean [***]. “Direct Labor Costs” shall mean [***]. “Manufacturing Overhead” attributable to such Product [***] shall mean [***] and [***].

- 1.31 “**Data**” means any and all scientific, technical, test, marketing or sales data pertaining to any Composition or Product that is generated by or on behalf of Pediatrix or its Affiliates or Sublicensees, or by or on behalf of ARS or its Affiliates or, to the extent Controlled by ARS with a right to disclose to Pediatrix, ARS Collaborators, including research data, clinical pharmacology data, CMC data (including analytical, manufacturing and quality control data and stability data), pre-clinical data, clinical data or submissions made in association with an IND or NDA with respect to any Product.
- 1.32 “**Develop**” means to develop (including clinical, non-clinical and CMC development), analyze, test and conduct preclinical, clinical and all other regulatory trials for the Composition or Product, as well as all related regulatory activities and any and all activities pertaining to new indications, pharmacokinetic studies and all related activities including work on new formulations, new methods of treatment and CMC activities including new manufacturing methods. “**Developing**” and “**Development**” have correlative meanings.
- 1.33 “**Development Plan**” is described in **Section 4.2**.
- 1.34 “**Development Supply Agreement**” has the meaning set forth in **Section 7.1(a)**.
- 1.35 “**Debarred**” has the meaning set forth in **Section 11.2(a)**.
- 1.36 “**Discontinued ARS Patent**” has the meaning set forth in **Section 10.2(a)**.
- 1.37 “**Discontinued Pediatrix Patent**” has the meaning set forth in **Section 10.2(b)**.
- 1.38 “**Drug Product**” has the meaning set forth in **Section 7.1(a)**.
- 1.39 “**EMA**” means the European Medicines Agency or any successor agency with comparable responsibilities.
- 1.40 “**Excluded Claim**” has the meaning set forth in **Section 15.3(f)**.
- 1.41 “**Executive Officers**” has the meaning set forth in **Section 3.3**.
- 1.42 “**Export Control Laws**” means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).
- 1.43 “**FCPA**” means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended; and all applicable local anti-bribery laws and regulations.
- 1.44 “**FDA**” means the U.S. Food and Drug Administration or any successor agencies with comparable responsibilities.
- 1.45 “**FDCA**” has the meaning set forth in **Section 11.2(a)**.
- 1.46 “**Field**” means all human uses including the diagnosis, treatment, palliation, or prevention of all indications, diseases and disorders.
- 1.47 “**First Commercial Sale**” means, on a Product-by-Product and region-by-region basis, the first sale by Pediatrix or any of its Affiliates or Sublicensees to a Third Party for end use or consumption of a Product in a region in the Pediatrix Territory after Regulatory Approval has been granted with respect to such Product in such region. [***].

- 1.48 “**First Region**” has the meaning set forth in **Section 8.3(b)(ii)**.
- 1.49 “**FTE**” means the equivalent of the work of a full-time individual for a twelve (12) month period.
- 1.50 “**GAAP**” means the generally accepted accounting principles of the applicable country or jurisdiction, consistently applied, and means the international financial reporting standards (“**IFRS**”) at such time as IFRS becomes the generally accepted accounting standard and Applicable Laws require that a Party use IFRS.
- 1.51 “**Generic Product**” means, with respect to the Product in a country or regulatory jurisdiction, any pharmaceutical product that (a) contains the same composition of active ingredient as such Product in the same pharmaceutical form as such Product; (b) has obtained regulatory approval in such country or regulatory jurisdiction (for an indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such country or regulatory jurisdiction) on an expedited or abbreviated basis in a manner that relied on or incorporated data submitted by ARS, Pediatrix, their Affiliates, licensees or sublicensees under the provisions of Section 505(j) of the U.S. Federal Food, Drug, and Cosmetic Act, Articles 10.1, 10.2, 10.3 or 10a of EU Pharma Directive 2001/83, or similar laws in the applicable country or regulatory jurisdiction; (c) is bioequivalent to the Product, as determined by the applicable Regulatory Authority in such country or regulatory jurisdiction; and (d) is sold in such jurisdiction by a Third Party that is not a sublicensee of Pediatrix or its Affiliates and did not purchase such product in a chain of distribution that included any of Pediatrix or its Affiliates or sublicensees.
- 1.52 “**Global Trial**” means a clinical trial designed to obtain data to be used to support filing for and obtaining Regulatory Approval of a Product in the Field in both (a) mainland China or other regions in the Pediatrix Territory and (b) the United States
- 1.53 “**GLP**” means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent laws and regulations in the Pediatrix Territory, each as may be amended from time to time.
- 1.54 “**Good Clinical Practice**” or “**GCP**” means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Pediatrix Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (d) the equivalent laws and regulations in the Pediatrix Territory, each as maybe amended from time to time.
- 1.55 “**Governmental Authority**” means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

- 1.56 “**ICC**” has the meaning set forth in **Section 15.3(a)**.
- 1.57 “**ICC Rules**” has the meaning set forth in **Section 15.3(a)**.
- 1.58 “**ICH**” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- 1.59 “**IND**” means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence human clinical trials in the applicable country.
- 1.60 “**Indemnitee**” has the meaning set forth in **Section 12.3**.
- 1.61 “**Indemnitor**” has the meaning set forth in **Section 12.3**.
- 1.62 “**Infringement Claim**” has the meaning set forth in **Section 10.5**.
- 1.63 “**Inventions**” means all inventions, whether or not patentable, discovered, made or conceived as a result of performance of activities contemplated by this Agreement.
- 1.64 “**Intellectual Property**” shall mean, collectively, all intellectual property rights and similar proprietary rights, including Trademarks, copyrights, Know-How and Patents, whether registered or unregistered, and all applications and registrations to register, and renewals and extensions of, any of the foregoing.
- 1.65 “**JSC**” and “**Joint Steering Committee**” has the meaning set forth in **Section 3.1**.
- 1.66 “**Know-How**” means all technical information, know-how and data, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical materials, expertise and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, nonclinical and clinical data, regulatory documents, data and filings, instructions, processes, formulae, expertise and information, relevant to the research, development, manufacture, use, importation, offering for sale or sale of, or which may be useful in studying, testing, developing, producing or formulating, products, or intermediates for the synthesis thereof. Know-How excludes Patents.
- 1.67 “**License**” has the meaning set forth in **Section 2.1**.
- 1.68 “**Losses**” has the meaning set forth in **Section 12.1**.
- 1.69 “**Manufacture**” or “**Manufacturing**” shall mean the activities required to manufacture Compositions or Products by a Party, itself or through its Affiliate or CMO, including test method development and stability testing, formulation development, process development, manufacturing scale up, process validation, the manufacturing of the starting material, fill and finish activities and quality assurance/quality control.
- 1.70 “**Manufacturing License Condition**” means any event identified in Section 2.1(b).
- 1.71 “**Materials**” has the meaning set forth in **Section 4.7**.

- 1.72 “**Medical Affairs Activities**” means the activities related to the dissemination of scientific information, coordination of medical information requests and field based medical scientific liaisons with respect to a product, including: (a) any associated activities of medical scientific liaisons and the provision of medical information services with respect thereto; (b) advisory boards; (c) conduct of scientific meetings; (d) publications and (e) any health and economics and research studies. For clarity, “Medical Affairs Activities” excludes Development and Commercialization.
- 1.73 “**Milestone Event**” means any event identified in **Section 8.2**.
- 1.74 “**Milestone Payment**” means any payment identified in **Section 8.2** to be made by Pediatrix to ARS on the occurrence of a Milestone Event.
- 1.75 “**NDA**” means a New Drug Application, as defined by the FDA, a Marketing Authorization Application (MAA), as defined by the EMA, or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory Authority in any country or jurisdiction for approval to market a pharmaceutical product (but not including application for Pricing and Reimbursement Approval).
- 1.76 “**Net Sales**” means, with respect to any Product, the gross amount invoiced by Pediatrix or its Affiliates or Sublicensees for sale or other transfer or disposition for value to Third Parties, less the following deductions, with respect to the sale or other transfer or disposition of such Product:

[***].

Such deduction amounts shall be determined in accordance with GAAP, consistently applied.

Upon any sale or other transfer or disposition of any Product that should be included within Net Sales for any consideration other than [***]. For clarity, in the event the Product is sold [***].

The transfer of a Product to an Affiliate, Sublicensee, or other Third Party (w) [***], (x) [***], or (z) [***].

In no event shall any particular amount identified above be deducted more than once in calculating Net Sales. [***].

Pediatrix and its Affiliates and Sublicensees shall not sell any Product in combination with or as part of a bundle with other products, or offer packaged arrangements to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product as compared with the weighted-average discount applied to the other products, as a percent of the respective list prices (or if not available, a good faith estimate thereof) of such products and the Product prior to applying the discount.

- 1.77 “**New IP**” has the meaning set forth in **Section 10.1**.
- 1.78 “**NMPA**” means the National Medical Products Administration of the People’s Republic of China, and local counterparts thereto, and any successor agency(ies) or authority having substantially the same function.
- 1.79 “**Patents**” means (a) all national, regional and international patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, and (b) any renewals, divisions, continuations (in whole but not in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issued thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
- 1.80 “**Pediatrix Indemnitee**” has the meaning set forth in **Section 12.1**.
- 1.81 “**Pediatrix Product Marks**” has the meaning set forth in **Section 10.7**.
- 1.82 “**Pediatrix Technology**” means all (i) all Know-How that Pediatrix or its Affiliates Control as of the Effective Date or during the Term that is necessary or reasonably useful for the research, Development, manufacture, testing, use, importation, offer for sale or sale of any Composition or Product (“**Pediatrix Know-How**”), and (ii) all Patents that Pediatrix or its Affiliates Control as of the Effective Date or during the Term that would be infringed, absent a license or other right to practice granted under such Patents, by the research, Development, manufacture, use, importation, offer for sale or sale of any Product (considering, for this purpose, pending patent applications to be issued with the then-pending claims) (“**Pediatrix Patents**”); *provided* that, if a Third Party becomes an Affiliate of Pediatrix after the Effective Date as a result of a Change of Control of Pediatrix, then Pediatrix Technology shall exclude the Know-How or Patents owned or controlled by such Third Party before the closing of such Change of Control transaction, unless such Know-How or Patent is already Controlled by Pediatrix or its Affiliates before the closing of such Change of Control transaction. For clarity, Pediatrix Technology shall exclude New IP (which shall be owned solely by ARS as set forth in **Section 10.1**).
- 1.83 “**Pediatrix Territory**” means the People’s Republic of China, including mainland China, Hong Kong, Macau and Taiwan, each shall be deemed a region for the purpose of this Agreement.

- 1.84 “**Person**” means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.
- 1.85 “**Pricing and Reimbursement Approval**” means, with respect to a Product, the approval, agreement, determination or decision of any Regulatory Authority establishing the price or level of reimbursement for such Product, as required in a given country or jurisdiction prior to sale of such Product in such jurisdiction.
- 1.86 “**Product**” means any pharmaceutical product containing a Composition as the sole active ingredient and delivered through nasal spray.
- 1.87 “**Regulatory Approval**” means any and all approvals, licenses, registrations, permits, notifications and authorizations (or waivers) of any Regulatory Authority that are necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of a Product in any country or jurisdiction.
- 1.88 “**Regulatory Authority**” means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a given jurisdiction, including the National Medical Products Administration (NMPA). For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority shall also include any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.
- 1.89 “**Regulatory Data**” means all regulatory information, materials, data and results relating to a Product which are necessary for Regulatory Approvals and Pricing and Reimbursement Approvals for such Product, including, but not limited to the e-CTD dossiers submitted to and approved by applicable Regulatory Authorities, in-vitro Product testing data and study data, data queries, data tables reports and case report forms generated during any pre-clinical or clinical study or registry study, for such Product.
- 1.90 “**Regulatory Exclusivity**” means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority in accordance with Applicable Laws with respect to a Product other than Patents, including, as applicable, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997, in the EU under national implementations of Article 10 of Directive 2001/83/EC, in mainland China under Section 66 of Provisions for Drug Registration (2007 as updated) (SFDA Order No 28), or rights similar thereto.
- 1.91 “**Regulatory Filing**” means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications and authorizations (or waivers) with respect to the testing, Development, manufacture or Commercialization of any Product made to or received from any Regulatory Authority in a given country, including any INDs and NDAs.
- 1.92 “**Safety Data**” means Data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities in or outside the Pediatrix Territory. Safety Data also includes “**adverse events**”, “**adverse drug reactions**” and “**unexpected adverse drug reactions**” as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.
- 1.93 “**SEC**” means the U.S. Securities and Exchange Commission, or any successor entity.
- 1.94 “**Second Region**” has the meaning set forth in **Section 8.3(b)(ii)**.

- 1.95 “**Sublicensee**” means a Third Party to whom Pediatrix grants a sublicense to research, Develop, make, have made, use, import, promote, distribute, offer for sale or sell any Product in the Field in the Pediatrix Territory (either independently from or in cooperation with Pediatrix), beyond the mere right to purchase Products from Pediatrix and its Affiliates. In no event shall ARS or any of its Affiliates be deemed a Sublicensee.
- 1.96 “**Supply Agreement**” means the Development Supply Agreement or the Commercial Supply Agreement, as applicable.
- 1.97 “**Tax Withholding Documents**” means documents prepared by ARS in order for ARS to obtain benefits under any applicable tax treaty, including the reduction or exemption from any withholding tax and the procurement of any available tax refunds, as described in **Section 9.2(b)**.
- 1.98 “**Term**” has the meaning set forth in **Section 14.1**.
- 1.99 “**Third Party**” means any entity other than ARS or Pediatrix or an Affiliate of ARS or Pediatrix, respectively.
- 1.100 “**Trademark**” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership including the goodwill and activities associated with each of the foregoing.
- 1.101 “**Upstream Licenses**” means any and all agreements between ARS, or any of its Affiliates, on the one hand, and any Third Party (the “**Upstream Licensors**”), on the other hand, pursuant to which ARS has (a) in-licensed any Patent or Know-How Controlled by such Third Party that are included as part of the ARS Patents or ARS Know-How or (b) agreed to provisions that would require Pediatrix to make any payments (including royalties) to any Third Party or to undertake or observe any restrictions or obligations with respect to the Development, Manufacture or Commercialization of the Products in the Field. **Exhibit 2** sets forth a list of all Upstream Licenses as of the Effective Date.
- 1.102 “**Upstream Licensors**” has the meaning set forth in **Section 1.101**.
- 1.103 “**U.S.**” means the United States of America, including its territories and possessions and the District of Columbia.
- 1.104 “**Valid Claim**” means (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a pending patent application that was filed in good faith, has not been pending for more than [***] from its priority date, and has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.
2. **GRANT OF LICENSES**
- 2.1 **Licenses Granted to Pediatrix.** Subject to the terms and conditions of this Agreement, ARS hereby grants to Pediatrix, as for ARS Patents until expiration of the last-to-expire Valid Claim in such ARS Patents, and as for ARS Know-How, during the Term, the following license (the “**License**”):

- (a) an exclusive (even as to ARS, except as expressly set forth herein), nontransferable (except in accordance with **Section 16.5**), royalty-bearing license, with the right to grant sublicenses as provided in **Section 2.2**, under the ARS Technology to Develop, use, register, and import Compositions and Products in the Field and in the Pediatrix Territory and to promote, offer for sale and sell Products in the Field and in the Pediatrix Territory, which license includes the rights (i) to incorporate Regulatory Data within the ARS Technology in Regulatory Filings with Regulatory Authorities in the Pediatrix Territory or in Commercialization materials and (ii) to cross-reference Regulatory Filings Controlled by ARS outside the Pediatrix Territory, in each case (i) and (ii) solely for the purposes of (A) obtaining and holding Regulatory Approval for Products in the Field in the Pediatrix Territory or (B) supporting Commercialization activities for Products in the Field in the Pediatrix Territory.
- (b) an exclusive (even as to ARS), nontransferable (except in accordance with **Section 16.5**), royalty-bearing license, with the right to grant sublicenses as provided in **Section 2.2**, under the ARS Technology to Manufacture Composition and Products in the Pediatrix Territory solely for the purpose of exercising the license granted in **Section 2.1(a)**; provided that the license in this Section 2.1(b) shall be subject to and effective only upon after demonstration by Pediatrix to ARS that Pediatrix or its Affiliate or CMO is able to manufacture Compositions and Products in a manner and at a level of quality that is no less than the manner and quality of manufacture of Compositions and Products by ARS or its Affiliates or CMOs (that Pediatrix or its Affiliate or CMO possesses such ability, the “**Manufacturing License Condition**”). In the event that within [***] after Pediatrix’s demonstration described in the preceding sentence the Parties cannot agree on whether Pediatrix, its Affiliate, or CMO meets the Manufacturing License Condition, then the Parties shall expeditiously and in good faith refer such matter for expedited resolution to an Third Party expert mutually agreed upon by the Parties who has at least ten (10) years of experience in the manufacture of pharmaceutical products (or who has such other similar credentials as mutually agreed by the Parties), and such expert’s decision on the matter shall be binding upon the Parties (and, for clarity, such matter shall not be subject to the dispute resolution procedures set forth in **Article 15** (Dispute Resolution)).

2.2 Sublicenses. Pediatrix shall have the right to grant sublicenses under the licenses granted in **Section 2.1** to (a) any Affiliate (with the right to further sublicense to other Affiliates of Pediatrix) with the prior written notice to ARS; *provided* that such sublicense shall automatically terminate if the sublicensee ceases to be an Affiliate of Pediatrix, (b) Third Party subcontractor engaged by Pediatrix with the prior written notice to ARS, solely to the extent necessary for the subcontractor to perform certain obligations of Pediatrix under this Agreement and *provided* that Pediatrix retains the economic interest in the Products, and (c) any Third Party in the Pediatrix Territory with the prior written consent of ARS which consent shall not be unreasonably withheld, delayed or conditioned (for clarity, any further sublicense by such Third Party sublicensees shall also require ARS’s consent). All sublicenses granted under the licenses granted in **Section 2.1** shall be in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement. Pediatrix shall ensure that each agreement with a Sublicensee grants ARS all rights with respect to Data, Inventions, Intellectual Property, and Regulatory Filings made or generated by such Sublicensee as if such Data, Inventions, Intellectual Property, and Regulatory Filings were made or generated by Pediatrix. Pediatrix shall be responsible for the compliance of its Sublicensees with the terms and conditions of this Agreement. When Pediatrix requests ARS’s consent to any sublicense, Pediatrix shall provide ARS with a full and complete copy of such sublicense agreement [***]. Within [***] after entering into any such sublicense, Pediatrix shall deliver a fully executed and redacted (to the extent necessary) copy of the agreement to ARS. Pediatrix shall remain directly responsible for all of its obligations under this Agreement that have been delegated, subcontracted or sublicensed to any Affiliates or Sublicensees or subcontractors.

2.3 Licenses Granted to ARS. Subject to the terms and conditions of this Agreement, Pediatrix hereby grants to ARS:

- (a) an exclusive (even as to Pediatrix and its Sublicensees, except as expressly set forth herein), royalty-free, fully-paid, irrevocable, perpetual license, with the right to sublicense through multiple tiers, under the Pediatrix Technology to research, Develop, make, have made, use, register, import, promote, sell and offer for sale Compositions and Products outside the Pediatrix Territory, which license includes the rights (i) to incorporate Regulatory Data within the Pediatrix Technology in Regulatory Filings with Regulatory Authorities outside the Pediatrix Territory and (ii) to cross-reference Regulatory Filings Controlled by Pediatrix in the Pediatrix Territory, in each case solely for the purpose of (A) obtaining Regulatory Approval for Products outside the Pediatrix Territory or (B) supporting commercialization activities for Products outside the Pediatrix Territory; and
- (b) a non-exclusive, royalty-free, fully-paid license, with the right to sublicense through multiple tiers, under the Pediatrix Technology to exercise the reserved rights in **Section 2.4(b)**.

2.4 Reserved Rights. ARS hereby expressly reserves:

- (a) all rights to practice, and to grant licenses under, the ARS Technology outside of the scope of the licenses granted in **Section 2.1**, for any and all purposes, and
- (b) the right to use the ARS Technology in the Field in the Pediatrix Territory in order to perform its obligations under this Agreement.

Subject only to the rights expressly granted under **Section 2.3**, Pediatrix hereby expressly reserves all rights to practice, and to grant licenses under, the Pediatrix Technology for any and all purposes.

2.5 No Implied Licenses; Negative Covenant. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How or other Intellectual Property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or sublicensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.6 Technology Transfer and Assistance.

- (a) Promptly after the Effective Date and in any event within [***] following the Effective Date, ARS shall, at its costs and expenses, disclose and make available to Pediatrix in reasonable form all ARS Know-How, Regulatory Data, and Regulatory Filings in ARS or its Affiliate's Control as of the Effective Date.
- (b) Thereafter, throughout the Term, ARS shall without additional compensation, disclose and make available to Pediatrix, in whatever form Pediatrix may reasonably request (including by providing copies thereof), all ARS Know-How, Regulatory Data, and Regulatory Filings not previously provided to Pediatrix, promptly after the earlier of the creation, development, making, conception or reduction to practice of such ARS Know-How, Regulatory Data, and Regulatory Filings.
- (c) From the Effective Date to December 31, 2022, ARS shall, at Pediatrix's request, provide Pediatrix with reasonable access to ARS personnel involved in the Development of Compositions and Product, either in-person at ARS's facility or by teleconference for up to [***], at [***] costs of Pediatrix. In the event Pediatrix reasonably requests assistance from ARS that would require ARS to provide assistance (i) in the Calendar Year 2021 in [***] in excess of the amounts described in the preceding sentence or (ii) any time after December 31, 2022, ARS [***] provide such assistance to Pediatrix and Pediatrix shall reimburse ARS for such technical assistance and up to a number of [***] as agreed by the Parties in writing at [***] based on written invoices provided by ARS from time to time and within [***] of the receipt of an invoice from ARS.

- (d) Pediatrix shall and shall cause its Affiliates to, without additional compensation, disclose and make available to ARS, in whatever form ARS may reasonably request (including by providing copies thereof), any Pediatrix Know-How not previously provided to ARS, promptly after the earlier of the development, making, conception or reduction to practice of such Pediatrix Know-How.
- 2.7 Exclusivity.** Pediatrix hereby covenants that, during the Term, neither it nor its Affiliates shall, directly or indirectly (including via a license to a Third Party), develop, manufacture, market, promote, sell, or otherwise commercialize any Competitive Product anywhere in the world. ARS hereby covenants that, during the Term, neither it nor its Affiliates shall, directly or indirectly (including via a license to a Third Party), develop, manufacture, market, promote, sell, or otherwise commercialize any Product (except as expressly contemplated under this Agreement) or Competitive Product in the Pediatrix Territory. If a Third Party becomes an Affiliate of a Party after the Effective Date as a result of a Change of Control of a Party, and such new Affiliate is engaged in any activities of a Competitive Product that, if conducted by such Party, would breach its exclusivity obligations set forth in this **Section 2.7**, then such new Affiliate shall have [***] from the closing of such Change of Control transaction to wind down or divest such Competitive Product, and the continuation of such activities for the Competitive Product during such [***] period shall not constitute a breach of this **Section 2.7**, so long as such new Affiliate conducts such activities independently of the activities of this Agreement.
- 2.8 No Diversion.** Each Party hereby covenants and agrees that it shall not, shall ensure, that its Affiliates, and sublicensees shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Product, including via Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory or to any Third Party that such Party knows (or reasonably should know after due inquiry) has previously exported or is likely to export the Product to the other Party's territory. Neither Party shall engage, nor permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of the Product located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or its sublicensees receives any order for the Product from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such order Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product to any Third Party for use in or distribution into the other Party's territory, except as permitted under this Agreement under **Section 2.4**.
- 2.9 Compliance with Law.** Each Party shall conduct, and shall use Commercially Reasonable Efforts to cause its sublicensees, contractors, and consultants to conduct, all of its activities contemplated under this Agreement in accordance with all Applicable Laws.
- 3. GOVERNANCE**
- 3.1 Joint Steering Committee.** Promptly after the Effective Date (within [***] in any event), the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**"), composed of [***] Party ([***) to oversee and guide the strategic direction of the collaboration of the Parties under this Agreement. The JSC shall in particular:

- (a) coordinate the Development, regulatory, Commercialization, and other activities of the Parties under this Agreement, and provide a forum for and facilitate communications between the two Parties under this Agreement;
- (b) discuss and determine a strategy for the Development, Manufacture and Commercialization of the Product in the Pediatrix Territory, and approve any (i) Development Plans, and (ii) amendments to the Development Plan;
- (c) review and coordinate strategy for Regulatory Filings for the Product in the Pediatrix Territory;
- (d) discuss and review Medical Affairs Activities for the Product in the Pediatrix Territory;
- (e) review and discuss the Commercialization Plan for Commercialization of the Product in the Pediatrix Territory;
- (f) facilitate exchange of Regulatory Data; and
- (g) perform such other functions as appropriate to further the purpose of this Agreement, as expressly set forth in the Agreement or allocated to it by the Parties' written agreement.

3.2 Membership and Meetings.

- (a) **Members.** The JSC representative shall have appropriate knowledge and expertise to make recommendations and decisions arising within the scope of the JSC's responsibilities. Each Party may replace its JSC representatives on written notice to the other Party, but each Party shall strive to maintain continuity in the representation of its JSC members. Each Party shall appoint one (1) of its representatives to act as a co-chairperson of the JSC. The co-chairpersons shall jointly prepare and circulate agendas to JSC members at least [***] before each regularly scheduled JSC meeting and shall direct the preparation of reasonably detailed minutes for each JSC meeting, which shall be approved by the co-chairpersons and circulated to JSC members within [***] of such meeting.
- (b) **Meetings.** The JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than [***] every [***], unless otherwise agreed by the Parties in writing. Upon reasonable written request by any Party to hold ad-hoc meetings, both Parties agree to schedule such ad-hoc meetings within a reasonable time frame. Meetings of the JSC may be held in person, or by audio or video teleconference, and all in-person meetings shall be held at locations alternately selected by the Parties. Each Party shall be responsible for all of its own expenses of participating in [***] meetings. No action taken at any JSC meeting shall be effective [***].
- (c) **Non-Member Attendance.** Each Party may from time to time invite a [***] of participants, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; *provided* that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least [***] prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.3 Decision-Making. All decisions of the JSC shall be made by [***], with each Party’s representatives collectively having [***]. If after reasonable discussion and good faith consideration of each Party’s view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as to such matter within [***] after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, such disagreement shall be referred to the Chief Executive Officer of ARS and the Chief Executive Officer of Pediatrix or its designee (collectively, the “**Executive Officers**”) for resolution. If the Executive Officers are not able to resolve such matter within [***] after such matter has been referred to them, the following should apply: if such matter relates primarily to [***], then the Executive Officer of [***] shall be entitled to make the final decision regarding such matter; *provided*, that, if [***] reasonably believes that such decision [***] would be reasonably expected to cause (a) a [***], (b) a [***], or (c) [***], the Executive Officer of [***] shall be entitled to make the final decision regarding such matter.

3.4 Limitations on Authority. The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, the JSC shall not have the power to amend this Agreement, and no decision of the JSC may be in contravention of any terms and conditions of this Agreement.

3.5 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (the “**Alliance Manager**”). Each Alliance Manager shall be responsible for alliance management between the Parties on a day-to-day basis throughout the Term. Each Alliance Manager shall be permitted to attend JSC meetings as appropriate as non- voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the day-to-day activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JSC.

4. DEVELOPMENT

4.1 Development and Medical Affairs Responsibilities.

- (a) **Development in the Pediatrix Territory.** Subject to the terms and conditions of this Agreement, Pediatrix shall be responsible, at its sole cost and expense, for all Development that is necessary for or otherwise supports Regulatory Approval in the Pediatrix Territory for Products, including all clinical trials, and activities related to post- approval commitments and commercialization tests in the Pediatrix Territory. Pediatrix may reasonably request that ARS conduct, or assist Pediatrix with, certain Development activities for the Products in the Pediatrix Territory on Pediatrix’s behalf, at Pediatrix’s expense. If ARS agrees to conduct or assist with any such activities, the Parties shall amend the Development Plan accordingly, on terms to be negotiated in good faith, including at minimum that Pediatrix shall reimburse all reasonable internal (at a fully- burdened rate) and external costs incurred by ARS to conduct or assist with such activities in accordance with the Development Plan; [***].
- (b) **Medical Affairs Activities in the Pediatrix Territory.** Pediatrix shall be responsible for all Medical Affairs Activities to be conducted with respect to each Product in the Field solely in the Pediatrix Territory at its own cost and expense, and shall keep ARS reasonably informed on the Medical Affairs Activities planned and/or performed by Pediatrix, its Affiliates and sublicensees for the Product in the Field in the Pediatrix Territory. For clarity, Pediatrix shall not conduct any Medical Affairs Activities for the Product outside the Pediatrix Territory.

- (c) **Development Outside the Pediatrix Territory.** Subject to **Section 4.3**, ARS (itself and with ARS Collaborators, as applicable) shall be responsible, at its sole cost and expense, for all Development of Compositions and Products that support obtaining and maintaining Regulatory Approval outside the Pediatrix Territory. ARS, itself or through ARS Collaborators, may conduct all such activities in its sole discretion.
- 4.2 Development Plan.** Subject to **Section 4.1(a)**, Pediatrix shall be obligated to conduct Development activities that are necessary for or otherwise support Regulatory Approval in the Pediatrix Territory for Products, and Pediatrix shall conduct all such Development activities in a manner materially consistent with a written Development plan which shall contain: (a) an outline and synopsis of the clinical trials to be conducted by Pediatrix in the Pediatrix Territory, and (b) the material activities to be performed by the Parties to obtain the Regulatory Approvals for the Products in the Pediatrix Territory (the “**Development Plan**”). Pediatrix shall share the Development Plan with the JSC for review, discussion and approval as soon as practicable after the Effective Date. From time to time, but at least [***], Pediatrix shall propose updates or amendments to the Development Plan and submit such proposed updated or amended plan to the JSC for review, discussion, and approval. Once approved by the JSC, the updated or amended Development Plan shall become effective.
- 4.3 Global Trials.** If the Parties agree to conduct a Global Trial, then the Parties and, if applicable, the relevant ARS Collaborators, shall discuss in good faith and determine the terms under which the Parties will conduct such Global Trial, including the allocation between the Parties of costs and expenses, decision-making process and authority for trial design and protocols, management of budget overages, allocation of Development activities and responsibilities and data sharing procedures. Pediatrix shall determine, in its sole discretion, whether and to what extent it participates in any cost-sharing or other activities related to Global Trials. ARS shall also determine, in its sole discretion, whether and to what extent it participates, and any of its ARS Collaborators participate, in any cost-sharing or other activities related to Global Trials. Upon agreement to conduct a Global Trial, the Parties shall enter into a written agreement setting forth all such agreed terms.
- 4.4 Conduct of Development Activities.** Pediatrix shall perform its obligations under this Agreement in compliance with all Applicable Laws, including the FCPA and good scientific and clinical practices under the Applicable Laws of the country or jurisdiction in which such activities are conducted.
- 4.5 Records and Updates.** Pediatrix shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of Pediatrix in the performance of Development activities pursuant to this Agreement. Pediatrix shall keep the JSC regularly informed of the status of material Development activities with respect to Compositions and Products in the Field in the Pediatrix Territory conducted by it or on its behalf pursuant to this Agreement. Without limiting the foregoing, at least every [***], Pediatrix shall provide the JSC with summaries in reasonable detail of all data and results generated or obtained in the course of Pediatrix’s performance of activities with respect to Compositions and Products in the Field in the Pediatrix Territory. Pediatrix shall document all non-clinical and clinical trial data in formal written study reports according to Applicable Laws and applicable national and international guidelines (e.g., ICH, GCP, GLP and cGMP).
- 4.6 Development Diligence.** Pediatrix shall use Commercially Reasonable Efforts to Develop Product in the Field throughout the Pediatrix Territory in a manner materially consistent with the Development Plan.

4.7 Materials Transfer. Subject to **Section 2.6** and except as contemplated in **Sections 14.5** and **14.6**, in order to facilitate the Development activities contemplated by this Agreement, either Party may provide to the other Party certain materials, including but not limited to, the drug substance and its related compounds including impurities, metabolites and other tangible substance Controlled by the supplying Party (collectively, “**Materials**”) at [***] for use by the other Party solely for the purpose of performing its Development activities. For avoidance of doubt, the supply Drug Product for Development use are not subject to this **Section 4.7** and shall be governed by **Section 7.1** hereof. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party shall remain the sole property of the supplying Party, shall be used only in furtherance of the other Party’s Development activities conducted in accordance with this Agreement, shall not be used or delivered to or for the benefit of any Third Party, without the prior written consent of the supplying Party, and shall be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used by the recipient Party with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. If applicable, the receiving Party may require supplying Party to provide to the recipient Party the certificate of analysis for the Materials supplied by the supplying Party and represent and warrant that the qualities and standards of such Materials meet the specifications specified in the certificate of analysis. Except as expressly set forth in the preceding sentence, THE MATERIALS ARE PROVIDED “**AS IS**” AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

5. REGULATORY ACTIVITIES AND PRICING APPROVALS

5.1 Conduct of Regulatory Activities. Pediatrix shall be solely responsible, at its own cost and expense, for formulating regulatory strategy and for preparing, filing, obtaining and maintaining Regulatory Approvals for Products in the Field in the Pediatrix Territory. Pediatrix shall be the holder of all Regulatory Approvals for Products in the Field in the Pediatrix Territory, except if ARS is required by Applicable Laws to hold an Import Drug License or equivalent for any Product in the Pediatrix Territory, in which case ARS shall (a) hold such Regulatory Approval for Pediatrix’s benefit, (b) appoint Pediatrix (or an Affiliate or Sublicensee of Pediatrix) as its authorized exclusive legal agent of record to interact with NMPA and serve as its exclusive distributor for the Product in the Pediatrix Territory, and Pediatrix shall reimburse ARS for all cost and expense incurred in connection therewith, (c) shall provide access to and copies of such Regulatory Filings, Regulatory Approvals and any Pricing and Reimbursement approvals to Pediatrix promptly upon Pediatrix’s request, and (d) shall promptly transfer such Regulatory Approval to Pediatrix or its designee when allowed by Applicable Laws. Pediatrix shall use Commercially Reasonable Efforts to file NDAs and, as applicable, seek Pricing and Reimbursement Approval for and seek and maintain Regulatory Approval for Products in the Field in all regions throughout the Pediatrix Territory. Pediatrix shall keep ARS regularly informed of, the preparation, Regulatory Authority review and approval of substantive submissions and material communications with Regulatory Authorities with respect to Products in the Field in the Pediatrix Territory. ARS shall use Commercially Reasonable Efforts to assist with Pediatrix with interactions with Regulatory Authorities with respect to Products in the Field in the Pediatrix Territory, and Pediatrix shall reimburse ARS for any third party costs incurred to provide such assistance that are agreed upon writing by both Parties. Parties shall conduct all such activities in accordance with Applicable Laws.

- (a) **Regulatory Costs.** Except as agreed otherwise by the Parties under **Section 4.3**, Pediatrix shall bear all expenses to conduct all regulatory activities in the Pediatrix Territory under this Agreement including regulatory filing or equivalent fees, and any costs to translate, analyze or re-analyze any data for regulatory authorities in the Pediatrix Territory.
- (b) **Regulatory Filings.** Pediatrix shall be responsible for all regulatory activities leading up to and including the obtaining of the Regulatory Approval for a Product from the Regulatory Authority on a region-by-region basis in the Pediatrix Territory, subject to the following coordination:

- (i) Each Party shall fully disclose all such Regulatory Data included or incorporated into its Regulatory Filings that are derived from the other Party's respective territory;
 - (ii) Each Party shall promptly notify the other Party of any regulatory materials (other than routine correspondence, administrative documents and excluding documents related to Pricing and Reimbursement Approval) relating to any Composition or Product submitted by or on behalf of each Party to or received from any Regulatory Authority in the Pediatrix Territory. If any such materials are not in the English language, Pediatrix shall provide ARS with an English summary at the time of provision, and at ARS's request [***], a true, complete, accurate and certified English translation thereof as soon as practicable.
 - (iii) Each Party shall promptly provide the other Party with copies of any material documents, information and correspondence received from a Regulatory Authority in the Pediatrix Territory relating to any Composition or Product, and Pediatrix shall provide ARS with an English summary at the time of provision, and at ARS's request [***], an English translation thereof.
 - (iv) Pediatrix shall provide ARS for review and comment copies of all material Regulatory Filings to be submitted to a Regulatory Authority in the Pediatrix Territory (other than routine correspondence, administrative documents and excluding documents related to Pricing and Reimbursement Approval) with an English summary (and at ARS's request [***], an English translation thereof) prior to the relevant submission to allow sufficient time for review, and whenever possible, at least [***] in advance of their intended date of submission.
 - (v) ARS shall provide any comments in due course in order to not delay regulatory activities in the Pediatrix Territory. Pediatrix shall in good faith take into account ARS' comments.
 - (vi) Within [***] after a Regulatory Filing is submitted to any Regulatory Authority in the Pediatrix Territory, each Party shall, and shall require its Affiliates and Sublicensees to, provide the other Party an electronic copy thereof. For avoidance of doubt, Regulatory Filings also include discussions with respect to labeling for a Product in the Pediatrix Territory.
 - (vii) For the avoidance of doubt, ARS shall not file any Regulatory Filings in the Pediatrix Territory without first obtaining prior consent from Pediatrix, and Pediatrix shall not file any Regulatory Filings outside the Pediatrix Territory without first obtaining prior consent from ARS.
- (c) **Regulatory Meetings.** Pediatrix and its Affiliates shall be responsible for conducting interactions with Regulatory Authorities in connection with the Product in the Field in the Pediatrix Territory. Pediatrix shall provide ARS with reasonable advance notice of all meetings, conferences and discussions (whether in person or by telephone or video conference) scheduled with any Regulatory Authority in the Pediatrix Territory concerning the Products. Pediatrix shall lead any such meeting or discussion and ARS shall have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Laws or Regulatory Authority at ARS's sole cost and expense. At Pediatrix's request, ARS shall reasonably cooperate with Pediatrix in preparing such meeting or discussion. If ARS elects not to participate in such meetings, conferences or discussions, Pediatrix shall provide written summaries of such meetings, conferences or discussions in English as soon as reasonably practicable after the conclusion thereof.

- (d) **Diligence.** Pediatrix shall use Commercially Reasonable Efforts to prepare, obtain, maintain, and renew all necessary Regulatory Approvals for the Products in the Field in the Pediatrix Territory, including using Commercially Reasonable Efforts to prepare, obtain, maintain, and renew all necessary Regulatory Approvals for Products. In connection therewith, Pediatrix shall use Regulatory Data and/or the Regulatory materials provided by ARS to Pediatrix, which use shall be in compliance with all Applicable Laws, including all laws governing protection of personal data in the Pediatrix Territory. If additional quality, pre-clinical or clinical data is required by Applicable Law to obtain Regulatory Approvals in the Pediatrix Territory for such Product, Pediatrix, at its sole cost and expense, shall be responsible for conducting such necessary additional quality, pre-clinical or clinical Development; *provided, however,* that the foregoing shall not limit Pediatrix's diligence or other obligations under this Agreement.
- (e) **Pricing.** Pediatrix shall use Commercially Reasonable Efforts to prepare, obtain, and maintain all necessary Pricing and Reimbursement Approvals for each Product for which NDA approval has been obtained in the Pediatrix Territory. In connection therewith, Pediatrix shall use Regulatory Data and/or the Regulatory materials provided by ARS to Pediatrix, which use shall be in compliance with all Applicable Laws, including laws governing protection of personal data in the Pediatrix Territory. [***] shall have final decision-making authority to determine and establish the price and terms of sale (including any rebates or discounts) for each Product in the Field for each region in the Pediatrix Territory in conformance with Applicable Law.

5.2 Regulatory Activities outside the Pediatrix Territory. ARS agrees to keep Pediatrix informed of the preparation, Regulatory Authority review and approval of submissions and communications with Regulatory Authorities with respect to Products in the Field outside the Pediatrix Territory. In addition, ARS shall, upon reasonable request by Pediatrix, [***] provide Pediatrix with copies of any material documents, information and correspondence received from a Regulatory Authority outside the Pediatrix Territory, to the extent the requested items are in ARS's possession and for which ARS has the legal right to disclose and transfer. In the event that Regulatory Data of ARS shall be incorporated in the Regulatory Filing to obtain Regulatory Approvals in any region in the Pediatrix Territory, and ARS has been informed in writing of such Regulatory Data that have been so incorporated, ARS shall, to the extent the requested items are in ARS's possession and for which ARS has the legal right to disclose and transfer, [***] provide Pediatrix copies of any modification, correction and revision of such Regulatory Data to fulfill Pediatrix's obligation in Development and Regulatory Approval in the Pediatrix Territory. Pediatrix shall fully disclose to ARS all such Regulatory Data that has been incorporated into the Regulatory Filing. Upon Pediatrix's reasonable request and expense, ARS shall assist Pediatrix to fulfill the requirements of any Regulatory Authority in the Pediatrix Territory related to Regulatory Data provided by ARS and incorporated in the Regulatory Filing in the Pediatrix Territory, and Pediatrix shall reimburse all reasonable external costs agreed upon in writing by both Parties that are incurred by ARS to conduct such activities.

5.3 Inspections and Audits.

- (a) **By Regulatory Authorities.** In the event Pediatrix receives any correspondence, inquiry or request for an inspection or audit from a Regulatory Authority which relates to Regulatory Data or Product, Pediatrix shall promptly notify ARS in writing of such correspondence, inquiry or request of any inspection or audit. ARS shall cooperate with Pediatrix, at Pediatrix's expense, in responding to such correspondence, inquiry or any inspection or audit concerning such Regulatory Data, and Pediatrix shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by ARS to conduct such activities; [***].

- (b) **By Pediatrix.** In the event that Regulatory Data provided by ARS shall be incorporated in the Regulatory Filing to obtain Regulatory Approvals in Pediatrix Territory, ARS shall permit Pediatrix or its authorized representatives, which are subject to ARS' reasonable prior approval, to conduct a reasonable examination or quality inspection of such Regulatory Data (but no more than once per Calendar Year).

5.4 Adverse Event Reporting; Pharmacovigilance Agreement. As between the Parties: (a) [***] shall be responsible for the timely reporting of all quality issues, complaints and Safety Data relating to Products to the appropriate Regulatory Authorities outside the Pediatrix Territory and shall timely report to [***] the content of the report made to the Regulatory Authorities; and (b) except as otherwise agreed in writing by the Parties, [***] shall be responsible for the timely reporting of all quality issues, complaints and Safety Data relating to Products to the relevant Regulatory Authorities in the Pediatrix Territory, in each case in accordance with Applicable Laws of the relevant countries or jurisdictions and Regulatory Authorities. In addition, [***] shall be responsible for responding to technical and medical questions from all sources in the Pediatrix Territory relating to the use and functioning of the Products, and shall also serve as the batch release, product defect and recall contact in the Pediatrix Territory, for which [***] shall provide reasonably necessary assistance. The Parties shall cooperate with each other with respect to their respective pharmacovigilance responsibilities, and each Party shall be solely responsible for its costs relating to its respective pharmacovigilance responsibilities. The Parties shall negotiate in good faith and enter into, in timely manner, a mutually acceptable pharmacovigilance agreement with respect to the Products, pursuant to which ARS shall hold and control the global safety database for the Products. Until such pharmacovigilance agreement is established, [***] shall report quality issues, complaints and Safety Data relating to clinical trials in the Pediatrix Territory up until the submission of the application to regulatory authorities in the Pediatrix Territory. Unless otherwise mutually agreed, such pharmacovigilance agreement shall cover the exchange of safety information and appropriate management of pharmacovigilance activities to fulfill all legal and regulatory requirements both inside and outside of the Pediatrix Territory.

6. COMMERCIALIZATION

6.1 Commercialization. Pediatrix shall be responsible for Commercializing Products in the Field in the Pediatrix Territory during the Term, subject to the terms and conditions of this Agreement. Pediatrix shall perform all Product Commercialization activities, and [***], all at [***] cost. [***]: (a) [***]; (b) [***]; (c) [***]; (d) [***]; and (e) [***].

6.2 Commercialization Plan. No later than [***] after the submission of the first NDA for Product approval to Regulatory Authorities in any region of the Pediatrix Territory, Pediatrix shall prepare a preliminary, non-binding and reasonably detailed plan for the Commercialization of Products in the Field in the Pediatrix Territory during the first [***] after First Commercial Sale in the Pediatrix Territory (the "**Commercialization Plan**"). Pediatrix shall update the Commercialization Plan [***] and shall promptly provide each such update and any material amendments to each Commercialization Plan to the JSC for review and discussion before adopting such update and amendment. Pediatrix shall conduct Commercialization activities for the Product in the Pediatrix Territory in a manner materially consistent with the Commercialization Plan.

- 6.3 Commercialization Reports.** Pediatrix shall update ARS at each regularly scheduled JSC meeting regarding the significant Commercialization activities with respect to the Product in the Field in the Pediatrix Territory. Each such update shall include a reasonably detailed summary of Pediatrix's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Product in the Field in the Pediatrix Territory, covering subject matter at a level of detail reasonably required by ARS and sufficient to enable ARS to determine Pediatrix's compliance with its diligence obligations pursuant to **Section 6.4**.
- 6.4 Diligence.** During the Term, Pediatrix shall use Commercially Reasonable Efforts to market, promote and otherwise Commercialize Products in the Field throughout the Pediatrix Territory in any region in which Regulatory Approval is obtained, unless agreed otherwise in writing with ARS. Without limiting the foregoing, Pediatrix shall use Commercially Reasonable Efforts to achieve First Commercial Sale of a Product in a given region in the Pediatrix Territory within a reasonable time, and generally targeting within [***] after the date on which Pediatrix is notified that the Product has received Regulatory Approval in such region in the Pediatrix Territory.

7. MANUFACTURE AND SUPPLY

7.1 Development Supply.

- (a) **Obligations.** Subject to the terms and conditions of the Development Supply Agreement, ARS, itself or through any Affiliate or CMO, shall Manufacture and supply to Pediatrix, and Pediatrix shall purchase from ARS, all Products, in the form of drug product, which is the vial containing the active substance and the sprayer delivery device ("**Drug Product**") for all Development of Compositions and Products in the Field in the Pediatrix Territory to be conducted by Pediatrix or its Affiliate in accordance with this Agreement. The Parties shall negotiate in good faith and enter into a separate Drug Product supply agreement (the "**Development Supply Agreement**"), along with a quality agreement, reasonably in advance of anticipated first Development supply of Drug Product to Pediatrix in the Pediatrix Territory. Unless agreed otherwise by the Parties in writing, all Drug Product supplied by ARS under this **Section 7.1** or the Development Supply Agreement shall be used solely to conduct Development in the Field in the Pediatrix Territory in accordance with the terms of this Agreement.
- (b) **Price.** All Drug Product supplied by ARS for Development use shall be supplied at a price of [***] percent ([***]%) of [***]. ARS shall invoice Pediatrix within thirty (30) days after delivery of Drug Product pursuant to this **Section 7.1**, and Pediatrix shall pay each such invoice within [***] after receipt of the respective corresponding air waybill. The [***] of such Drug Product may be changed due to [***]. In such case, ARS shall [***] notify Pediatrix of the proposed changed price and reason for such change. For avoidance of doubt, Pediatrix shall be solely responsible to bear and pay for any customs or other taxes (including but not limited to VAT) or duties that become payable as a result of Pediatrix's purchase of such Drug Product from ARS.

7.2 Commercial Supply.

- (a) **Commercial Supply Agreement.** Unless and until Pediatrix notifies ARS in writing that it does not need the commercial supply of the Products from ARS after the manufacturing technology transfer described in **Section 7.2(c)**, ARS (either itself or through its Affiliate or CMO) shall Manufacture and supply, and Pediatrix shall purchase from ARS, all of Pediatrix's and its Affiliates' and Sublicensees' requirements for Drug Product for commercial use in the Field in the Pediatrix Territory, pursuant to a separate commercial supply agreement to be negotiated in good faith and entered into between the Parties (the "**Commercial Supply Agreement**"), along with a quality agreement, reasonably in

advance of anticipated First Commercial Sale of Product in the Pediatrix Territory. In accordance with the terms of the Commercial Supply Agreement, ARS shall supply unpackaged and unlabeled Drug Product for commercial use in the Field in the Pediatrix Territory at a price of [***] percent ([***]%) of [***]. ARS shall invoice Pediatrix within [***] after each delivery of Drug Product to Pediatrix pursuant to the Commercial Supply Agreement, and the payment terms for such invoice shall be determined in the Commercial Supply Agreement. In addition, Pediatrix shall be solely responsible to bear and pay for any customs, or other taxes (including but not limited to VAT) or duties that become payable as a result of Pediatrix's purchase of such Products from ARS for sale in a region in the Pediatrix Territory where such taxes or duties would be due and payable.

- (b) **Pediatrix Responsibilities.** Notwithstanding any other provision of this Agreement, Pediatrix, at its sole cost and expense, shall be responsible for labeling, packaging (other than primary packaging), releasing and distributing the Products in the Field in the Pediatrix Territory in compliance with all Applicable Laws related thereto, including all quality related obligations and any incremental Manufacturing validations required by local Governmental Authorities in the Pediatrix Territory.
- (c) **Pediatrix's Manufacture and Transition.** Upon written notice to ARS and satisfaction of the of the Manufacturing License Condition in accordance with **Section 2.1(b)**, Pediatrix may elect to assume responsibility for manufacturing and supplying all of the Drug Product requirements for Pediatrix's and its Affiliates' and Sublicensees' Commercial use in the Pediatrix Territory. ARS shall, within [***] following ARS's receipt of such written notice, provide access to and transfer to Pediatrix, or an Affiliate or a CMO all Know-How Controlled by ARS or its Affiliates that is necessary or used by ARS or a CMO of ARS, for Pediatrix to Manufacture the Compositions and Product in the Pediatrix Territory. Upon reasonable request from Pediatrix and at Pediatrix's cost, ARS shall provide to Pediatrix all necessary assistance and services to enable Pediatrix to Manufacture the Compositions and Product in substantially the same manner as ARS, its Affiliate or a CMO on behalf of ARS Manufactures the Compositions and Product for Pediatrix or its Affiliates.

For clarity, in case Pediatrix assumes full responsibility for the manufacturing and supplying of Drug Product as described in the foregoing subsection (c), ARS shall not unreasonably refuse Pediatrix the right to use the CMO (including the CMO for the manufacturing of the starting material) that is the same as the one ARS uses to manufacture Drug Product or is otherwise reputable and recognized in the Pediatrix Territory. The Parties agree to discuss in good faith a joint purchasing arrangement, to the extent permitted by Applicable Law.

7.3 Information on Manufacture. To the extent ARS, itself or through any Affiliate or CMO, supplies Drug Product to Pediatrix for Development or Commercialization under this Agreement, ARS shall, at ARS's cost, make available to Pediatrix all information, in its possession and that ARS has the legal right to transfer, that is relevant and necessary to maintain or obtain Regulatory Approval for the Product, to enable Pediatrix to maintain or obtain the Regulatory Approval in the Pediatrix Territory. ARS shall, [***], use Commercially Reasonable Efforts to require that its CMO provide Pediatrix access to and the right to use ARS' Drug Master File, to the extent that such information is reasonably useful for Development or Commercialization of Products in the Field for the Pediatrix Territory, including preparation and filing of NDAs for a Product with the applicable Regulatory Authorities in the Pediatrix Territory, in accordance with this Agreement.

8. FEES AND PAYMENTS

8.1 Definitive Agreement Upfront Payment. Pediatrix shall make a one-time, non-refundable, non-creditable payment to ARS of three million US dollars (\$3,000,000) within [***] after the Effective Date.

8.2 Milestone Payments.

(a) Regulatory and Commercial Milestone Payments.

- (i) Pediatrix shall notify ARS immediately (within [***] in any event) upon achievement of the Milestone Event set below. Within [***] after the first achievement of the Milestone Event below (whether by Pediatrix or any of its Affiliates or Sublicensees) and Pediatrix’s receipt of a corresponding invoice from ARS, Pediatrix shall pay to ARS the [***] Milestone Payment corresponding to the Milestone Event as shown below.

Regulatory and Commercialization Milestone Events	Milestone Payments
[***]	\$[***]

- (ii) For clarity, the Milestone Payments set forth in this **Section 8.2(a)** shall be payable only once, upon the first achievement of the Milestone Event for the first Product in the Field in the Pediatrix Territory to achieve the Milestone Event. Therefore, the maximum total amount payable under this **Section 8.2(a)** is \$4,000,000. Notwithstanding the foregoing, Pediatrix’s failure to notify ARS in accordance with this **Section 8.2(a)** shall not relieve it of its obligation to make payments set above.

(b) Aggregate Annual Net Sales Milestone Events and Milestone Payments.

- (i) As part of the royalty report in Section 8.3(g), Pediatrix shall notify ARS if any of the Aggregate Annual Net Sales Milestone Event is achieved in the time period to which the royalty report pertains. After the end of each Calendar Quarter in which Aggregate Annual Net Sales of all Products first exceed any threshold indicated in the “**Aggregate Annual Net Sales Milestone Events**” column listed below and Pediatrix’s receipt of a corresponding invoice from ARS, Pediatrix shall pay to ARS the corresponding non-refundable, non-creditable Milestone Payment set forth below in accordance with Section 8.3(g):

Aggregate Annual Net Sales Milestone Events	Milestone Payments
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]
[***]	\$[***]

- (ii) For clarity, the Milestone Payments corresponding to each Aggregate Annual Net Sales Milestone Event set forth in this **Section 8.2(b)** shall be payable only once, upon the first achievement of the applicable Aggregate Annual Net Sales Milestone Event, and shall be additive so that if all [***] Aggregate Annual Net Sales Milestone Events set forth in **Section 8.2(b)(i)** are achieved in the same Calendar Year, Pediatrix shall pay to ARS all [***] corresponding Milestone Payments. The maximum total amount payable under this **Section 8.2(b)** is \$80,000,000. Notwithstanding the foregoing, Pediatrix's failure to notify ARS in accordance with this **Section 8.2(b)** shall not relieve it of its obligation to make payments set above.

8.3 Additional Drug Product Supply Payments.

- (a) **Royalty Rate.** Subject to the terms and conditions of this Agreement, in each Calendar Quarter, Pediatrix shall pay ARS the royalties at the rate set forth below on aggregate annual Net Sales of Products in a given Calendar Year ("**Aggregate Annual Net Sales**") in all regions in the Pediatrix Territory combined during the Royalty Term, as such royalty amounts are calculated by multiplying the applicable royalty rate set forth below by the corresponding amount of the portion of Aggregate Annual Net Sales within each royalty rate tier in such Calendar Year.

Aggregate Annual Net Sales in the Pediatrix Territory (Tier)	Royalty Rate
For the portion of Aggregate Annual Net Sales of all Products less than or equal to \$[***]	[***]%
For the portion of Aggregate Annual Net Sales of all Products in excess of \$[***], but less than or equal to \$[***]	[***]%
For the portion of Aggregate Annual Net Sales of all Products in excess of \$[***], but less than or equal to \$[***]	[***]%
For the portion of Aggregate Annual Net Sales of all Products in excess of \$[***]	[***]%

- (b) Royalty Term.

- (i) Pediatrix's obligations to pay royalties under this **Section 8.3** shall continue, on a Product-by-Product and region-by-region basis in the Pediatrix Territory, until the latest of (i) expiration of the last-to-expire Valid Claim of the ARS Patents set forth in **Exhibit 1** covering such Product in such region; (ii) the expiration of all Regulatory Exclusivities that covering such Product in such region; or (iii) ten (10) years after the First Commercial Sale of such Product in such region (the "**Royalty Term**"). All Net Sales of all Products in all regions in the Pediatrix Territory shall be added together to determine the Aggregate Annual Net Sales and applicable royalty tier described in **Section 8.3(a)**.

- (ii) For clarity, if a Product is first sold in a region in which the Royalty Term for such Product has expired or any royalty reduction applies (the, “**First Region**”), and such Product is subsequently exported from such region and imported into a region in which the Royalty Term for such Product has not expired or the royalty reduction does not apply (the, “**Second Region**”), [***].
- (c) **No Valid Claim.** On a Product-by-Product and region-by-region basis in the Pediatrix Territory, If a Product is sold in a region during the applicable Royalty Term at a time when there is no Valid Claim in the ARS Patents set forth in **Exhibit 1** that covers such Product in such region, then the royalty rate applicable to the Net Sales of such Product in such region during such time shall be reduced by [***] percent ([***]%) of the rate set forth in **Section 8.3(a)**.
- (d) **Generic Competition.** On a Product-by-Product and region-by-region basis in the Pediatrix Territory, if a Generic Product is sold in such region in any, then the royalty payment payable to ARS with respect to such Product in such region during such [***] shall be reduced by [***] percent ([***]%) of the rate set forth in **Section 8.3(a)**, Where, if the unit volume of Generic Product(s) sold in such region in a Calendar Quarter is at least [***] percent ([***]%) of the total unit volume of Generic Product(s) plus unit volume of Product sold by Pediatrix, its Affiliates and Sublicensees in such region in such [***], then the royalty payment payable to ARS with respect to such Product in such region during such [***] shall be reduced by [***] percent ([***]%). Unless otherwise agreed by the Parties, the unit volumes of Generic Product(s) sold during a [***] shall be as reported by [***] or any successor to [***] or any other independent sales auditing firm reasonably agreed upon by the Parties.
- (e) **Third Party IP.**
 - (i) Notwithstanding anything to the contrary hereunder, ARS shall be solely responsible for any and all payments ARS owes to the Upstream Licensors under the applicable Upstream Licenses and in no event shall Pediatrix, its Affiliates, Sublicensees or contractors be liable for any of such payments. Without limiting the foregoing, ARS shall be solely responsible for any royalty payments to Aegis under the Aegis Agreement (which may be amended) under which ARS obtained rights to certain ARS Patents or ARS Know-How.
 - (ii) If Pediatrix obtains a license from a Third Party under any Patent owned or controlled by such Third Party that would be infringed, absent such a license, by the practice of the ARS Technology in the Development, Manufacture or Commercialization of a Product in the Field in a region in the Pediatrix Territory, then Pediatrix shall have the right to deduct, from the royalty payment that would otherwise have been due pursuant to this **Section 8.3** with respect to Net Sales of such Product in such region in a [***], an amount equal to [***] percent ([***]%) of the royalties paid by Pediatrix to such Third Party pursuant such license on account of the sale of such Product in such region during such [***]. For clarity, the royalty reduction under this **Section 8.3(e)(ii)** shall apply only to Third Party Patent that is necessary for the freedom to operate of the ARS Technology, and shall not apply to any other intellectual property that Pediatrix may elect to use or incorporate into the Product.
- (f) **Royalty Floor.** Notwithstanding the foregoing, the operation of **Sections 8.3(c), 8.3(d), and 8.3(e)(ii)** individually or in combination shall not reduce the royalties that would otherwise have been due under **Section 8.3(a)** with respect to Net Sales of any Product in any region during any [***] by more than [***] percent ([***]%).

- (g) **Royalty and Net Sales Milestone Payment.** Within [***] days after the end of each [***], commencing with the [***] during which the First Commercial Sale of a Product is made anywhere in the Pediatrix Territory, Pediatrix shall provide to ARS a report setting forth a calculation of the royalties due to ARS for such [***] and whether any sales milestone has been achieved during such time period. Promptly following the receipt of the applicable quarterly report, ARS shall invoice Pediatrix for the royalties due to ARS with respect to Net Sales by Pediatrix, its Affiliates and their respective Sublicensees for such [***] and, if any sales milestone is achieved, the corresponding sales milestone payment. Pediatrix pay such amounts to ARS within [***] following Pediatrix's receipt of such invoice; [***].

9. PAYMENT; RECORDS; AUDITS

- 9.1 **Exchange Rate; Manner and Place of Payment.** All references to dollars and "\$" herein shall refer to U.S. dollars. All payments hereunder shall be payable in U.S. dollars unless otherwise expressly stated. When conversion of payments from any currency other than U.S. dollars is required, the Parties shall use the average rate of exchange for U.S. dollars prevailing on the last day of each of [***] hereunder as published in The Wall Street Journal under the heading "Foreign Exchange," unless otherwise agreed upon in writing by the Parties. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by ARS, unless otherwise specified in writing by ARS.

9.2 Taxes.

- (a) **Cooperation and Coordination.** The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible and in compliance with Applicable Laws, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use Commercially Reasonable Efforts to cooperate and coordinate with each other to achieve such objective and intent. Pediatrix shall not change the country or jurisdiction from which all of its payments to ARS originate (which, for the avoidance of doubt, the Parties agree is the Cayman Islands) without the prior written consent of ARS. The Parties shall cooperate to help each other obtain benefits under any applicable tax treaty, including the reduction or exemption from any withholding tax and the procurement of any available tax refunds.
- (b) **Payment of Tax.** Each Party shall be responsible for all taxes, fees, duties, levies or similar amounts imposed on its own income, assets, capital, employment, personnel, and right or license to do business. If Applicable Laws requires Pediatrix to withhold any taxes from payments made to ARS under this Agreement, then such taxes shall be deducted by Pediatrix as required by and shall be paid by Pediatrix to the proper tax authorities; *provided* that Pediatrix shall cooperate and work with ARS to complete necessary steps and procedures, or ARS shall provide the Tax Withholding Documents to Pediatrix prior to such payment to ARS for avoiding or minimizing withholding taxes. Pediatrix shall use Commercially Reasonable Efforts to provide ARS with [***] advance written notice before making any such tax deduction or withholding of the intention to make such deduction or withholding, and shall use Commercially Reasonable Efforts to cooperate with any reasonable request from ARS to obtain reduction of or relief from such deduction or withholding. In case the Tax Withholding Documents are not available to Pediatrix at the due date of such payments to ARS or the Tax Withholding Documents provided by ARS to

Pediatrix do not call for a complete exemption on withholding taxes, Pediatrix shall (i) deduct applicable withholding taxes from the payment made to ARS, (ii) timely pay such taxes to the proper taxing authority, and (iii) send proof of such withholding tax payment to ARS and certify its receipt by the taxing authority within [***] following such payment. Pediatrix shall assist ARS in filing for the refund, if any, of any withholding taxes paid within [***] following the receipt of the Tax Withholding Documents from ARS. Any such refund filing shall request that the amount of the refund be wired directly to an ARS authorized bank account.

- (c) **Source of Payment.** To the extent (i) any payment under this Agreement is triggered due to activities of an Affiliate or sublicensee of Pediatrix incorporated or established in the Pediatrix Territory, whose Applicable Laws require the withholding of taxes in relation to such payment if it were to be made from such Affiliate or sublicensee of Pediatrix to ARS, and (ii) Pediatrix receives a payment from its such Affiliate or sublicensee in relation to such activity, and such payment is reduced due to withholding taxes required by Applicable Laws to be withheld on such payment, then Pediatrix shall have the right to deduct an amount that equals to [***] percent ([***]%) of the deducted amount for withholding taxes from the payments due to ARS under this Agreement. Pediatrix shall promptly provide to ARS applicable receipts evidencing payment of such withholding taxes and other documentation reasonably requested by ARS. Upon ARS's request, Pediatrix shall provide reasonable assistance to ARS for ARS to recover or obtain a credit in relation to any such withholding taxes. For the avoidance of doubt, this **Section 9.2(c)** only applies to withholding for income taxes and does not apply to any other taxes including but not limited to VAT or other surcharges or surtaxes. In addition, for the avoidance of doubt, ARS shall not be responsible for bearing any withholding tax levied on any amount which is larger than the amount of the actual payment due to ARS from Pediatrix.

- 9.3 Records; Audit.** Pediatrix shall keep, and shall cause its Sublicensees to keep, complete and accurate records pertaining to the sale or other transfer or disposition for value of Products in sufficient detail to permit ARS to confirm the accuracy of all payments due hereunder. Such records shall be kept for such period of time required by Applicable Laws, but no less than [***] following the end of the Calendar Year to which they pertain. ARS shall have the right to cause an independent, international, certified public accounting firm [***] to Pediatrix to audit such records to confirm payments for a period covering not more than [***] following the Calendar Year [***] to which they pertain. Such audits may be exercised during normal business hours upon [***] prior written notice to Pediatrix, and except for good cause, shall not be more than [***]. Prompt adjustments shall be made by the Parties to reflect the results of such audit. ARS shall bear the full cost of such audit unless such audit discloses an underpayment by Pediatrix of more than [***] percent ([***]%) of the total amount owed under this Agreement for the period then being audited, in which case, Pediatrix shall bear the cost of such audit and shall promptly remit to ARS the amount of any underpayment plus such audit costs plus interest (as set forth in **Section 9.4** below) from the original due date. Any overpayment by Pediatrix revealed by an audit shall be credited against future payments owed by Pediatrix to ARS (and if no further payments are due, shall be refunded by ARS to Pediatrix within [***]).

- 9.4 Late Payments.** In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at a per annum rate of [***] percent ([***]%) [***]; *provided, however,* that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights and/or remedies it may have as a consequence of the lateness of any payment.

10. INTELLECTUAL PROPERTY

10.1 Ownership.

- (a) The Parties acknowledge and agree that, as between the Parties, all right, title and interest in and to any ARS Technology shall be owned solely by ARS, and all right, title and interest in and to any Pediatrix Technology shall be owned solely by Pediatrix.
- (b) All right, title, and interest in and to any inventions made, developed, conceived or reduced to practice by or on behalf of Pediatrix, its Affiliates or Sublicensees (whether solely or jointly with ARS) in the course of performance of this Agreement that are related to the Composition or Product, including Data, and any Patents and Know-How relating thereto (collectively, the “New IP”) shall be owned solely by ARS. In connection with the foregoing: (i) Pediatrix shall promptly disclose in writing to ARS all New IP, (ii) Pediatrix hereby does, and shall cause its Affiliates and Sublicensees and its and their employees and representatives to, assign and transfer to ARS all right, title, and interest in and to such New IP and agrees to take all further acts reasonably required to evidence such assignment and transfer to ARS; and (iii) such New IP shall constitute ARS Know-How or ARS Patents, as applicable, for purposes of this Agreement. Notwithstanding the foregoing, ARS Patents primarily derived from New IP shall not be considered ARS Patents for purposes of determining Royalty Term or royalty reductions.
- (c) Other than New IP, ownership of inventions and intellectual property rights generated by or on behalf of each Party or jointly by Parties shall follow inventorship in accordance with the patent law of the United States. Inventions made solely by either Party shall be exclusively owned by such Party. Inventions jointly made by both Parties shall be owned jointly.
- (d) All Intellectual Property owned by a Party as of the Effective Date shall continue to be owned by such Party, and except as expressly set forth in this Agreement, neither Party shall have any rights to any Intellectual Property of the other Party.

10.2 Patent Prosecution and Maintenance.

- (a) Subject to this **Section 10.2(a)**, ARS shall have the sole right, as between ARS and Pediatrix, but not obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all ARS Patents, at its sole cost and expense and by counsel of its own choice. Pediatrix shall, upon request of ARS, provide ARS with all reasonable assistance and cooperation in connection therewith. ARS shall keep Pediatrix reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of ARS Patents, including content, timing and jurisdiction of the filing of such ARS Patents in the Pediatrix Territory. In the event that ARS desires to abandon or cease prosecution or maintenance of any ARS Patent in any region in the Pediatrix Territory (“**Discontinued ARS Patent**”), ARS shall provide reasonable prior written notice to Pediatrix of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such ARS Patent in the relevant patent office) and such Discontinued ARS Patent in such region shall not be taken into account in determining the Royalty Term or royalty reductions. Pediatrix shall, upon written notice to ARS provided no later than [***] after such notice from ARS, have the right, but not the obligation, at its cost and expense, to file, prosecute and/or maintain such Discontinued ARS Patent in the applicable region or regions in the Pediatrix Territory, at Pediatrix’s sole cost and expense, in the name of and on behalf of ARS. In such case, Pediatrix shall keep ARS regularly and reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of each of such Discontinued ARS Patents, including content, timing and jurisdiction of the filing of such

Discontinued ARS Patents, and shall consult with, and consider in good faith the requests and suggestions of, ARS with respect to strategies for filing and prosecuting such Discontinued ARS Patents (particularly to avoid prosecution inconsistencies with ARS Patents in the Pediatrix Territory that ARS has not abandoned and corresponding Patents of ARS outside the Pediatrix Territory). If Pediatrix does not provide such election within such [***] after such notice from ARS, ARS may, in its sole discretion, continue prosecution and maintenance of such ARS Patent or discontinue prosecution and maintenance of such ARS Patent. ARS shall have the sole right, as between ARS and Pediatrix, but not obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all Patents Controlled by ARS outside of the Pediatrix Territory that relate to any Composition or Product (including any Patents within the New IP), at its sole cost and expense and by counsel of its own choice.

- (b) Subject to this **Section 10.2(b)**, Pediatrix shall have the sole right, as between ARS and Pediatrix, but not obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all Pediatrix Patents worldwide, at its sole cost and expense and by counsel of its own choice. In the event that Pediatrix desires to abandon or cease prosecution or maintenance of any Pediatrix Patent in any country outside the Pediatrix Territory ("**Discontinued Pediatrix Patent**"), Pediatrix shall provide reasonable prior written notice to ARS of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Pediatrix Patent in the relevant patent office). In such case, upon ARS's written election provided to Pediatrix no later than [***] after such notice from Pediatrix, ARS shall have the right to assume prosecution and maintenance of such Discontinued Pediatrix Patent at ARS's sole cost and expense, in the name of and on behalf of Pediatrix. In such case, ARS shall keep Pediatrix regularly and reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of each of such Discontinued Pediatrix Patents, including content, timing and jurisdiction of the filing of such Discontinued Pediatrix Patents, and shall consult with, and consider in good faith the requests and suggestions of, Pediatrix with respect to strategies for filing and prosecuting such Discontinued Pediatrix Patents (particularly to avoid prosecution inconsistencies with Pediatrix Patents that Pediatrix has not abandoned). If ARS does not provide such election within such [***] after such notice from Pediatrix, Pediatrix may, in its sole discretion, continue prosecution and maintenance of such Pediatrix Patent or discontinue prosecution and maintenance of such Pediatrix Patent. Pediatrix shall have the sole right, as between ARS and Pediatrix, but not obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all Patents Controlled by Pediatrix in the Pediatrix Territory at its sole cost and expense and by counsel of its own choice.

- 10.3 Cooperation of the Parties.** Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Patents under **Section 10.2** and in the obtaining and maintenance of any extensions, supplementary protection certificates and their equivalent with respect thereto respectively, at its own cost (except as expressly set forth otherwise in this **Article 10**). Such cooperation includes: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, reasonably requested by the other Party so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by **Section 10.2**; and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

10.4 Infringement by Third Parties.

- (a) **Notice.** In the event that either ARS or Pediatrix becomes aware of any infringement or threatened infringement by a Third Party of any ARS Patent, or any declaratory judgment or equivalent action challenging any ARS Patent in connection with any such infringement, it shall promptly notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, filed by such Third Party.
- (b) **Response.** Subject to this **Section 10.4(b)**, [***] shall have the first right, as between ARS and Pediatrix, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any ARS Patent by a Third Party that is developing or commercializing a Product or Competitive Product in the Field in the Pediatrix Territory (a “**Product Infringement**”), [***]. In such case, [***] counsel shall reasonably cooperate with [***] and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the Pediatrix Territory. When [***] becomes a party to such action in the Pediatrix Territory, [***] shall have the right, at its own expense, to be represented in any such action, by counsel of [***] own choice, and [***] and its counsel shall reasonably cooperate with [***] and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the Pediatrix Territory. If [***] fails to bring an action or proceeding with respect to a Product Infringement of any ARS Patent in the Pediatrix Territory within (i) [***] following receipt or delivery (as applicable) of the notice of alleged infringement or (ii) [***] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then following a discussion with [***] regarding the reasons why [***] did not bring such action or proceeding, which reasons [***] shall consider in good faith, [***] shall have the right, but not the obligation, to bring and control such action or proceeding to enforce or defend the ARS Patent against the Product Infringement in the Pediatrix Territory at its own expense and by counsel of its own choice, and [***] shall have the right, at its own expense, to be represented in any such action or proceeding by counsel of its own choice. [***] and its counsel shall reasonably cooperate with [***] and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the Pediatrix Territory.
- (c) **Recovery.** Except as otherwise agreed by the Parties in writing as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to ARS Patents against Product Infringement shall be used first to [***], and any remaining compensatory, punitive, or other damages that were awarded in respect of Products (including awards made in respect of lost sales or lost profits with respect to Products) shall be [***].
- (d) **Cooperation.** In the event a Party brings an action in accordance with this **Section 10.4**, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party to such action.
- (e) ARS shall have the sole right, but not the obligation, to bring and control any action or proceeding to enforce or defend the ARS Patent against any infringement or challenge that is not a Product Infringement, [***], and shall be entitled to retain all recoveries.

10.5 Infringement of Third Party Rights. Each Party shall promptly notify the other Party in writing of any allegation by a Third Party that the Manufacture, Development, use or Commercialization of any Composition or Product in the Field in the Pediatrix Territory infringes or may infringe the intellectual property rights of a Third Party (each an “**Infringement Claim**”). The notice shall set

forth the facts of the Infringement Claim in reasonable detail, to the extent such notifying Party has the right to disclose them. [***] shall have the first right to control any defense of any such Infringement Claim at its own expense and by counsel of its own choice, and [***] shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If [***] fails to defend against such Infringement Claim action, or notifies [***] that it does not intend to defend against such Infringement Claim action, within (A) ninety (90) days following the notice of alleged infringement or (B) [***] or as promptly as reasonably practical before the time limit, if any, set forth in the appropriate laws and regulations for the response to such action, whichever comes first, [***] shall have the right, but not the obligation, to defend any such Infringement Claim action at its own expense and by counsel of its own choice, and [***] shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

10.6 Consent for Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any action or proceeding in the Pediatrix Territory under this **Article 10** that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld, conditioned or delayed.

10.7 Trademarks. Pediatrix may use (pursuant to this **Section 10.7**) the Trademarks Controlled by ARS in the Pediatrix Territory as ARS may provide to Pediatrix in writing from time to time (the "**ARS Product Marks**") and may use the English mark thereof with Chinese phonetic translation below. ARS hereby grants to Pediatrix, during the Term and subject to the terms and conditions of this Agreement, a royalty-free, exclusive license under ARS's rights to use such ARS Product Marks in connection with the Commercialization of the Products in the Field in the Pediatrix Territory in compliance with Applicable Laws and this Agreement. Pediatrix shall comply with ARS's brand usage guidelines provided to Pediatrix in its use of the ARS Product Marks. Pediatrix may also brand the Products in the Pediatrix Territory using other Trademarks, including Trademarks specific for the Products that differ from the ARS Product Marks and do not contain the name of ARS (the "**Pediatrix Product Marks**"). Subject to consultation with ARS through the JSC, Pediatrix shall be responsible for selecting, registering, prosecuting, defending, and maintaining all Pediatrix Product Marks at Pediatrix's sole discretion, cost and expense. Pediatrix shall own all rights in the Pediatrix Product Marks in the Pediatrix Territory and shall register and maintain the Pediatrix Product Marks in the Pediatrix Territory that it determines reasonably necessary.

10.8 ARS Controlled Patents Outside the Pediatrix Territory. For clarity, ARS reserves all rights to prepare, file, prosecute (including any interferences, reissue proceedings and re-examinations), maintain, defend and enforce all Patents owned or controlled by ARS related to Compositions and Products outside the Pediatrix Territory. In the event that ARS becomes aware of any infringement or threatened infringement by a Third Party of any such Patent outside the Pediatrix Territory, or any declaratory judgment or equivalent action challenging any such Patent in connection with any such infringement outside the Pediatrix Territory, ARS shall notify Pediatrix in writing to that effect.

10.9 Patents Licensed From Upstream Licensors. Each Party's rights under this **Article 10** with respect to the prosecution and enforcement of any ARS Patent that is in-licensed by ARS from Upstream Licensors under Upstream Licenses shall be subject to the rights retained by Upstream Licensors to prosecute and enforce such Patent.

11. REPRESENTATIONS AND WARRANTIES

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate

or partnership action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it, and (d) except for any Regulatory Approvals, Regulatory Filings, or similar approvals necessary for the Development, Manufacture or Commercialization of Products, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained, and it has the right to grant the licenses granted by it under this Agreement.

11.2 Mutual Covenants. Each Party hereby covenants to the other Party as follows:

- (a) Neither Party shall use in any capacity, in connection with the Development, manufacture or Commercialization of any Product, any individual or entity who has been Debarred. Each Party shall inform the other Party in writing immediately upon becoming aware that any individual or entity who is performing hereunder is Debarred, or if any claim is pending or, to the best of such Party's knowledge, is threatened, relating to the Debarment of such Party or any individual or entity used in any capacity by such Party in connection with the Development, manufacture or Commercialization of any Product. "**Debarred**" means, with respect to an individual or entity, that such an individual or entity (a) is debarred by the FDA pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act ("**FDCA**"), or is the subject of a conviction described in such section (or subject to a similar sanction of any other applicable Regulatory Authority), (b) is the subject of an FDA debarment investigation or proceeding (or similar proceeding of any other applicable Regulatory Authority), or (c) has been charged with or convicted under U.S. Law for conduct relating to the development or approval, or otherwise relating to the regulation, of any product under the Generic Drug Enforcement Act of 1992.

11.3 Additional ARS Representations and Warranties. ARS represents and warrants to Pediatrix that, as of the Effective Date:

- (a) all ARS Patents as of the Effective Date are listed in **Exhibit 1**. Except as otherwise noted in **Exhibit 1**, ARS is the sole and exclusive owner of the ARS Patents, all of which are free and clear of any claims, liens, charges or encumbrances that would conflict or interfere with any rights or licenses granted by ARS to Pediatrix under this Agreement. With respect to ARS Patents not solely owned by ARS, ARS licenses such ARS Patents in a manner that permits exclusive sublicenses as provided in this Agreement. All ARS Patents owned by ARS and, to ARS's knowledge, all other ARS Patents, are (i) subsisting and in good standing and (ii) being diligently prosecuted in the respective patent offices in accordance with Applicable Laws, and have been filed and maintained properly. To ARS's knowledge, as if the Effective Date, all issued ARS Patents are valid and enforceable;
- (b) (i) ARS has obtained from all individuals and entities that participated with ARS in the invention of any ARS Patents (except for any ARS Patents in-licensed by ARS under the Upstream Licenses) effective assignments of all ownership rights of such individuals and entities in such ARS Patents either pursuant to written agreements or by operation of law; (ii) to its knowledge, all such assignments are valid and enforceable, and (iii) to its knowledge, the inventorship of the ARS Patents that are solely owned by ARS or its Affiliates is properly identified on each issued patent or patent application in such ARS Patents;
- (c) all application, registration, maintenance and renewal fees in respect of the ARS Patents have been paid and to ARS's knowledge, all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining such ARS Patents;

- (d) ARS has not received any written notice or does not otherwise have knowledge prior to Effective Date that its activities with the Product has infringed or would infringe any Third Party Patents;
- (e) ARS has not, of the Effective Date, granted any Third Party rights under the ARS Technology or to Develop, Manufacture, register, use or Commercialize the Product in the Field in the Pediatrix Territory that would conflict with Pediatrix's rights hereunder;
- (f) there are no pending or, to ARS's knowledge, no threatened in writing, adverse actions, suits or proceedings against ARS involving the ARS Technology or Product;
- (g) ARS has not initiated or been involved in any proceedings or claims in which it alleges that any Third Party is or was infringing or misappropriating any ARS Patents or ARS Know- How;
- (h) the ARS Technology includes (i) all Know-How Controlled by ARS or its Affiliates that is necessary to Develop, Manufacture and Commercialize the Compositions and Products in the Field in the Pediatrix Territory as such Development, Manufacture, and Commercialization is currently being conducted by ARS or contemplated to be conducted by the Parties hereunder, and (ii) all Patents in the Pediatrix Territory that are Controlled by ARS or its Affiliates that are necessary to Develop, Manufacture and Commercialize a Product in the Field in the Pediatrix Territory as such Development, Manufacture, and Commercialization is currently being conducted by ARS or contemplated to be conducted by the Parties hereunder;
- (i) ARS has complied in all material respects with all material Applicable Laws applicable to its Development and Manufacture of Products in the Field;
- (j) ARS has taken all reasonable precautions to preserve the confidentiality of the ARS Know- How that is existing and documented as of the Effective Date;
- (k) all Upstream Licenses as of the Effective Date are listed in **Exhibit 2**. ARS and its Affiliates
- (i) have been in compliance (1) with all payment terms and (2) in all material respects with all other terms and conditions with the Upstream Licenses as of the Effective Date and all Upstream Licenses as of the Effective Date are in full force and effect; (ii) have not received any written notice that alleges breach or default by ARS of, requests a material amendment of, termination of any Upstream License; (iii) are not aware of any material breach, potential breach, default, or potential default of any Upstream License; (iv) are not aware of any other facts that would result in a material amendment or termination of any Upstream License; and (v) have full rights and authority to grant Pediatrix the right and license to Manufacture the Compositions and Product by Pediatrix, its Affiliates, or Pediatrix's CMO in the Pediatrix Territory as contemplated under this Agreement (subject to Intravail or dodecyl maltoside being supplied by Aegis to ARS, its Affiliates and its sublicensees including Pediatrix per the Aegis Agreement).

11.4 Covenants of ARS. ARS covenants to Pediatrix that during the Term:

- (a) It shall not grant any license or other right under the ARS Technology that is inconsistent with the License;
- (b) ARS and its Affiliates (i) [***] (1) [***] and (2) [***]; (ii) [***] [***]; (iii) [***]; (iv) [***].

- 11.5 Disclaimer.** Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED “**AS IS**” AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing, (a) neither Party represents or warrants that any true and accurate data obtained in compliance with the laws and regulations of a particular country or jurisdiction from conducting clinical trials in that country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted by pursuant to this Agreement or the safety or usefulness for any purpose of the technology it provides hereunder.
- 12. INDEMNIFICATION**
- 12.1 Indemnification by ARS.** ARS hereby agrees to defend, indemnify and hold harmless Pediatrix, its Sublicensees and their respective directors, officers, employees and agents (each, an “**Pediatrix Indemnitee**”) from and against any and all liabilities, expenses and losses, including reasonable legal expenses and attorneys’ fees (collectively, “**Losses**”), to which any Pediatrix Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, Manufacture sale or other Commercialization of any Composition or Product by ARS or its Affiliates or ARS Collaborators (excluding any activities by or on behalf of Pediatrix or its Affiliates or Sublicensees, or any activities under any Supply Agreement, which are separately addressed in such Supply Agreement), (b) the negligence or willful misconduct of any ARS Indemnitee, or (c) the breach by ARS of any warranty, representation, or covenant made by ARS in this Agreement; except, in each case (a)-(c), to the extent Pediatrix is obligated to indemnify ARS Indemnitees under **Section 12.2**.
- 12.2 Indemnification by Pediatrix.** Pediatrix hereby agrees to defend, indemnify and hold harmless ARS, its Affiliates and the ARS Collaborators and their respective directors, officers, employees and agents (each, an “**ARS Indemnitee**”) from and against any and all Losses to which any ARS Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, Manufacturing, sale or other Commercialization of any Composition or Product by Pediatrix or its Affiliates or Sublicensees (excluding any activities by or on behalf of ARS or its Affiliates or ARS Collaborators), (b) the negligence or willful misconduct of any Pediatrix Indemnitee, or (c) the breach by Pediatrix of any warranty, representation or covenant made by Pediatrix in this Agreement; except, in each case (a)-(c), to the extent ARS is obligated to indemnify Pediatrix Indemnitees under **Section 12.1**.
- 12.3 Procedure.** A Party that intends to claim indemnification under this **Article 12** (the “**Indemnitee**”) shall promptly notify the indemnifying Party (the “**Indemnitor**”) in writing of any Third Party claim, demand, action or other proceeding (each, a “**Claim**”) in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate at its expense in the Indemnitor’s defense of and settlement negotiations for any Claim with counsel of the Indemnitee’s own selection. The

indemnity arrangement in this **Article 12** shall not apply to amounts paid in settlement of any action with respect to a Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld, conditioned, or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this **Article 12** if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

- 12.4 Insurance.** Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.
- 12.5 Limitation of Liability.** EXCEPT FOR LIABILITY FOR BREACH OF **ARTICLE 13** AND UNLESS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *PROVIDED, HOWEVER*, THAT THIS **SECTION 12.5** SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS **ARTICLE 12**.
- 13. CONFIDENTIALITY**
- 13.1 Confidential Information.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, during the Term and for [***] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other (disclosing) Party under this Agreement, and both receiving Parties shall keep confidential and, subject to **Sections 13.2, 13.3** and **13.5**, shall not publish or otherwise disclose the terms of this Agreement. Each receiving Party may use the disclosing Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations. Each receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors and other representatives do not disclose or make any unauthorized use of the disclosing Party's Confidential Information. Each receiving Party shall promptly notify the disclosing Party upon discovery of any unauthorized use or disclosure of the disclosing Party's Confidential Information. New IP shall be considered the Confidential Information of ARS, and ARS shall be considered the disclosing Party and Pediatrix the receiving Party with respect to all New IP.
- 13.2 Exceptions.** The obligations of confidentiality and restriction on use under **Section 13.1** shall not apply to any information that the receiving Party can demonstrate through contemporaneous written records: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party or its representatives, generally known or available to the public; (b) is known by the receiving Party at the time of receiving such information, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, or contractors; (c) is hereafter furnished to the receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the receiving Party without the use of Confidential Information belonging to the disclosing Party.

13.3 Authorized Disclosure. Each receiving Party may disclose Confidential Information belonging to the disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;
- (b) regulatory filings for Products (for Pediatrix, only in the Pediatrix Territory) that such Party has a license or right to Develop hereunder in a given country or jurisdiction;
- (c) prosecuting or defending litigation arising under this Agreement;
- (d) complying with applicable court orders or governmental regulations; and
- (e) disclosure to its and its Affiliates' employees, contractors and agents, to ARS Collaborators (in the case of ARS) and to Sublicensees (in the case of Pediatrix), in each case on a need- to-know basis in connection with the Development and manufacture of Compositions, and Development, manufacture and Commercialization of Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non- use at least as stringent as those herein; and
- (f) disclosure to potential and actual investors, acquirers, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration in such receiving Party, in each case under written or professional obligations of confidentiality and non-use at least as stringent as those herein.

Notwithstanding the foregoing, in the event a receiving Party is required to make a disclosure of the disclosing Party's Confidential Information pursuant to **Section 13.3(c)** or **(d)**, and before making any such disclosure, it shall, except where impracticable or prohibited, give prompt advance written notice to the disclosing Party of such requirement and its intended disclosure, and shall cooperate with the disclosing Party's efforts to limit or avoid such disclosure and/or to seek a protective order, confidential treatment of such Confidential Information or other available remedy. In any event, the Parties agree to take all reasonable action to avoid disclosure of a disclosing Party's Confidential Information hereunder. Any information disclosed pursuant to **Section 13.3(c)** or **(d)** shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this **Article 13**.

13.4 Publications. ARS shall have the right to review and comment on any material proposed for public disclosure or publication by Pediatrix regarding results of and other information regarding the other Pediatrix's Development or Commercialization activities with respect to Products, whether by oral presentation, manuscript or abstract, or other means of public disclosure, and including disclosures to the investment community, if such proposed public disclosure or publication might negatively affect Development and/or Commercialization of Products outside the Pediatrix Territory. For the sake of clarity, any press release by Pediatrix shall follow the process set forth in **Section 13.5** below, and not the process contained in this **Section 13.4**. Before any such material described in this **Section 13.4** is submitted for publication or presentation of any such material is made, Pediatrix shall deliver a complete copy in the English language to ARS prior to submitting the material to a publisher or initiating any other public disclosure. ARS shall review any such material and give its comments to Pediatrix as soon as practicable. With respect to oral presentation materials and abstracts, ARS shall make reasonable efforts to expedite review of such oral presentation materials and abstracts, and shall return its comments if any, on such items as soon as practicable to Pediatrix. Pediatrix shall comply with ARS' request to delete references to ARS' Confidential Information in any such material and shall delay any submission for publication or other public disclosure for a period of up to an additional [***] for the purpose of preparing and filing appropriate patent applications.

- 13.5 Publicity; Public Disclosures.** The Parties may issue an initial press release following the Effective Date. It is understood that each Party may desire or be required to issue subsequent press releases relating to this Agreement or activities hereunder. The Parties shall consult with each other reasonably and in good faith with respect to the text and timing of all press releases prior to the issuance thereof, to the extent practicable, *provided* that a Party may not unreasonably withhold, condition or delay consent to such press releases, and that either Party may issue such press releases or make such disclosures to the SEC or other applicable stock exchange or similar agencies as it determines, based on advice of counsel, are reasonably necessary to comply with rules of the stock exchange or Applicable Law. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties shall consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or other stock exchange or as otherwise required by Applicable Laws; *provided* that each Party shall have the right to make any such filing as it reasonably determines necessary under the rules of the stock exchange or Applicable Laws. In addition, following the initial press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.
- 13.6 Prior Confidentiality Agreement.** As of the Effective Date, the terms of this **Article 13** shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.
- 13.7 Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this **Article 13**. In addition to all other remedies, a Party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this **Article 13**.
- 14. TERM AND TERMINATION**
- 14.1 Term.** This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this **Article 14** or by mutual written agreement of the Parties, shall continue, on a Product-by-Product and region-by-region basis, until the expiration of the applicable Royalty Term in the Pediatrix Territory (the "**Term**"). Upon expiration (but not termination) of this Agreement for a Product in a region in the Pediatrix Territory, Pediatrix's licenses under **Section 2.1** shall become perpetual, irrevocable, exclusive, fully paid-up and royalty free with respect to such Product in such region.
- 14.2 Termination for Cause.**
- (a) **Material Breach.** Each Party shall have the right to terminate this Agreement in its entirety upon written notice of termination delivered to the other Party, if such other Party materially breaches this Agreement and has not cured such breach within sixty (60) days (thirty (30) days with respect to any payment breach) after receipt of written notice from the non-breaching Party describing such breach and demanding its cure; *provided* that if such breach is not reasonably capable of cure within the above cure period, but is capable of cure within 120 days from such notice, then, *provided* the breaching Party submits a reasonable cure plan to remedy such breach, the above cure period shall be automatically extended for so long as the breaching Party continues to use Commercially Reasonable Efforts to cure such breach in accordance with the cure plan, but for no more than 60 additional days. If the allegedly breaching Party in good faith disputes such material breach and provides written notice of that dispute to the other Party within the applicable period set forth above, the matter shall be addressed under the dispute resolution provisions in **Article 15**, and the termination shall not become effective unless and until it has been determined under **Article 15** that the allegedly breaching Party is in material breach of this Agreement and has failed to cure such breach within the time periods provided in this **Section 14.2(a)**. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

- (b) **Bankruptcy.** Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files a voluntary insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within [***] after the commencement thereof.
- 14.3 Termination for Patent Challenge.** ARS shall have the right to terminate this Agreement in its entirety upon written notice to Pediatrix if Pediatrix or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, (a) commences any interference or opposition proceeding with respect to, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any ARS Patent, or (b) institutes, actively participates as an adverse party in, or otherwise provides material support to, any action, suit or other proceeding to invalidate any ARS Patent or to obtain a ruling that any claim within any ARS Patent is unenforceable or not patentable; *provided, however*, that ARS shall not have the right to terminate this Agreement under this **Section 14.3**, if (i) such challenge was brought by a Sublicensee and Pediatrix has terminated such sublicense within thirty (30) days of ARS's notice to Pediatrix under this **Section 14.3**, (ii) such challenge is based solely on the scope of an ARS Patent or whether a claim therein qualifies as a Valid Claim and made in defense of a breach claim first brought by ARS against Pediatrix pursuant to this Agreement, or (iii) such challenge is dismissed within thirty (30) days of ARS's notice to Pediatrix under this **Section 14.3** and not thereafter continued.
- 14.4 Termination by Pediatrix.**
- (a) **Termination without Cause.** Pediatrix shall have the right to terminate this Agreement at any time for any reason or for no reason upon ninety (90) days written notice to ARS.
- 14.5 Effects of Termination in Certain Situations.** Upon any termination of this Agreement by ARS pursuant to **Section 14.2, 14.3** or the termination of this Agreement by Pediatrix pursuant to **14.4**, the following shall apply:
- (a) **Termination of Licenses and Other Rights.** All licenses granted to Pediatrix shall automatically terminate, all other rights and obligations of the Parties under this Agreement shall terminate except as provided in to **Section 14.8**, and all sublicenses under the ARS Technology granted from Pediatrix to any Sublicensee shall automatically terminate (*provided* that, upon the request of a Sublicensee that is not in breach of the sublicense agreement, ARS shall consider in good faith to enter into direct agreement with such Sublicensee), in each case on the effective date of termination.
- (b) **Pediatrix Technology.** The license granted to ARS pursuant to **Section 2.3** shall continue and shall become worldwide.
- (c) **Assignments.** ARS shall notify Pediatrix within [***] after the effective date of termination whether it wishes to obtain the assignments set forth in this **Sections 14.5(c)**. Except as otherwise specified below, all such assignments under **Sections 14.5(c)** shall be without cost to ARS.

- (i) **Regulatory Filings.** As promptly as practicable (and in any event within [***]) after such notice, Pediatrix shall: (A) to the extent not previously provided to ARS, deliver to ARS true, correct and complete copies of all Regulatory Filings (including Regulatory Approvals) for Products in the Field in the Pediatrix Territory, and provide to ARS all Pediatrix Know-How not previously disclosed to ARS; (B) to the extent permissible under Applicable Laws, transfer and assign, or cause to be transferred or assigned, to ARS or its designee (or to the extent not so assignable, take all reasonable actions to make available to ARS or its designee all of the benefits of) all Regulatory Filings (including Regulatory Approvals) for Products in the Field in the Pediatrix Territory, whether held in the name of Pediatrix or its Affiliate or Sublicensee; and (C) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this **Section 14.5(c)(i)** to ARS. If the assignment of the Regulatory Filings to ARS is not permitted by Applicable Law or otherwise upon ARS's request, [***], Pediatrix shall continue to hold any such Regulatory Filings for the sole benefit of ARS or its designee (in which case, Pediatrix shall appoint ARS or its designee as the exclusive distributor (with the right to subcontract and appoint subdistributors) under such Regulatory Filings for the Product in the Pediatrix Territory, and also as its agent to interact with the applicable Regulatory Authority in the Pediatrix Territory with respect to such Regulatory Filings), until such time ARS or its designee files its own Regulatory Filings and obtains its own Regulatory Approvals for the Product in the Pediatrix Territory, at which time Pediatrix shall terminate or withdraw its Regulatory Filings for the Product in the Pediatrix Territory.
- (ii) **Trademarks.** Pediatrix shall, and hereby does, effective upon such termination, assign to ARS all of Pediatrix's and its Affiliates' right, title and interest in and to any and all Pediatrix Product Trademarks in the Pediatrix Territory, including all goodwill therein, and Pediatrix shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment.
- (d) **Wind-Down.** Pediatrix shall, as directed by ARS, either wind-down any ongoing Development activities of Pediatrix and its Sublicensees with respect to any Compositions or Products in the Field in the Pediatrix Territory in an orderly fashion or promptly transfer such Development activities to ARS or its designee, in compliance with all Applicable Laws.
- (e) **Transition Assistance.** Pediatrix shall, [***], provide reasonable consultation and assistance for a period of no more than [***] for the purpose of transferring or transitioning to ARS all Pediatrix Know-How not already in ARS's possession and, at ARS's request, all then-existing commercial arrangements relating specifically to Compositions and Products that Pediatrix is able, using Commercially Reasonable Efforts, to transfer or transition to ARS, in each case, to the extent reasonably necessary or useful for ARS to commence Developing, manufacturing, or Commercializing Products in the Pediatrix Territory. The foregoing shall include transferring, upon request of ARS, any agreements with Third Party suppliers or vendors that specifically cover the supply or sale of Compositions or Products in the Pediatrix Territory. If any such contract between Pediatrix and a Third Party is not assignable to ARS (whether by such contract's terms or because such contract does not relate specifically to Compositions or Products) but is otherwise reasonably necessary or useful for ARS to commence Developing, manufacturing, or Commercializing Products in the Pediatrix Territory, or if Pediatrix manufactures the Product itself (and thus there is no contract to assign), then at ARS's cost, Pediatrix shall reasonably cooperate with ARS to negotiate for the continuation of services or supply from such entity, or Pediatrix shall supply such Composition or Product, as applicable, to ARS for a reasonable period (not to exceed [***]) until ARS establishes an alternate, validated source of such services or supply of finished, packaged, labeled Product for the Pediatrix Territory. Such supply shall be at a price equal to [***]% [***], with such cost calculated as [***].

- (f) **Remaining Inventories.** Pediatrix shall have the right, for a period of [***] following termination of this Agreement, to sell or otherwise dispose of any Products, as applicable, on hand at the time of such termination or in the process of Manufacturing; provided that Pediatrix continue to pay royalty to ARS on the sale of such Products. Thereafter, at ARS's election and request, Pediatrix shall transfer to ARS or its designee some or all inventory of Compositions and Products then in the possession or control of Pediatrix, its Affiliates or sublicensees, at a price equal to [***], with such cost calculated as described [***].
- 14.6 Effects of Termination by Pediatrix.** If Pediatrix terminates this Agreement pursuant to **Section 14.2**:
- (a) **Sections 14.5(a), 14.5(c)-14.5(f)** shall apply, *provided that*, [***] shall reimburse all internal (at a fully-burdened rate) and external costs incurred by [***] to conduct activities under **14.5(c)-14.5(f)**, notwithstanding anything to the contrary in **14.5(c)-14.5(f)**.
- (b) The license granted to ARS pursuant to **Section 2.3** shall continue outside the Pediatrix Territory. Upon ARS's request, Pediatrix shall negotiate in good faith with ARS the terms and conditions to expand such license to the Pediatrix Territory.
- 14.7 Confidential Information.** Upon termination of this Agreement in its entirety, except to the extent that a receiving Party obtains or retains the right to use the disclosing Party's Confidential Information, each receiving Party shall promptly return to the disclosing Party, or delete or destroy, all relevant records and materials in such receiving Party's possession or control containing Confidential Information of the disclosing Party; *provided that* such receiving Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations. All Pediatrix Know-How assigned to ARS after the termination of this Agreement as set forth in **Section 14.5** and **14.6(a)** shall be deemed ARS's Confidential Information and no longer Pediatrix's Confidential Information.
- 14.8 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: **Article 1**(Definitions), **Article 8** (Fees and Payments) (solely to the extent payments have accrued prior to the effective date of termination), **Article 9** (Payments; Records; Audits) (solely to the extent payments have accrued prior to the effective date of termination), **Article 12** (Indemnification)(excluding **Section 12.4** (Insurance)), **Article 13** (Confidentiality), **Article 15** (Dispute Resolution), **Article 16** (General Provisions), **Section 10.1** (Ownership), **Section 11.5** (Disclaimer), **Section 14.1** (Term) (which shall survive only with respect to licenses that have become perpetual and irrevocable prior to the expiration or early termination of this Agreement), and **Section 14.5** (Effects of Termination in Certain Situations) through **Section 14.11** (Rights in Bankruptcy) (as applicable).
- 14.9 Exercise of Right to Terminate.** The use by either Party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto; *provided, however*, that termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.
- 14.10 Damages; Relief.** Subject to **Section 14.8**, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

14.11 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to “*intellectual property*” as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. A Party that is a licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. In the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property that are necessary for use and exploitation of such other Party’s licenses and rights hereunder, and same, if not already in its possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party. In the event where any Third Party other than the bankrupt Party (including but not limited to CMO) owns or possesses a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property that are necessary for use and exploitation of such other Party’s licenses and rights hereunder, and same, the bankrupt Party shall procure such Third Party to deliver such complete duplicate to the other Party, upon such other Party’s written request.

15. DISPUTE RESOLUTION

15.1 Objective. The Parties recognize that disputes as to matters (i) arising under, or relating to, this Agreement or (ii) either Party’s rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this **Article 15** to resolve any such dispute if and when it arises.

15.2 Resolution by Executive Officers. Except as otherwise provided in **Article 3**, if an unresolved dispute as to matters arising under or relating to this Agreement or either Party’s rights and obligations hereunder arises, either Party may refer such dispute to the Executive Officers, who shall meet in person or by telephone within [***] after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of such Executive Officers within such [***] period (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with **Section 15.3**.

15.3 Arbitration.

- (a) If the Parties do not resolve a dispute as provided in **Section 15.2**, and a Party wishes to pursue the matter, each such dispute that is not an Excluded Claim (defined below) shall be resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce (“*ICC*”) as then in effect (the “*ICC Rules*”), which ICC Rules are deemed to be incorporated by reference into this clause, using the laws of the State of New York. The arbitration award rendered in any such arbitration shall be final and not appealable and may be executed by any court of competent jurisdiction. If either Party intends to commence binding arbitration of such dispute, such Party shall provide written notice to the other Party informing the other Party of such intention and the issues to be resolved. Within [***] after the receipt of such notice, the other Party may, by written notice to the Party initiating binding arbitration, add additional issues to be resolved.
- (b) The arbitration shall be conducted by a panel of [***] appointed in accordance with the ICC Rules, none of whom shall be a current or former employee or director, or a then-current stockholder, of either Party, their respective Affiliates or any Sublicensee. The place of arbitration shall be New York City, NY, and all proceedings and communications shall be in English.

- (c) It is the intention of the Parties that discovery, although permitted as described herein, shall be limited except in exceptional circumstances. The arbitrators shall permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than [***] after selection of the arbitrators, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration shall be concluded within [***] from such meeting. Failing any such mutual agreement, the arbitrators shall design and the Parties shall follow procedures to such effect.
- (d) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non- compensatory damages. The award shall be in writing and shall describe the basis for the award and the arbitrators' decision(s). The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a Party in connection with the arbitration be paid by the other Party. Each Party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.
- (e) Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations.
- (f) As used in this Section, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns (i) the validity, enforceability or infringement of a patent, trademark or copyright or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

16. GENERAL PROVISIONS

- 16.1 **Governing Law.** This Agreement, and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded.
- 16.2 **Entire Agreement; Modification.** This Agreement is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.
- 16.3 **Relationship Between the Parties.** The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

- 16.4 Non-Waiver.** The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.
- 16.5 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations of a Party hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed); *provided, however*, that either Party may, upon the prior notice to the other Party, assign or otherwise transfer this Agreement in its entirety without the other Party's consent:
- (a) in connection with the transfer or sale to a Third Party of all or substantially all of the business or assets of such Party relating to Products, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise, *provided* that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by operation of law (*e.g.*, in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) prior to the closing of such transaction or developed or acquired by the acquiring party thereafter independent of this Agreement shall not be included in the technology licensed hereunder; or
 - (b) to an Affiliate, *provided* that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein shall be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this **Section 16.5** shall be null and void.

- 16.6 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates and each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, without sublicense or assignment, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by such Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party (or such Affiliate) without any obligation to first proceed against such Party's Affiliate (or such Party).
- 16.7 Severability.** If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.
- 16.8 Notices.** Any notice to be given under this Agreement must be in writing and delivered either in person, or by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, or (c) facsimile or electronic mail (with written confirmation of the recipient) thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this **Section 16.8**. Notice shall

be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt; (ii) if air mailed, [***] after the date of postmark; (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries, (iv) if sent by facsimile, the date of confirmation of receipt if during the recipient Party's normal business hours, otherwise the next business day, and (v) if notice is given by electronic mail, a hard copy shall be provided via air mail (postage prepaid) requiring return receipt, or courier service; the receipt of such hard copy by the receiving Party shall constitute notice here under.

If to Pediatrix, notices must be addressed to:

Pediatrix Therapeutics
Attention: Chief Executive Officer
Facsimile:

with a copy to:

F-Prime Capital, 1 Main St., 13th Flr, Cambridge, MA 02142
Attention: Ketan Patel and Chong Xu
Facsimile:

If to ARS, notices must be addressed to:

ARS Pharmaceuticals, Inc.
3525 Del Mar Heights Rd., #855 San Diego, CA 92130, USA
Attention: Chief Executive Officer
Facsimile:

with a copy to:

ARS Pharmaceuticals, Inc.
3525 Del Mar Heights Rd., #855 San Diego, CA 92130, USA
Attention: Chief Business Officer
Facsimile:

- 16.9 Force Majeure.** Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due, except that the force majeure event itself prevents the making of such payment) by reason of any event beyond such Party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, epidemic, pandemic or related government orders, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and *provided* that the affected Party has not directly or indirectly caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given in writing to the other Party within [***] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure, provided the affected Party shall promptly undertake and continue to undertake all reasonable efforts necessary to cure such force majeure or to perform its obligations despite the ongoing force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or labor dispute.

- 16.10 Interpretation.** The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word “including” and similar words means including without limitation. The word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.
- 16.11 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 16.12 Counterparts; Electronic or Facsimile Signatures.** This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or be executed by facsimile or PDF signature or other electronic signature means, and upon such delivery such electronic delivery or facsimile, PDF or electronic signature(s) shall be deemed to have the same effect as if the original signature had been delivered to the other Party.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties hereto have caused this Collaboration And Distribution Agreement to be executed and entered into by their duly authorized representatives as of the Effective Date.

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal
Name: Richard Lowenthal
Title: President & Chief Executive Officer
Date: 28 February 2021

PEDIATRIX

By: /s/ Ketan Patel
Name: Ketan Patel
Title: Officer
Date: 1 March 2021

SIGNATURE PAGE TO COLLABORATION AND LICENSE AGREEMENT

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED
BECAUSE IT IS BOTH (I) NOT ATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND
CONFIDENTIAL.**

ARS PHARMACEUTICALS, INC.

and

RECORDATI IRELAND, LTD

LICENSE AND SUPPLY AGREEMENT

for the finished product

ARS-1

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62. ANNEXES	51

This **LICENSE AND SUPPLY AGREEMENT** (the **Agreement**) is made and entered into effective as of the last date of execution by the parties hereto (the **Effective Date**) by and between:

ARS PHARMACEUTICALS, INC., a company incorporated and existing under the laws of Delaware (hereinafter, **ARS**), having its registered office at 3525 Del Mar Heights Rd., #855, San Diego, CA 92130, U.S., represented by Richard Lowenthal, in his capacity as President & Chief Executive Officer of the company, duly authorized;

- on the one side -

and

RECORDATI IRELAND, LTD, a company incorporated and existing under the laws of Ireland (**Recordati**), having its registered office at Raheens East, Ringaskiddy, Co Cork, P43 KD30, Republic of Ireland, represented by Cédric Ripert, in his capacity as Managing Director of the company, duly authorized,

- on the other side -

(ARS and Recordati are referred to collectively as the **Parties**, and each of them a **Party**).

WHEREAS:

- (A) ARS is a company engaged, *inter alia*, in the field of developing, registering manufacturing, purchasing, selling and distributing of certain pharmaceutical products;
- (B) ARS is engaged in the development of the Product;
- (C) Recordati is a pharmaceutical company, with a size and a position on the market adequate to, directly or through its Affiliates or Sublicensees, Commercialize specialty care pharmaceuticals throughout the Territory;
- (D) Recordati has completed a satisfactory due diligence on the Product and on ARS' capability and ARS has completed a satisfactory due diligence on Recordati's capability; and
- (E) by entering in this Agreement, the Parties intend to confirm the terms and conditions under which ARS desires to grant to Recordati, and Recordati desires to obtain from ARS, an exclusive license to Commercialize the Product in the Territory.

Now, in light of the above, it is hereby agreed as follows.

SECTION I – CERTAIN DEFINITIONS

1. RECITALS AND ANNEXES

- 1.01** The recitals and the annexes attached hereto (the **Annexes**) constitute an integral part of this Agreement.

2. DEFINITIONS AND INTERPRETATION

2.01 As used in this Agreement, the following terms, unless the context otherwise requires, shall have the meanings set out below:

[***]	means [***] limited liability company;
[***] <i>License Agreement</i>	means the license agreement executed between [***] and ARS on 18 June 2018, as may be amended (subject to Paragraph 38.01(vii)), granting rights with respect to Excipient for use in Products;
[***] <i>Supply Agreement</i>	means the supply agreement executed between [***] and ARS on 18 June 2018, as may be amended (subject to Paragraph 38.01(vii)), pursuant to which [***] undertook to supply to ARS the Excipient;
<i>Affiliate</i>	means, with regards to a Party, any Person that, directly or indirectly through one or more intermediaries, controls, is under control of, or is under common control with such Party, but for only so long as such control exists save that, in respect of Recordati, no member of the [***] network shall be considered as an Affiliate of Recordati; where “ control ” as used in this definition means (i) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, or by contract relating to voting rights or corporate governance; or (ii) direct or indirect beneficial ownership of more than 50% of the voting share capital or other equity interest in such Person;
<i>Aggregate Supply Price</i>	means the sum of the results of each of the multiplication of: (i) Supply Price applicable to the relevant Presentation; and (ii) the number of Presentations indicated in the relevant invoice;
<i>Agreement</i>	has the meaning given in the Headings;
<i>Annexes</i>	has the meaning given in Clause 1;
<i>Annual Cap</i>	means, on a Calendar Year basis, the sum of the: (i) First Cap; (ii) Second Cap; and (iii) Third Cap;
<i>Annual Aggregate Supply Price</i>	means, on a Calendar Year basis, the sum of the results of each of the multiplication of: (i) [***]; and (ii) [***];
<i>Annual Net Sales</i>	means, with respect to any Annual Net Sales Period, the Net Sales earned in such Annual Net Sales Period;
<i>Annual Net Sales Period</i>	means (i) the period from the First Launching Date through 31 December of the Calendar Year in which the First Launching Date took place; and (ii) each Calendar Year thereafter;

Anti-Falsification Regulations

means the serialisation, aggregation and other safety and traceability requirements under the EU Falsified Medicines Directive 2011/62/EU (EUFMD) (and delegated legislation including Regulation (EU) 2016/161) and/or the Drug Supply Chain Security Act and/or any successor legislation or materially equivalent legislation enacted or adopted as of the date hereof in the Territory;

Applicable Laws

means all present and future applicable provisions of all statutes, laws, rules, regulations, administrative codes, ordinances, decrees, orders, decisions, injunctions, awards, judgments, permits and licenses of or issued from any competent court, governmental, tax or revenue authorities or Regulatory Authority, including those relating to or governing the use or regulation of the fulfilment of each Party's obligation set out in this Agreement;

[***]

means [***], a company engaged in the field of developing, manufacturing and supplying drug delivery solutions (such as the [***]) for pharmaceutical usage;

ARS

has the meaning given in the Headings;

ARS Intellectual Property Rights

means all Intellectual Property Rights in relation to the Product (including, without limitation, the Compound and/or the Excipient contained in the Product), in the Territory which are Controlled by ARS as of the Effective Date or become during the Term Controlled by ARS, including, without limitation, the Dossier(s), the Patents and the ARS Know-How; including, without limitation, all rights granted to ARS under the [***] License Agreement in respect to the Excipient(s) and/or the Product;

ARS Know-How

means any and all Know-How relating to the Product (including, without limitation, the Compound and/or the Excipient contained in the Product), in the Territory which is Controlled by ARS as of the Effective Date or become during the Term Controlled by ARS;

ARS Representatives

has the meaning given in Paragraph 41.02;

Breach Process Dispute

has the meaning given in Paragraph 45.01(i);

Calendar Year

means (i) for the first Calendar Year of the Term of this Agreement, the period beginning on the Effective Date and ending on 31 December of the Calendar Year in which the Effective Date took place; (ii) for each Calendar Year thereafter, each successive period beginning on 1 January and ending, 12

(twelve) consecutive calendar months later, on 31 December; and (iii) for the last Calendar Year of the Term of this Agreement, the period beginning on 1 January of the Calendar Year in which this Agreement expires or terminates and ending on the effective date of expiration or termination of this Agreement;

Calendar Quarter

means the respective period of 3 (three) consecutive calendar months ending on 31 March, 30 June, 30 September and 31 December; provided however that (i) the first Calendar Quarter of this Agreement shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (ii) the last Calendar Quarter shall end upon the expiration of termination of this Agreement;

[***]

means [***], a company engaged in the field of supplying active pharmaceutical ingredients for pharmaceutical usage;

cGDP

means the current good distribution practices of medicinal products for human use in accordance with the Directive 2001/83/EC and Commission Delegated Regulation (EU) No 1252/2014 (3) and EudraLex Volume 4, Part II as complemented by the European Commission Guidelines dated 5 November 2013 (2013/C 343/01);

cGMP

means the current good manufacturing practices in accordance with all Applicable Laws, including: (i) International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); Guidance for Industry: Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, and (ii) EudraLex Volume 4 of “The rules governing medicinal products in the European Union”; and (iii) the United States of America Food and Drug Administration Code of Federal Regulations Title 21;

CoA

means the certificate of analysis confirming the quality of the Product and demonstrating that the batch conforms to the Specifications in the destination country of the Territory, according to the requirements of the analytical certification contained in the document “International harmonised requirements for batch certification” (EMA/INS/MRA/387218/2011);

CoC	means the certificate of conformity confirming that the manufacturing stages of the batch of the Product have been carried out in full compliance with the cGMP requirements of the countries of the Territory and with the requirements of the applicable Marketing Authorisations, in full respect of the batch certification requirements contained in the EU cGMP, annex (Appendix II);
Commercially Reasonable Efforts	means, with respect to the efforts to be expended by a Party to achieve any objective, [***];
Commercialize	means all activities relating to the market access, pre-marketing, marketing, distribution, import, use, sale and offer for sale of a product and Commercializing , Commercialization and Commercialized shall be construed accordingly;
Common Technical Document	is the document assembling all the quality, safety and efficacy information in a common format developed by the EMA, the FDA and the Japanese Ministry of Health, Labour and Welfare or any successor agency, maintained by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
Competing Product	means [***];
Compound	means epinephrine [***];
Confidential Information	all Know-How and other proprietary scientific, marketing, financial or commercial information or data that is not publicly available, and that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic or visual form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement;
Concept	has the meaning given in Paragraph 5.01;
Concept Development Activity	has the meaning given in Paragraph 5.01;
Condition Precedent	has the meaning given in Paragraph 23.01;
Control or Controlled	means, with respect to any Intellectual Property Right, possession of the right, whether by ownership, licence or otherwise (but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement), to use, assign, or

	grant a licence, sub-licence or other right to or under, such Intellectual Property Rights, without violating the terms of any agreement or other arrangement with any Third Party and without requiring any further consent from a Third Party;
Counter Inspection	has the meaning given in Paragraph 21.04;
Cure Period	has the meaning given in Paragraph 45.01(i);
Dossier	means the Common Technical Document in respect of the Product;
Effective Date	has the meaning given in the Headings;
EMA	means the European Medicines Agency and its committees (e.g. PDCO) and any successor agency;
End-Users	has the meaning given in Paragraph 14.02 (ii);
EU	means the European Union;
EU Marketing Authorization	means the marketing authorization granted in the EU for authorising medicinal products as regulated by Directive (EC) 2001/83 as amended from time to time, and Regulation (EC) No 726/2004 as amended from time to time;
EU Territory	means all the countries of the EU and their possessions as better described in Annex 1 , and any amendment to such list according to Applicable Laws and agreed in writing by the Parties;
Ex-EU Marketing Authorization	means any and all marketing authorizations and other similar forms of licenses and permits that are obtained from the competent Regulatory Authority in the Ex-EU Territories as necessary for the Commercialization of the Product within the Ex-EU Territories;
Ex-EU Territory	means the countries and their possessions described in Annex 2 , expressly excluding, for the avoidance of doubt, the UK;
Excipient	means [***]'s proprietary chemically synthesizable delivery enhancement agents (including without limitation the Intravail® absorption enhancement agents), licensed by [***] to ARS, that, among other things, allow non-invasive systemic delivery of potent peptide, protein, and small and large molecule drugs;

FDA	means the U.S. Food and Drug Administration and any successor agency;
Feedback	has the meaning given in Paragraph 39.03(iii);
Field	means the treatment, palliation, diagnosis, or prevention of any human or animal disease, disorder, or condition;
First Cap	has the meaning given in Paragraph 28.04(i);
First Launching Date	means the day of the 1 st (first) sale of the Strength 1 Presentation to an End-User;
Force Majeure	means any act, circumstance or event beyond the reasonable control of either of the Parties, including but not limited to earthquakes, hurricanes, fires, storms, tidal waves or other acts of God, riots, strikes, lockouts, picketing, boycotts, shortage in energy, breakage or accidents to one of the Parties' plants, machinery, equipment, pipelines and storage which could not have been reasonably foreseen or prevented, insurrections, rebellions, civil disturbances, epidemic(s), pandemic(s), war and dispositions or orders of governmental authority;
Forecast	has the meaning given in Paragraph 18.01;
GAAP	means the generally accepted accounting principles of the applicable country or jurisdiction, consistently applied, and means the international financial reporting standards (" IFRS ") at such time as IFRS becomes the generally accepted accounting standard and Applicable Laws require that a Party use IFRS;
Improvement	shall mean and include changes, modifications and amendments, conceived, reduced to practice or otherwise developed, relating to the formulation, the device or use of the Compound and Excipient delivered intranasally in the Field which: (i) significantly improve the clinical efficacy of the form of Compound and Excipient delivered intranasally; (ii) significantly reduce any side effects, drug interactions or other adverse effects of the form of Compound and Excipient delivered intranasally; (iii) otherwise represent significant physical enhancements;
Indemnified Party	has the meaning given in Paragraph 42.01;
Indemnifying Party	has the meaning given in Paragraph 42.01;
Inspection	has the meaning given in Paragraph 21.01;

Intellectual Property Rights

means all rights in respect of the following: (i) all inventions, materials, compounds, compositions, substances and other results of whatsoever nature, whether or not patentable, and whether or not applied for registration as a patent; (ii) Know-How; (iii) all patents, including all reissues, extensions, renewals, patents of addition, substitution, re-registrations, re-examinations, as well as all patent applications, including all provisional applications, continuations, continuations-in-part and divisionals; (iv) copyrights; (v) trademarks, and similar marks; and (vi) designs;

Joint Steering Committee or JSC

means the committee to be established by the Parties with a view to oversee the activities to be performed by each Party pursuant to this Agreement;

JSC Meeting

has the meaning given in Paragraph 33.01;

Key-Countries

means [***];

Know-How

means all technical, secret processes or formulae or other secret information concerning industrial, commercial or scientific experience, whether protected or not by patent, copyright or a related right, including know-how, information, inventions, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, ideas, technical assistance, designs, drawings, assembly procedures, specifications, data, results and other intangible materials, including pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques and all tangible embodiments of any of the foregoing in written, electronic or any other form (including the oral form) or other tangible materials that are used as research or development tools, such as assays and reference substances;

License

has the meaning given in Clause 3.01;

Losses

has the meaning given in Paragraph 41.01;

Manufacture

means the manufacturing, processing, compounding, storage, filling, packaging, labelling, leafleting, testing, waste disposal, quality assurance and control, dispatch, sample retention and, to the extent permitted by Applicable Laws and required under the applicable Technical and Quality Agreement, stability testing and release, preparation of Annual Product Quality Reviews of the Product and **Manufactured** and **Manufacturing** shall be construed accordingly;

Market Exclusivity Period	means in respect of a Product in a particular country of the Territory, the shortest period provided for in the relevant Applicable Law of such country after which a Regulatory Authority may grant a marketing authorization to a Third Party by reference to data filed with or available to such Regulatory Authority by ARS, Recordati or any of their Affiliates or Third Party Local Distributor in respect of that Product pursuant to the Applicable Law;
Marketing Authorizations	means collectively the EU Marketing Authorization, the Ex-EU Marketing Authorization and UK Marketing Authorization;
Marketing Authorization Holder	means a Person to which a Marketing Authorization is issued by the competent Regulatory Authority in the Territory for the purpose of Commercializing a pharmaceutical product after evaluation for safety, efficacy and quality;
Material Breach	means a breach of a breaching-Party of this Agreement that it is so fundamental that it renders it unacceptable for the non-breaching Party to continue the business relationship with the breaching-Party;
Medical Device Regulation	means the provisions set out under the Directive 93/42/EEC and Regulation (EU) 2017/745;
MHRA	means the Medicines and Healthcare products Regulatory Agency in the UK and any successor agency;
Minutes	has the meaning given in Paragraph 39.03(iii);
Net Sales	means [***].
New IP	has the meaning given in Paragraph 43.01;
New Launching Date	means the day of any new 1 st (first) sale of any new Strength 3 Presentation to an End-User;
Non-Fit for Use Notice	has the meaning given in Paragraph 21.02;
[***]	means [***], a company engaged in the field of supplying glass containers for pharmaceutical usage;
Parties	has the meaning given in the Headings;

Party	has the meaning given in the Headings;
Patent(s)	means any and all patent documents pending or granted on the Product (and/or the Compound and/or the Excipient contained in the Product) which are Controlled by ARS as of the Effective Date or become during the Term of this Agreement Controlled by ARS; the Patents at the Effective Date are listed in Annex 3 ;
Paediatric Development	means all those activities or studies requested by the PDCO and described in the Paediatric Investigational Plan attached as Annex 4 ;
PDCO	means the Paediatric Committee of the EMA or any successor committee fulfilling comparable functions;
Person	means any individual, company, firm, partnership, joint venture, corporation, proprietorship, association, trust, governmental body, agency or institution of a government, unincorporated organization, or any other organization or entity, private or public (including international, supranational, foreign, federal, national, state, provincial, local or otherwise);
PO	has the meaning given in Paragraph 18.02;
Presentation	means each stock keeping unit of each Strength as described in Annex 6 . Presentations may be added or amended or updated from time to time with mutual written consent of the Parties;
Product	means any composition or derivative or Improvement (implemented pursuant to Paragraph 5.02,) of the Compound and the Excipient delivered intra-nasally through a device that is claimed in a Patent;
Product Purchase Agreement	has the meaning given in Paragraph 14.02(i);
Raw Materials	means all raw materials [***], primary packaging materials and components needed for the manufacturing of the Product;
Recall	means with respect to the Product, a “recall”, “correction” or “market” withdrawal, whether mandatory or voluntary, as those terms are defined by Applicable Laws, as the same may be amended from time to time, and shall include any post-sales warning or mailing of information regarding the Product;
Recordati	has the meaning given in the Headings;

Recordati's Development Activities	means all of those clinical or non-clinical activities carried out by or on behalf of Recordati or its Affiliates or Sublicensees on the Product (i) after EU Marketing Authorization approval and UK Marketing Authorization approval for regulatory or commercial purposes; or (ii) before and after Ex-EU Marketing Authorization approval for regulatory or commercial purposes;
Recordati Livery	means the packaging to be used in relation to the Product in the Territory, which includes Recordati's proprietary Trademarks, logo, get-up and branding, the design and prototypes which are provided by Recordati to ARS from time to time and including any Trademarks and trade dress belonging or licensed to Recordati;
Recordati Representatives	has the meaning given in Paragraph 41.01;
Regulatory Approvals	means the grant of an Ex-EU Marketing Authorization or of the EU Marketing Authorization or of the UK Marketing Authorization, and any pricing approval, reimbursement approval, or any other approval required to Commercialize the Product in any country or other regulatory jurisdiction of the Territory;
Regulatory Authority	means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in a given country or region in the Territory with authority over the manner in which a clinical study is conducted or which is responsible for granting and administering any marketing authorization and other governmental approvals necessary or useful to manufacture, distribute, promote, market and sell pharmaceutical products, or for pharmacovigilance of such products;
Remaining Strength 1 Studies	means those studies as described in Annex 5 ;
Remaining Strength 2 Studies	means those studies as described in Paediatric Development;
Remaining Strength 3 Studies	means those studies as described in Paediatric Development;
[***]	means [***], a company engaged in the field of providing, <i>inter alia</i> , nasal spray and sterile manufacturing production services for pharmaceutical usage;
Royalty Report	has the meaning given in Paragraph 29.02;
Sample	has the meaning given in Paragraph 38.01(iv);

Second Launching Date	means the day of the 1 st (first) sale of Strength 2 Presentation to an End-User;
SDEA	means the agreement to be executed by the Parties with the scope to detail the responsibilities of each Party regarding safety information exchange and each Party's pharmacovigilance obligations and tasks for the Product to ensure compliance with regulatory requirements, which may be modified, amended or supplemented from time to time by written agreement between the Parties;
Second Cap	has the meaning given in Paragraph 28.04(ii);
Second Source	means the company engaged, <i>inter alia</i> , in the field of manufacturing and selling of medicinal products which can be used by the Parties as an alternative Manufacturing and supplying source of the Product (including also for the Territory) to be validated pursuant to the terms and conditions of this Agreement;
Specifications	means the technical specifications and testing methods for the Product approved by the relevant Regulatory Authority. Specifications may be added or amended or updated, and in any case approved by the relevant Regulatory Authority, from time to time with mutual written consent of the Parties;
Strength(s)	means collectively the Strength 1, Strength 2 and Strength 3;
Strength 1	means the Product in [***] form intended for [***];
Strength 2	means the Product in [***] form (or any other dosage form) intended for [***];
Strength 3	means the Product in any dosage form or delivery system different from Strength 1 and Strength 2 developed by ARS, intended for [***];
Sublicensee	means those Third Parties to be appointed by Recordati, if deemed necessary by Recordati, for the Commercialization of the Product within one or more countries in the Territory;
Supply Price	means the supply price set out in Annex 6 ;
Tax Withholding Documents	means documents prepared by ARS in order for ARS to obtain benefits under applicable tax treaty or domestic provisions, including the reduction or exemption from any withholding tax and the procurement of any available tax refunds, as described in Paragraph 32.02;

Technical and Quality Agreement	means the agreement to be executed by the Parties which sets out among other things the Parties' respective responsibilities for each step of the activities involved in the quality control of the Product and the communication processes between the Parties with respect thereto, which may be modified, amended or supplemented from time to time by written agreement between the Parties;
Technology Transfer Activity	means all of the activities necessary for reproducing the Manufacturing activities of the Product as described in the approved Dossier and according to the Specifications;
Term	has the meaning given in Paragraph 44.01;
Terminated Party	has the meaning given in Paragraph 45.01;
Terminating Party	has the meaning given in Paragraph 45.01;
Territory	means collectively the EU Territory, the Ex-EU Territory and the UK;
Tier 1 Royalty	has the meaning given in Paragraph 28.02(i);
Tier 2 Royalty	has the meaning given in Paragraph 28.02(ii);
Tier 3 Royalty	has the meaning given in Paragraph 28.02(iii);
Third Cap	has the meaning given in Paragraph 28.04(iii);
Third Party	means a Person other than a Party or an Affiliate of a Party;
Third Party Claim	has the meaning given in Paragraph 41.01;
Trademarks	means with regard to a certain country of the Territory, all marks, logos, trademarks and brand names designated by a Party to Commercialize the Product within one or more countries of the Territory;
UK	means the United Kingdom (including, for the avoidance of doubt, the Channel Islands, the Isle of Man and Gibraltar);
UK Marketing Authorization	means any and all marketing authorizations and other similar forms of licenses and permits that are obtained by the competent Regulatory Authority in the UK as necessary for the Commercialization of the Product within the UK.

2.02 In this Agreement:

- (i) words denoting the singular include the plural and the other way round;
- (ii) words denoting one gender include each gender and all genders; and
- (iii) the headings are for convenience only and do not affect the interpretation of this Agreement.

2.03 In this Agreement, unless otherwise specified or the context otherwise requires, a reference to:

- (i) a document, instrument or agreement (including, without limitation, this Agreement) is a reference to any such document, instrument or agreement as modified, amended, varied, supplemented or novated from time to time;
- (ii) a Section, a Clause or a Paragraph or an Annex is a reference to a section, a clause, a paragraph or an annex of this Agreement and a reference to this Agreement includes the Annexes; and
- (iii) a provision of any statute or other legislation is to be construed as a reference to such provision as amended or re-enacted or as its application is modified from time to time (whether before or after the date of this Agreement) and shall include a reference to any provision of which it is a re-enactment (whether with or without modification) and to any orders, regulations, instruments or other subordinate legislation (and relevant codes of practice) made under the relevant statute or other legislation except to the extent that any amendment or re-enactment coming into force after the date of this Agreement would increase or extend the liability of any Party to any other Person under this Agreement.

SECTION II – SCOPE OF THIS AGREEMENT

3. GRANT OF LICENSE

3.01 On and subject to the terms and conditions set out in this Agreement, ARS hereby grants to Recordati an exclusive (even as to ARS and to ARS' Affiliates, except as expressly set forth herein), royalty-bearing, sublicensable (as provided in Clause 3.03) license under the Patents until expiration of the last-to-expire Patent and under the ARS Intellectual Property Rights other than Patents during the Term to (i) perform Recordati's Development Activities on the Product for Commercialization in the Territory, (ii) Manufacture (or have Manufactured) the Product for Commercialization in the Territory, (iii) file and hold Regulatory Approvals for the Product in the Territory, and (iv) Commercialize the Product in the Territory (the *License*).

3.02 Without prejudice to the License granted to Recordati pursuant to Clause 3.01 above, ARS shall have and retain (a) all rights to practice, and to grant licenses under, the ARS Intellectual Property Rights outside the Territory, for any and all purposes, and (b) the right to develop and Manufacture (or have Manufactured) the Product in the Territory:

- (i) in order to exercise its rights and fulfill its obligations set out in this Agreement; and
- (ii) for the purpose of developing, filing for and obtaining regulatory approvals for and Commercializing the Product outside the Territory.

- 3.03** Recordati shall have the right to grant sublicenses of the rights granted under the License to (i) any Affiliate with written notice to ARS; (ii) any Third Party in countries of the Territory outside the Key-Countries with written notice to ARS; and (iii) any Third Party in the Key-Countries with the prior written consent of ARS, [***] subject to, and consistent with, the terms and conditions of this Agreement. Recordati shall ensure that each agreement with a Sublicensee grants ARS all rights with respect to data, results and Intellectual Property Rights made or generated by such Sublicensee as if such data, results and Intellectual Property Rights were made or generated by Recordati. Recordati shall be responsible for the compliance of its Sublicensees with the terms and conditions of this Agreement.
- 3.04** Subject to the terms and conditions of this Agreement, Recordati hereby grants to ARS, with the right of ARS to grant to its licensees with respect to the Products outside the Territory through multiple tiers, the royalty-free, fully-paid, irrevocable, perpetual right to cross-reference Marketing Authorizations and other regulatory filings of Recordati and its Affiliates and Sublicensees with respect to the Products in the Territory (and data included in such regulatory filings) solely for the purpose of (i) obtaining regulatory approval supporting Commercialization activities for Products outside the Territory, and/or (ii) fulfilling its obligations set out in this Agreement.
- 3.05** Subject to the terms and conditions of this Agreement, ARS hereby grants to Recordati, with the right of Recordati to grant to its Affiliates and Sublicensees with respect to the Products within the Territory through multiple tiers, the royalty-free, fully-paid, irrevocable, perpetual right to cross-reference Marketing Authorizations and other regulatory filings of ARS and its Affiliates and licensees with respect to the Products outside the Territory (and data included in such regulatory filings) solely for the purpose of (i) obtaining regulatory approval supporting Commercialization activities for Products within the Territory, and/or (ii) fulfilling its obligations set out in this Agreement.
- 3.06** Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Intellectual Property Rights owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or sublicensees to, practice any Intellectual Property Rights licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

4. LICENSE EXCLUSIVITY PERIOD

- 4.01** On the terms and conditions set out in this Agreement, starting from the Effective Date and up to the expiration (or the termination) of this Agreement, ARS undertakes:
- (i) not to grant any further licenses or rights to any Third Party (including, without limitation, its Affiliates) which are encompassed by the License; and
 - (ii) not to exercise (and cause its Affiliates not to exercise) any of the rights encompassed by License, except as expressly provided herein.

5. IMPROVEMENTS

- 5.01** In the event that during the Term, ARS conceives an Improvement concept (each a **Concept**) ARS will [***] deliver to Recordati a written proposal to commence cooperating on the Concept development activity (the **Concept Development Activity**) which shall include, *inter alia*, a complete written disclosure of the Concept.
- 5.02** Should Recordati be willing to cooperate with ARS on the Concept Development Activity, the Parties shall commence good faith negotiation of a separate agreement setting out the Parties':
- (i) obligations in respect to the Concept Development Activity; and
 - (ii) rights in respect to the possible Improvement arising out of the Concept Development Activity.

- 5.03** In case Recordati does not indicate willingness to cooperate on the Concept Development Activity within a [***] period starting from the date on which ARS delivered to Recordati the proposal set out in Paragraph 5.01 above or the Parties are unable to agree on the terms and conditions of the separate agreement described in Paragraph 5.02 above within a [***] period starting from the date on which the ARS delivered to Recordati the proposal set out in Paragraph 5.01 above, ARS shall have the right (but not the obligation) to carry out the Concept Development Activity at its own costs and risk.
- 5.04** In the event that the Improvement arising out of the Concept Development Activity carried out by ARS pursuant to Paragraph 5.03 above can be reasonably utilized in the Territory, ARS shall deliver to Recordati a written proposal to exploit the rights under such Improvement in the Territory.
- 5.05** Should Recordati be willing to exploit the Improvement described ARS proposal pursuant to Paragraph 5.04 above, the Parties shall negotiate in good faith the terms and conditions according to which ARS will license to Recordati the rights to exploit such Improvement in the Territory.
- 5.06** In case the Parties are unable to agree on the terms and conditions of the license agreement described in Paragraph 5.05 above within a [***] period starting from the date on which the ARS delivered to Recordati the proposal set out in Paragraph 5.04 above, neither Party shall exploit such Improvement in the Territory.
- 5.07** It is acknowledged by the Parties that any improvement, which either does not have any impact on the Dossier or the impact on the Dossier is limited to regulatory variations which do not imply any clinical or material development, will not be considered an Improvement and the rights to such any improvement shall be included in the rights granted to Recordati pursuant to this Agreement without any additional charge. For clarity, the following modifications to the Product cannot be considered as an Improvement:
- (i) any change in the size or to the shape or to the appearance of the device, also in order to comply with the new Medical Device Regulation, while keeping the same function as the approved device;
 - (ii) any change in the Manufacturing process or in the Raw Material with the scope to reduce costs or increase efficiency of the Manufacturing process;
 - (iii) any change in the device with the scope to increase the compliance of the administration.

SECTION III – DEVELOPMENT AND REGULATORY MATTERS

6. DEVELOPMENT OF THE PRODUCT IN THE TERRITORY

- 6.01** As of the Effective Date, to ARS' knowledge based upon feedback ARS has received from EMA, the studies of Strength 1 that it has completed are the only studies of Strength 1 that would be required by EMA to grant the EU Marketing Authorization for the Strength 1.
- 6.02** ARS undertakes to:
- (i) perform [***]:
 - (a) the Remaining Strength 1 Studies;
 - (b) the Remaining Strength 2 Studies and

- (c) the Remaining Strength 3 Studies (if Strength 3 is required by EMA and provided that ARS and Recordati agree to make Commercially Reasonable Efforts to renegotiate or modify the Paediatric Development requirements for Strength 3, in good faith, irrespective of the Party who is the Marketing Authorization Holder, with EMA or other Regulatory Authorities in the Territory after approval of either Strength 1 or Strength 2);
- (ii) use Commercially Reasonable Efforts to complete:
 - (a) the Remaining Strength 1 Studies by no later than the end of the [***] accordance with the timeline set out in Annex 5;
 - (b) the Remaining Strength 2 Studies with a view to allowing submission of the post-approval variation to the EU Marketing Authorization and to the UK Marketing Authorization by [***] and the related stability studies of the Strength 2 by [***] in accordance with the timeline set out in Annex 4; and
 - (c) the Remaining Strength 3 Studies (if Strength 3 is required by EMA) by [***] in accordance with the timeline set out in Annex 4 or as otherwise required by EMA.

6.03 The Parties agree that the following development activities and the related development costs shall be borne according to the following scheme:

- (i) any studies requested by the EMA to be performed before the grant of the EU Marketing Authorization for Strength 1, Strength 2 and Strength 3, and/or by the MHRA before the grant of the UK Marketing Authorization, shall be performed by ARS at its own costs;
- (ii) any post-approval studies requested by the relevant Regulatory Authority to be performed after the grant of an EU Marketing Authorization for the Product (Strength 1, Strength 2 and Strength 3), and/or after the grant of the UK Marketing Authorization shall be performed by Recordati at its own costs (in case such studies are required also outside the Territory, the Parties shall discuss in good faith how to split the costs of such studies); and
- (iii) any studies requested by Regulatory Authorities other than the EMA and the MHRA to grant the Ex-EU Marketing Authorization or after the grant of the Ex-EU Marketing Authorization for the Product, shall be performed by Recordati at its own costs.
- (iv) The Parties shall discuss in good faith the way to conduct such requested studies, provided that (a) the Parties shall cooperate and implement risk minimization activities in order to reduce the potential impact on the business of both Parties, and (b) each Party shall have the final say on the manner to conduct the study that has to be performed by such Party.

6.04 For the avoidance of doubt, the results and all Intellectual Property Rights arising from:

- (i) the activities set out under Paragraph 6.03(i) above shall be the exclusive property of ARS and included in the License;
- (ii) the activities set out under Paragraphs 6.03(ii) and 6.03(iii) above shall be New IP subject to Paragraph 43.01 and included in the License but Recordati shall have the royalty-free, fully paid-up right (with the right to sublicense) to use such New IP for the Territory during the Term.

7. REGULATORY ACTIVITIES IN THE TERRITORY

- 7.01** As of the Effective Date, based upon the Feedback and the Minutes, ARS plans to submit the application for the EU Marketing Authorization for the Strength 1 to the EMA on the legal basis of article 8(3) of the EU Directive 2001/83/EC.
- 7.02** Notwithstanding the provision set out in Paragraph 7.01 above, in order to avoid any possible delays after submission of the EU Marketing Authorization application for the Strength 1 to the EMA pursuant to the provision set out in Paragraph 7.03 and Paragraph 7.04(i) below, ARS, starting from the Effective Date, undertakes to promptly commence also:
- (i) the preparation of a Dossier and other documentation required under article 10(a) of the EU Directive 2001/83/EC;
 - (ii) the activities necessary in order to allow the UniDose System as described in the Dossier to be compliant to the EU Regulation 2017/745 by [***] and promptly provide Recordati with the documentation necessary to evidence such compliance in accordance with the relevant EU guidelines as soon as available, and in any event by no later than [***].
- 7.03** Starting from the Effective Date, ARS and Recordati undertake to discuss in good faith the most appropriate legal basis for the submission of the EU Marketing Authorization application for the Strength 1 to the EMA. ARS shall provide Recordati the comments of *Rapporteur* and of *Co-Rapporteur* on the Minutes and the final minutes and, also based on such comments, Parties shall finally determine the legal basis for the application for the EU Marketing Authorization for the Strength 1 to the EMA, which may include a different type of submission to be made in accordance with article 10(a) of the EU Directive 2001/83/EC.
- 7.04** ARS undertakes to:
- (i) submit the application for the EU Marketing Authorization for the Strength 1 to the EMA, using Commercially Reasonable Efforts to do so on [***] and in any case [***], with a view to obtaining a positive validation of such submission from the EMA; provided that should EMA raises questions during validation, ARS undertakes to take any action needed to address such questions, including promptly changing the legal basis of the submission (if needed).
 - (ii) submit the application for the UK Marketing Authorization for the Strength 1 to the MHRA, using Commercially Reasonable Efforts to do so no later than [***], with a view to obtaining a positive validation of such submission from the MHRA;
 - (iii) include in the applications set out in points (i) and (ii) above, 2 (two) Trademarks respectively indicated and owned by ARS and Recordati;
 - (iv) manage the regulatory process with an aim to obtain EU Marketing Authorization and the UK Marketing Authorization in a timely manner;
 - (v) promptly – after the grant of the EU Marketing Authorization and of the UK Marketing Authorization of the Strength 1, even at different times and upon written request by Recordati – transfer to Recordati the ownership of each such Marketing Authorizations in order for Recordati to become the Marketing Authorization Holder;
 - (vi) deliver to Recordati a copy of the Dossier as submitted to EMA and the MHRA pursuant to points (i) and (ii) above and all the following documentation and/or information and/or correspondence with those Regulatory Authorities even at different times, that is useful or required for regulatory purposes in the Territory; and

- (vii) promptly cooperate with Recordati in order to implement the changes, modifications and/or updates to the Dossier requested by any Regulatory Authority of the Territories concerning the Product.
- 7.05** After the completion of the activity set forth in Paragraph 7.04(v) and 7.04(vi) above, Recordati undertakes to:
- (i) use Commercially Reasonable Efforts to submit the application for the post-approval variation to the EU Marketing Authorization and to the UK Marketing Authorization of the Strength 2 and/or Strength 3, with an aim to obtain such Regulatory Approvals in a timely manner;
 - (ii) use Commercially Reasonable Efforts to submit the application for the Ex-EU Marketing Authorization for the Product on a country-by-country basis to the Regulatory Authorities in the Ex-EU Territory in the time frame as defined by Recordati taking into account the commercial impact on a country-by-country basis; and
 - (iii) comply with all regulatory activities that are required to a Marketing Authorization Holder under Applicable Laws.
- 7.06** The Parties acknowledge that any regulatory activities pursuant to Paragraph 7.01 and 7.05 above need the collaboration of both Parties in order to be successfully completed. As such, the Parties agree that:
- (i) promptly by no later than [***] from the Effective Date, ARS shall deliver to Recordati the latest version of the Dossier together with any other documentation and/or information in ARS's possession and Control that is useful or required for the purpose of obtaining Regulatory Approvals in the EU Territory, or complying with all Applicable Laws, with respect to the Product;
 - (ii) within [***] following receipt of the documentation set out in Paragraph 7.06(i) above, Recordati shall review such documentation and provide comments to ARS;
 - (iii) promptly after the comments provided by Recordati to ARS, ARS shall review such comments and:
 - (a) in case of agreement, ARS shall promptly implement such comments; or
 - (b) in case of disagreement between the Parties, the matter will be promptly addressed to the JSC; and
 - (iv) after the submission of the application for the EU Marketing Authorization and the UK Marketing Authorization, ARS will promptly provide Recordati with all documentation and communications with respect to the Product received from the Regulatory Authorities and with all ARS' drafts documents with respect to the Product in response to such Regulatory Authorities, for Recordati's review. The provisions set out in Paragraphs 7.06(ii) to 7.06(iii) above shall apply *mutatis mutandis*.

8. REGULATORY COSTS

8.01 [***] will bear:

- (i) all of the Regulatory Authorities' fees relating to the applications, filing, obtainment, variations and transfer of the Marketing Authorizations in the Territory and all the costs for maintenance of such Marketing Authorizations in the Territory; and
- (ii) Third Parties costs related to regulatory activities conducted by ARS upon Recordati's written request, to support Recordati for the applications, filing, obtainment, variations and transfer of the Marketing Authorizations in the Territory; for the avoidance of doubt, ARS acknowledges that any costs relating to Third Party appointed by ARS without the prior written request of Recordati will be fully borne by ARS.

8.02 [***] undertakes:

- (i) in the event Recordati, Recordati's Affiliates or a Sublicensee, following Commercialization of the Product in the EU Territory and UK, receives from EMA and/or MHRA a mandatory requirement to modify the Dossier, [***], will make its Commercially Reasonable Efforts to support [***] to promptly submit such modification to EMA and/or MHRA (as the case may be) in order to implement such modification, provided however that ARS undertakes to supply the Product under the current Dossier until the aforementioned modifications are implemented and approved by EMA and/or MHRA (as the case may be);
- (ii) in the event Recordati, Recordati's Affiliates or a Sublicensee, following Commercialization of the Product in the Ex-EU Territory, receives from any Regulatory Authority in the Ex-EU Territory a mandatory requirement to modify the Dossier, [***], will make its Commercially Reasonable Efforts to support [***] to promptly submit such modification to the relevant Regulatory Authority in the Ex-EU Territory in order to implement such modification, provided however that [***] undertakes to supply the Product under the current Dossier until the aforementioned modifications are implemented and approved by the relevant Regulatory Authority in the Ex-EU Territory; and [***] shall reimburse all external costs incurred by [***] to conduct such modifications, provided such items and costs are discussed and agreed upon in advance between [***] and [***];
- (iii) in the event Recordati deems appropriate to implement certain modifications to the Dossier, including changes in the design, Manufacturing or packaging, [***], at [***], will make its Commercially Reasonable Efforts to support [***], to promptly submit such modification to relevant Regulatory Authority of the Territory in order to implement such modification; provided however that [***] undertakes to supply the Product under the current Dossier until the aforementioned modifications are implemented and approved by the relevant Regulatory Authority;
- (iv) in the event ARS deems appropriate to implement certain modifications to the Dossier (including, for the avoidance of doubt, changes of the Product suppliers listed in Clause 9 below), ARS will:
 - (a) promptly request in writing [***] implement such modifications [***];
 - (b) [***], promptly submit all the documentation concerning such modification to the Marketing Authorization Holder in order to allow such Marketing Authorization Holder to file such documentation with the relevant Regulatory Authority; and

(c) [***],

provided however that ARS undertakes to supply the Product under the current Dossier until the aforementioned modifications are implemented and approved by the relevant Regulatory Authority.

8.03 For the avoidance of doubt, the Parties acknowledge that the changes and modifications arising out of:

- (i) the activities set out under Paragraph 8.01 shall be the exclusive property of Recordati and ARS shall have the rights set forth in Paragraph 3.04 to such changes and modifications;
- (ii) the activities set out under Paragraph 8.02 shall be the exclusive property of ARS and included in the License and Recordati shall have the rights set forth in Paragraph 3.05 to such changes and modifications

SECTION IV – MANUFACTURING OF THE PRODUCT

9. MANUFACTURING UNDERTAKINGS

9.01 On the terms and conditions set out in this Agreement, ARS undertakes to [***]:

- (i) [***] to supply – pursuant to the term of the [***] Supply Agreement – to [***] the Excipient as described in the Dossier to be supplied in adequate quantities and adequate lead time in order to allow the Manufacture of the Product pursuant to the provisions set out in Paragraph 9.01(v) below;
- (ii) [***] (or any other supplier following approval in the Dossier) to supply to [***] the glass vial as described in the Dossier to be supplied in adequate quantities and adequate lead time in order to allow the Manufacture of the Product pursuant to the provisions set out in Paragraph 9.01(v) below and pursuant to the Applicable Laws;
- (iii) [***] (or any other supplier following approval in the Dossier) to supply to [***] the [***] (or equivalent system) as described in the Dossier to be supplied in adequate quantities and adequate lead time in order to allow the Manufacture of the Product pursuant to the provisions set out in Paragraph 9.01(v) below and pursuant to the Applicable Laws (including, for the avoidance of doubt, the Medical Device Regulation);
- (iv) [***] (or any other supplier following approval in the Dossier) to supply to [***] the Compound as described in the Dossier to be supplied in adequate quantities and adequate lead time in order to allow the Manufacture of the Product pursuant to the provisions set out in Paragraph 9.01(v) below and pursuant to the Applicable Laws;
- (v) [***] (or other contract manufacturer engaged by ARS in accordance to this Agreement) to:
 - (a) use its Commercially Reasonable Effort to Manufacture – by no later than first Calendar Quarter [***] – scale-up pilot batches of the Product in compliance with the Applicable Laws (including, but not limited to, all applicable cGMP standards) and prepare and deliver to Recordati the relevant documentation to be used for the updating of the Dossier;

- (b) use its Commercially Reasonable Effort to devote adequate Manufacturing capacity to be capable of Manufacturing and supplying the Product for the Territory to Recordati in accordance with the terms and conditions of this Agreement;
- (c) purchase the Raw Materials in sufficient quantities to enable the continued Manufacturing of the Product for the Territory in accordance with the terms and conditions of this Agreement;
- (d) Manufacture, supply, store and test the Product for the Territory (including disposing of all waste and other materials) in compliance with the terms and conditions of:
 - (1) this Agreement;
 - (2) the Dossier and the Specifications;
 - (3) the Technical and Quality Agreement; and
 - (4) the Applicable Laws relating to the Manufacturing and supplying of the Product, including, but not limited to, all applicable cGMP standards and/or guidelines and cGDP;
- (e) maintain records to allow performance of a complete batch history via batch tracing of the Product for the Territory; and
- (f) keep on file for the relevant Product shelf life such Manufacturing records and analytical results pertaining to the Manufacture of each lot of the Product for the Territory as are required under the Dossier.

10. LABELLING AND PACKAGING

10.01 Starting from the Effective Date and up to the expiration or termination of this Agreement, Recordati grants to ARS the non-exclusive, paid-up, royalty-free, transferable license to use the Recordati Livery and the Recordati's Trademarks which ARS is requested to use in order to perform its obligation set out in this Agreement.

10.02 For the avoidance of doubt, ARS acknowledges that ARS will not acquire, in whatsoever manner, any rights or interests in the Recordati Livery and/or Recordati's Trademarks.

10.03 ARS undertakes:

- (i) not to use (or have used) the Recordati Livery and/or Recordati's Trademarks for any purpose other than the fulfilment of ARS' obligations set out in this Agreement;
- (ii) not to make, or cause to be made, changes, modifications and/or updates to the Recordati Livery and/or Recordati's Trademarks;
- (iii) not to use nor register any trademarks which, in any way, might conflict with or imitate the Recordati's Trademarks and to refrain from acting in a way which could diminish their value;
- (iv) to make it explicitly clear to its employees and to [***] (or other contract manufacturer engaged by ARS in accordance to this Agreement) that the ownership of the Recordati Livery and/or Recordati's Trademarks vest and belong exclusively to Recordati; and

- (v) to promptly notify Recordati in writing, of any infringement, counterfeiting or passing off [***] of the Recordati's Trademarks of which ARS becomes aware.

10.04 ARS undertakes to [***] (or other contract manufacturer engaged by ARS in accordance to this Agreement) to:

- (i) label and package the Product for the Territory using the Recordati Livery;
- (ii) procure that serialisation and aggregation of the Product or other measures implemented pursuant to Anti-Falsification Regulations will be carried out in accordance with the Technical and Quality Agreement, the Applicable Laws including, but not limited to, all applicable cGMP standards and/or guidelines and cGDP; and
- (iii) support at its own costs and in compliance with the Anti-Falsification Regulations and the Applicable Laws, the implementation of the serialization data exchange with Recordati.

10.05 The Parties acknowledge that the Marketing Authorization Holder shall be responsible, at its own costs for:

- (i) the creation of the serial codes pursuant to the Anti-Falsification Regulations to be provided to [***] (or other contract manufacturer engaged by ARS in accordance to this Agreement) during the Term; and
- (ii) the uploading of master data and such serial codes into the European Hub (EMVS) or into the system foreseen by the Anti-Falsification Regulations in force on a Territory country-by-country basis.

10.06 ARS further undertakes to [***] (or other contract manufacturer engaged by ARS in accordance to this Agreement):

- (i) not to use any labels, packages or other materials containing the Recordati Livery for any other products; and
- (ii) to store the Recordati Livery and pack inventory of the same in compliance with the terms and conditions of:
 - (a) this Agreement;
 - (b) the Dossier;
 - (c) the Technical and Quality Agreement; and
 - (d) the Applicable Laws relating to the storage of the Product, including, but not limited to, all applicable cGMP standards and/or guidelines and cGDP.

11. QUALITY TEST OF THE PRODUCT

11.01 ARS undertakes to [***] (or other contract manufacturer engaged by ARS in accordance to this Agreement) to:

- (i) test the Compound, the Raw Material, the [***] (or equivalent system approved in the Dossier) and the Product for the Territory according to the Dossier and the Specifications; and

- (ii) perform in process and final quality controls on the Product for the Territory according to cGMP and to the Specifications set forth in the Dossier and the Technical and Quality Agreement and shall approve the release of the Product in accordance with EU cGMP prior to shipment of the Product to Recordati by means of issuing of a CoA and a CoC.

12. AUDIT OF PRODUCT MANUFACTURING FACILITIES

- 12.01** Upon reasonable prior notice to ARS and during regular business hours, Recordati or the entity designated by Recordati and reasonably acceptable to ARS shall have the right [***] to audit the Product's Manufacturing facility, including the access to the Manufacturing, packaging, warehousing and laboratory areas related to the Manufacture of the Product for the Territory, to check the compliance with Applicable Laws, cGMP and cGDP with the provisions of this Agreement and the Technical and Quality Agreement (also for the purpose of qualifying such Manufacturing facility). This right for Recordati and/or the entity designated by Recordati includes access to audit documents and records relating to the performance of the Manufacture of the Product for the Territory.
- 12.02** ARS shall, within [***] of any written notice of any deficiencies discovered during such inspection, respond to Recordati with a plan to remedy any deficiencies within a reasonable time which may be noted in any such audit.
- 12.03** ARS will maintain all legally required and proper records relating to the Manufacture of the Product for the Territory in accordance with industry practice and, if required in writing by Recordati, will provide Recordati with copies of such records relating to all stages of the Manufacturing and supplying of the Product for the Territory.
- 12.04** In addition to the above, ARS undertakes to promptly notify Recordati in writing, in accordance with the Technical and Quality Agreement, of any inspection of the Product Manufacturing facility requested or proposed or scheduled with any governmental authority that relates to the Product or to general matters at the Product Manufacturing facility that might affect the Product for the Territory.
- 12.05** Pursuant to the provisions of Paragraph 12.04 above, ARS undertakes to ensure that any implementation requested by any governmental authority's audit report to the Product Manufacturing site will be [***] fulfilled [***].

13. TECHNOLOGY TRANSFER

- 13.01** ARS acknowledges that it is of the Parties' best interest that a second Manufacturing and supplying source of the Product is validated and thus ARS undertakes to use Commercially Reasonable Efforts to qualify a Second Source at its [***] discretion.
- 13.02** Notwithstanding the provisions set out in the above Paragraph 13.01, Recordati may appoint a Second Source for the Manufacturing of the Product for its Territory. In such a case, ARS undertakes to use its Commercially Reasonable Effort in assisting Recordati and the Second Source appointed by Recordati, in the completion of the Technology Transfer Activities required to allow such Second Source to Manufacture technology transfer batches of the Product and to prepare the relevant documents for the updating of the Dossier.

SECTION V – SUPPLY OF THE PRODUCT

14. SUPPLIER APPOINTMENT

- 14.01** On the terms and conditions set out in this Agreement, Recordati hereby appoints ARS, who accepts, as its supplier for the Commercialization of the Product within the Territory.
- 14.02** The Parties agree that, as a result of the appointment set out in Paragraph 14.01 above:
- (i) the Parties shall enter into purchase agreements under which ARS shall sell to Recordati and Recordati shall purchase from ARS, the Product (each a **Product Purchase Agreement**); and
 - (ii) Recordati or its Affiliates or its Sublicensees shall Commercialize the Product to wholesalers or to or any other user or consumer of the Product, within the Territory (the **End-Users**).

15. SUPPLY EXCLUSIVITY PERIOD

- 15.01** On the terms and conditions set out in this Agreement, starting from the Effective Date and up to the expiration (or the termination) of this Agreement, ARS undertakes to Manufacture (or have Manufactured) and supply the Product for the re-sale into the Territory exclusively to Recordati, and Recordati undertakes to purchase all of its and its Affiliates' and Sublicensees' requirements of Product for the Territory from ARS.

16. NON-COMPETE

- 16.01** Starting from the Effective Date and up to the later of (i) expiration the last Patent in effect or (ii) expiration of the Market Exclusivity Period, both Parties mutually agree to undertake:
- (i) not to develop, register, purchase and/or Commercialize in the Territory any pharmaceutical products: (a) [***]; and (b) [***]; and
 - (ii) to discontinue and not initiate any discussions with any other Third Party regarding the business arrangements contemplated hereby in the Territory.

17. PRODUCT PRE-LAUNCHING PERIOD

- 17.01** Without prejudice to the provision set out under Paragraph 18.01 below, the Parties agree to collaborate with each other in order for Recordati to be able to launch the Product as soon as possible.
- 17.02** No later than [***] prior to the expected First Launching Date, Recordati shall submit to ARS a PO (as defined below) for a quantity of Product (Strength 1) which Recordati deems appropriate to fulfill Recordati's expected requirements of the Product (Strength 1) during the launch period as well as the [***] Forecast covering the requirements of the [***] starting from the First Launching Date in accordance with Paragraph 18.01.
- 17.03** No later than [***] prior to the expected Second Launching Date, Recordati shall submit to ARS a PO for a quantity of Product (Strength 2) which Recordati deems appropriate to fulfill Recordati's expected requirements of the Product (Strength 2) during the launch period and shall incorporate in the then current Forecast (in accordance with Paragraph 18.01) the requirements of Strength 2 for the [***] starting from the Second Launching Date.

17.04 No later [***] prior to the expected New Launching Date, Recordati shall submit to ARS a PO for a quantity of Product (Strength 3) which Recordati deems appropriate to fulfill Recordati's expected requirements of the Product (Strength 3) during launch period and shall incorporate in the then current Forecast (in accordance with Paragraph 18.01) the requirements of Strength 3 for the first [***] starting from the New Launching Date.

17.05 For avoidance of doubt, the above Pre-Launching Period POs shall be on a country-by country basis, and shall be binding.

18. FORECAST AND ORDERS

18.01 With the submission by Recordati of the PO set out under Paragraph 17.02, 17.03 and 17.04 above, and every month thereafter, Recordati shall provide ARS with a written rolling forecast of Recordati's expected requirements of Product on a country-by-country basis during the following [***] (each, a **Forecast**). For clarity, the initial rolling forecast that Recordati shall provide to ARS shall cover the [***] after expected First Launching Date.

18.02 Except for the first PO for each Strength as described under Clause 17 above, Recordati shall submit to ARS a written binding and irrevocable proposal to purchase the Product at [***] prior to the date of delivery set out in such order (each a **PO**). It is agreed that any PO shall, *inter alia*, include:

- (i) name of the Product including Presentation (per each Strength);
- (ii) the quantities of the Presentation (per each Strength) required on a country by country basis;
- (iii) the date by which the Presentation must be delivered and any delivery instructions;
- (iv) the delivery address;
- (v) the indication of the relevant Recordati Livery to be used to label and package the Presentation (per each Strength); and
- (vi) the Aggregate Supply Price.

18.03 The Parties acknowledge and agree that notwithstanding anything to the contrary:

- (i) the Forecast shall not be binding upon Recordati or ARS and shall be used for planning purposes only; however, the first [***] of Product forecasted in each Forecast delivered to ARS following the First Launching Date shall be binding upon ARS and Recordati unless otherwise agreed in writing by both Parties. In addition, starting from the first anniversary of the First Launching Date, if the PO related to the [***] of Product forecasted in each Forecast is lower by more [***] from the [***] of Product forecasted in the previous Forecast, Recordati shall be responsible for cost of the excess Product if ARS cannot sell such excess Product outside the Territory;
- (ii) each PO shall automatically be deemed binding if not rejected in writing by ARS within [***] following the issuance thereof and ARS shall not have the right to reject POs which comply with the provisions set out in this Agreement; and
- (iii) the Parties shall use their Commercially Reasonable Efforts in order to supply Product and to quickly react to the market demand of Products (or change thereof). However, ARS shall not be obligated to Manufacture or supply Recordati with Product in excess of [***] of the most recent [***] estimate of such Product provided to ARS in a Forecast.

19. PRODUCT PURCHASE AGREEMENT

19.01 Recordati and ARS, shall be deemed to have entered into a Product Purchase Agreement upon the acceptance (or deemed acceptance) by ARS of the relevant PO.

19.02 Each Product Purchase Agreement shall be governed by:

- (i) the terms and conditions of the relevant accepted (or deemed accepted) PO;
- (ii) the terms and conditions of this Agreement;
- (iii) the terms and conditions of the Technical and Quality Agreement;
- (iv) Applicable Laws; and
- (v) the governing laws of specified in Section XVII.

19.03 In case of conflict or ambiguity between the provisions of the Product Purchase Agreement(s) and/or the provisions of this Agreement and/or the provisions of the Technical and Quality Agreement:

- (i) this Agreement shall prevail – unless it is expressly set out that a deviation from this Agreement has been agreed upon in the relevant PO – on all matters other than those matters strictly concerning the quality of the Product; and
- (ii) the Technical and Quality Agreement shall prevail on all matters strictly concerning the quality of the Product.

20. DELIVERY

20.01 Unless otherwise agreed upon in the relevant Product Purchase Agreement, the delivery of the Product provided under each Product Purchase Agreement will be [***] contract manufacturer facility.

20.02 ARS shall be responsible, at its own costs and expenses, to apply for any prescribed permissions and to obtain documentation for the exportation and importation of the Product, if any.

20.03 ARS shall have the option to ship Product to Recordati up to [***] prior to date of delivery set out in each PO if [***] (or other contract manufacturer engaged by ARS in accordance to this Agreement) Manufactures and delivers Product up to [***] earlier.

20.04 For avoidance of doubt, ARS shall not accept any returns from Recordati except:

- (i) as pursuant to receipt of the Non-Fit for Use Notice per Clause 21 below; or
- (ii) for Products which have a minimum shelf life lower of [***] of the Product shelf life pursuant to the Specifications.

21. QUALITY INSPECTION OF THE PRODUCT AND CLAIMS

21.01 ARS acknowledges that Recordati may, at its own expenses, inspect and test each and any shipment of Product delivered by ARS pursuant to this Agreement in order to determine whether such Product is compliant with the Specifications (the *Inspection*).

- 21.02** Any claim of Recordati on defects of the Product shall be made in writing and shall report the results of the relevant Inspection (the **Non-Fit for Use Notice**).
- 21.03** The Non-Fit for Use Notice will be sent to ARS within:
- (i) in case of patent defects (e.g. damages to the packaging of the Presentation), [***] from the discovery of such defects;
 - (ii) in case of non-compliance of the Product with the Specifications, the earlier of: (a) [***] from the discovery of such defects; or (b) the elapsing of the relevant expiry date of such Product; or
 - (iii) in case of latent defects which are not detectable by means of the Inspection, the earlier of: (a) [***] from the discovery of such defects; or (b) the elapsing of the relevant expiry date of such Product.
- 21.04** Within [***] from receipt of the Non-Fit for Use Notice, ARS shall carry out the necessary investigation to assess whether to accept the findings of the relevant Inspection (the **Counter Inspection**).
- 21.05** In the event the results of the Counter Inspection:
- (i) confirm the results of the relevant Inspection ARS shall, [***]:
 - (a) replace the defective Product with shipping expenses at ARS' charge; or
 - (b) reimburse the Aggregate Supply Price to Recordati;
 - (ii) do not confirm the results of the relevant Inspection and the Parties do not reach – within a reasonable period of time following receipt of the Non-Fit for Use Notice – an agreement on the conformity of the Product to the Specifications, then the Parties, shall submit, together with representative samples of the relevant batch of the Product, to the judgment of an independent neutral external Third Party laboratory to be mutually agreed between the Parties, acting reasonably. The outcome of the test shall be binding to the Parties and the Party who has been decided against will pay all expenses charged by the aforementioned independent neutral external Third Party laboratory. In case the aforementioned outcome of the test shall confirm the results of the Inspection, Paragraph 21.05(i) shall apply *mutatis mutandis*.
- 21.06** It is however understood that in any event of alleged defectiveness of the Product either accepted or not by ARS, the Parties shall use their Commercially Reasonable Efforts to co-operate in such a way to avoid the risk of out of stock for Recordati and to put ARS in the effective position to replace the disputed Product.
- 21.07** For the avoidance of doubt, it is agreed that the provision of Paragraph 21.02 above, shall apply also in case of supervening defects, in so far they are not attributable to the Recordati's behavior or misuse of the Product.
- 22. INABILITY TO SUPPLY**
- 22.01** In the event that ARS cannot, or becomes aware that it will be unable to fulfil its Manufacturing and supply obligations set out in this Agreement for any reason – ARS undertakes to [***] notify Recordati in writing of such inability to Manufacture and supply the Product, stating the reasons thereof.

22.02 Following receipt of the notice set out in Paragraph 22.01 above and during the persisting of ARS' inability to Manufacture and supply the Product to Recordati ARS shall allocate the available Product and existing stock of Product available to ARS (or its Affiliates) proportionally among ARS, Recordati and ARS' licensees outside the Territory based upon the last [***] respective Commercialization in Presentation before the aforementioned inability to Manufacture and supply occurred.

22.03 Without prejudice to the provisions set out in Paragraph 22.02, if so requested by Recordati, ARS undertakes to use its Commercially Reasonable Efforts to fulfil its obligations set out in Clause 13 above.

SECTION VI – CONDITION PRECEDENT

23. CONDITION PRECEDENT

23.01 Recordati's undertaking set out under Section III, Section VII, Section IX, Clause 17 and Clause 18 of this Agreement, shall be conditional on the execution between ARS and [***] of a long term Manufacturing and supply agreement for the Product (the *Conditions Precedent*).

23.02 ARS acknowledges that the agreement set out under Paragraph 23.01 above shall not contain provisions conflicting with ARS undertakings set out in this Agreement.

23.03 ARS will promptly notify in writing Recordati upon becoming aware that the Condition Precedent has been satisfied transmitting complete executed copy of the relevant agreement set out under Paragraph 23.01 above.

SECTION VII – PAYMENTS

24. UPFRONT PAYMENT

24.01 Recordati – as partial consideration for the License – undertakes to pay to ARS a one-time, non-refundable upfront payment equal to Euro 10,000,000 (ten million) upon execution of this Agreement, with payment terms at [***] from the date of receipt of the relevant invoice by ARS.

25. REGULATORY MILESTONES

25.01 Following ARS written notice indicating that each of the below regulatory milestones has been achieved, Recordati – as partial consideration for the License – undertakes pay to ARS the following amounts:

(i) [***] once the [***];

(ii) [***];

(iii) [***].

25.02 In accordance with the provision set out in Paragraph 25.01 above, ARS shall issue the invoice for the payment of each relevant regulatory milestone once due with payment terms at [***] from the date of receipt of the relevant invoice.

26. LAUNCH MILESTONE

26.01 Recordati – as partial consideration for the License – undertakes to provide written notice and to pay to ARS the following amounts upon achievement of the below launch milestones:

- (i) Euro [***];
- (ii) Euro [***];
- (iii) Euro [***];
- (iv) Euro [***];
- (v) Euro [***].

26.02 In accordance with the provision set out in Paragraph 26.01 above, ARS shall issue the invoice for the payment of each relevant launch milestone once due with payment terms at [***] from the date of receipt of the relevant invoice.

27. SALES MILESTONES

27.01 Recordati – as final consideration for the License – undertakes to pay to ARS the following amounts upon achievement of the below sales milestones:

- (i) Euro [***] when Annual Net Sales first reach Euro [***];
- (ii) Euro [***] when Annual Net Sales first reach Euro [***];
- (iii) Euro [***] when Annual Net Sales first reach Euro [***];
- (iv) Euro [***] when Annual Net Sales first reach Euro [***];
- (v) Euro [***] when Annual Net Sales first reach Euro [***].

27.02 In accordance with the provision set out in Paragraph 27.01 above, ARS shall issue the invoice for the payment of each relevant sales milestone once due with payment terms at [***] from the date of receipt of the relevant invoice.

27.03 For the avoidance of doubt, the Parties acknowledge that each of the sales milestones payment would be made only once. The sales milestones shall be additive, so that if multiple sales milestone events set out in Paragraph 27.01 above are achieved in the same Calendar Year, then the milestone payments for all such sales milestone events set out in Paragraph 27.01 above that are achieved shall become payable.

28. SUPPLY PRICE AND ROYALTY

28.01 ARS shall supply the Product to Recordati at the relevant Supply Price set out in Annex 6.

28.02 Recordati shall pay to ARS tiered royalties quarterly on the Net Sales as follows:

- (i) [***] on the portion of Net Sales equal or below Euro [***] of Annual Net Sales (the **Tier 1 Royalty**);
- (ii) [***] on the portion of Net Sales above Euro [***] up to Euro [***] (the **Tier 2 Royalty**) of Annual Net Sales;
- (iii) [***] on the portion of Net Sales above Euro [***] (the **Tier 3 Royalty**) of Annual Net Sales.

28.03 Without prejudice to the provision set out in Paragraph 45.04 below, the Parties agree that – on a [***] – the total consideration to be paid by Recordati to ARS for all the Presentations cannot be higher than the Annual Cap.

28.04 The Parties acknowledge that on a Calendar Year basis:

- (i) If the sum of (a) the Tier 1 Royalty (after adjustment pursuant to Paragraph 28.05) plus (b) the Aggregate Supply Price for the Products sold that generated the Net Sales upon which the Tier 1 Royalty is calculated would exceed [***] of Annual Net Sales equal or below Euro [***] (the **First Cap**), then the Tier 1 Royalty for such Calendar Year shall be reduced as necessary so that such sum equals the First Cap;
- (ii) If the sum of (a) the Tier 2 Royalty (after adjustment pursuant to Paragraph 28.05) plus (b) the Aggregate Supply Price for the Products sold that generated the Net Sales upon which the Tier 2 Royalty is calculated would exceed [***] of Annual Net Sales above Euro [***] up to Euro [***] (the **Second Cap**), then the Tier 2 Royalty for such Calendar Year shall be reduced as necessary so that such sum equals the Second Cap;
- (iii) If the sum of (a) the Tier 3 Royalty (after adjustment pursuant to Paragraph 28.05) plus (b) the Aggregate Supply Price for the Products sold that generated the Net Sales upon which the Tier 3 Royalty is calculated would exceed [***] of Annual Net Sales above Euro [***] (the **Third Cap**), then the Tier 3 Royalty for such Calendar Year shall be reduced as necessary so that such sum equals the Third Cap.

28.05 The Parties acknowledge that, on a country-by-country basis, the Tier 1 Royalty, Tier 2 Royalty and Tier 3 Royalty shall be reduced by [***], should (and as long as) Competing Products collectively account for [***] or more of the in-market sales for the same indication for which the Products are marketed in such country on a [***] basis according to [***] data, either in unit or in volume, in a given country in the Territory; it being understood that in the event that the Competing Products no longer collectively accounts for [***] or more of all sales across all indications for which the Products are marketed in such country, then the reduction set out in this Paragraph 28.05 shall no longer apply.

28.06 In the event that the level of competition, patent protection or general commercial environment for the Product, on a country-by-country basis, materially affects the commercial viability of the Product in a country at the royalty rate applicable under Paragraph 28.05 above as shown in a written analysis provided by Recordati to ARS, the Parties shall negotiate in good faith an appropriate reduction to such royalty rates.

28.07 For the avoidance of doubt, ARS acknowledges that ARS will be responsible for any royalty payment due by ARS to Third Parties for the rights on the Product granted to ARS by such Third Parties (including [***]).

29. REPORT

29.01 Within [***] after the end of each [***] following the First Launching Date, Recordati shall furnish to ARS its estimates of gross sales in the Key-Countries [***].

29.02 Within [***] after the end of each [***] following the First Launching Date, Recordati shall furnish to ARS a written report (the **Royalty Report**) showing in reasonably specifics detail, on a country-by-country and Presentation-by-Presentation basis, (example of which is attached hereto as **Annex 7**):

- (i) the gross sales of the Product during such [***] and the calculation of the Net Sales from such gross sales during such [***];
- (ii) based upon such Net Sales and pursuant to the provisions set out in Paragraphs 28.02, 28.03, 28.04, 28.05 and 28.06 above and on the data included in the ARS Report, the calculation of the royalty applicable during the relevant [***] (for any foreign currency conversion to Euro required for the calculation of the relevant royalty, such conversion shall be made at the average of such [***] rates normally recorded and used by Recordati);

- (iii) the withholding taxes, if any, required by the Applicable Laws to be deducted with respect to such Net Sales;
- (iv) the exchange rates, if any, used to determining the amount of local currency transformed in Euro; and
- (v) any further adjustment to the calculation of royalties in compliance with this Agreement as required to correct any mistake from previous calculations (including final calculation of the aggregate royalties due in each [***] under this Agreement which shall be adjusted using the average [***] foreign currency conversion to Euro rates normally recorded and used by Recordati for consolidation purposes).

30. PAYMENT METHOD

30.01 ARS shall issue:

- (i) the invoice for the payment of the Aggregate Supply Price due to ARS under the relevant Product Purchase Agreement, upon shipment; and
- (ii) the invoice for the payment of the royalty set out in the Royalty Report, upon receipt of the Royalty Report.

30.02 Recordati shall pay:

- (i) the Aggregate Supply Price, within [***] from the date of receipt of the relevant invoice by ARS; and
- (ii) the royalty set out in the Royalty Report, within [***] from the date on which the relevant invoice has been received by Recordati.

30.03 All payments owed under this Agreement shall be paid in Euro in immediately available funds and shall be made by wire transfer to a United States of America or EU bank account held in the name of ARS (details of which will be set out in the relevant invoice). Recordati shall, upon ARS' request, provide all reasonable details of currency conversion applied for calculation of the royalties due pursuant to Paragraph 29.02(ii) and 29.02(v) above.

31. ACCOUNTING AUDIT

31.01 Upon the written request of a Party and no more than once in each [***], the other Party shall permit and independent certified public accounting firm of nationally recognized standing, selected by the requesting Party and reasonably acceptable to other Party, at the requesting Party's expenses, to have access during normal business hours to such of the records of the other Party as may be reasonably necessary to verify the accuracy of the Royalty Reports for any year ending not more than [***] prior to the date of such request. The accounting firm shall be required to sign a confidentiality agreement for the benefit of, and in a form reasonably acceptable to, the other Party, and shall disclose to ARS and Recordati only whether the Royalty Reports are correct or not and the specific details concerning any discrepancies. No other information shall be shared.

31.02 If such accounting firm concludes that:

- (i) additional payments were owed during the audited period by Recordati to ARS, Recordati shall pay such additional amounts within [***] after the date ARS delivers to Recordati (a) such accounting firm's written report so concluding; and (b) the relevant invoice;
- (ii) Recordati has made overpayments during the audited period, ARS shall refund to Recordati the amount overpaid within [***] after the date Recordati delivers to ARS (a) such accounting firm's written report so concluding, and (b) the relevant invoice.

31.03 The fees charged by the accounting firm shall be paid by requesting Party, except in the case of an audit by ARS of Recordati's records, such audit discloses an underpayment by Recordati of more than [***] of the amount of payments due to ARS under this Agreement for any applicable [***], in which case, Recordati shall bear the cost of such audit.

31.04 The Parties shall treat all financial information subject to review pursuant to this Clause 31, as confidential information pursuant to the provision of Clause 47 below and shall cause the accounting firm to retain all such information in confidence.

32. TAXES AND DUTIES

32.01 The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible and in compliance with Applicable Laws, taxes payable with respect to their arrangement under this Agreement and that they shall use Commercially Reasonable Efforts to cooperate and coordinate with each other to achieve such objective and intent. As such, if (i) Recordati is required to make a payment to ARS that is subject to a deduction or withholding of tax, and (ii) such withholding or deduction obligation arises as a result of an assignment of this Agreement by Recordati pursuant to Clause 54 below, then the sum payable by Recordati (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that ARS receives a sum equal to the sum that it would have received had no such assignment occurred. Notwithstanding the foregoing or anything herein to the contrary in this Agreement, if Recordati does not assign this Agreement pursuant to Clause 54 below, Recordati shall not have to increase any sum payable to ARS in respect to any deduction or withholding of tax which Recordati may become required to make on payments due to ARS under this Agreement following the Effective Date. The Parties shall cooperate to help ARS obtain benefits under any applicable tax treaty or domestic provisions, including the reduction or exemption from any withholding tax and the procurement of any available tax refunds.

32.02 If Recordati is required to withhold any tax from any payment made to ARS under this Agreement pursuant to the Applicable Laws, before making any such tax deduction or withholding, Recordati shall use Commercially Reasonable Efforts to provide ARS with 5 (five) days advance written notice of the intention to make such deduction or withholding, and shall use Commercially Reasonable Efforts to cooperate with any reasonable request from ARS to obtain reduction of or relief from such deduction or withholding. In case the Tax Withholding Documents are not available to Recordati at the due date of such payments to ARS or the Tax Withholding Documents provided by ARS to Recordati do not call for a complete exemption on withholding taxes, Recordati will (i) deduct applicable withholding taxes from the payment made to ARS, (ii) timely pay such taxes to the proper taxing authority, (iii) send proof of such withholding tax payment to ARS and certify its receipt by the taxing authority within [***] following such payment and (iv) to the extent that amounts are so deducted or withheld, and duly paid to the appropriate governmental authority in accordance with Applicable Law, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to ARS. Recordati shall use Commercially Reasonable Efforts to assist ARS in filing for the refund, if any, of any withholding taxes paid within [***] following the receipt of the Tax Withholding Documents from ARS. Any such refund filing shall request that the amount of the refund be wired directly to an ARS authorized bank account.

SECTION VIII – FURTHER OBLIGATION OF THE PARTIES

33. GOVERNANCE AND REPORTING

- 33.01** Pursuant to this Agreement, a Joint Steering Committee meeting to be held either by conference call or by physical meeting – at date, time, and location (if applicable) agreed by the Parties – shall be convened by either Party at least [***] for the first [***] after the First Launching Date and at least [***] thereafter (the *JSC Meeting*).
- 33.02** The JSC shall be comprised of at least [***]. A Party may change any one or more of its JSC representatives at any time upon written notice to the other Party. The representatives of the JSC will mutually agree on the schedule for JSC Meetings.
- 33.03** Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JSC. If a Party's representative is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative.
- 33.04** The JSC will:
- (i) coordinate the activities of the Parties under this Agreement, and provide a forum for and facilitate communications between the Parties under this Agreement;
 - (ii) discuss and determine a strategy for the development of the Product in the Territory, including, without limitation, discussion of the status of the Paediatric Development and/or any other clinical or non-clinical studies relating to the Product in the Territory;
 - (iii) discuss Manufacturing and product supply relating to the Product in the Territory;
 - (iv) monitor the progress of the regulatory procedures relating to the Product in the Territory including, without limitation, reviewing and coordinating strategy for regulatory filings for the Product in the Territory, and facilitate exchange of regulatory data for the Product;
 - (v) inform the Parties on the Commercialization of the Product;
 - (vi) discuss scientific publication and congresses strategies and plans related to the Product;
 - (vii) evaluate in good faith each Parties comments to the other Parties' regulatory strategy with a view to avoiding possible negative impacts on the regulatory strategy outside and inside of the Territory; and
 - (viii) discuss any other matters that that both Parties mutually intend to discuss.
- 33.05** Records of all significant decisions of the JSC will be reflected in written minutes of the JSC Meetings that shall be prepared by ARS and circulated to all JSC representatives (who took part to the relevant meeting) for review and comment before being signed by all of the JSC Meeting representatives and filed as final records of the JSC Meeting.

- 33.06** All decisions of the JSC shall be made by [***], with each Party's representatives collectively having one vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as to such matter within [***] after such matter was referred to the JSC, such disagreement shall be referred to the Chief Executive Officer of ARS and the Chief Executive Officer of Recordati (or the Senior Executive of Recordati appointed for the purpose) for resolution as follows:
- (i) if such matter relates [***], the Chief Executive Officer of [***] shall be entitled to make the final decision regarding such matter; provided that such decision shall be consistent with the terms and conditions of this Agreement;
 - (ii) if such matter relates to the [***], the Chief Executive Officer of [***] shall be entitled to make the final decision regarding such matter; provided that such decision shall be consistent with the terms and conditions of this Agreement; and
 - (iii) the JSC shall have only such powers as are expressly assigned to it in this Agreement, such powers shall be subject to the terms and conditions of this Agreement, and the JSC shall not have the power to amend or modify this Agreement.

34. PHARMACOVIGILANCE AND RECALL

34.01 Following the Effective Date, the Parties shall enter into good faith negotiation for the implementation of a SDEA. The Parties' respective rights, obligations and responsibilities relating to pharmacovigilance, safety data exchange and reporting shall be handled in accordance with the provisions of such SDEA to be entered into between the Parties within [***] from the Effective Date, being understood that from the Effective Date, ARS shall forward to Recordati any received or known safety information along with the relevant English translation within [***]. Once executed and effective between both Parties, the SDEA, shall be deemed to be an ancillary agreement to this Agreement, shall be governed exclusively by its own terms and conditions and shall be deemed to be several and independent from this Agreement. In the event of a conflict between any of the provisions of the SDEA and this Agreement, the latter shall prevail and apply, except if the conflict is with a provision having as object pharmacovigilance or safety data exchange or reporting matters to which the provision of the SDEA shall always prevail and apply.

34.02 In any event of request of Recall of the Product, the Parties shall comply with the Recall procedure set out in the Technical and Quality Agreement.

34.03 If the Recall is found to be the fault of:

- (i) ARS (in case of disagreement between the Parties, the matter shall be referred to the external laboratory pursuant to the terms set out in Paragraph 21.05(ii) above), ARS shall bear any costs and expenses reasonably incurred by either Party in connection with the Recall, without prejudice to other Recordati's rights under this Agreement and under the Applicable Laws; or
- (ii) Recordati (in case of disagreement between the Parties, the matter shall be referred to the external laboratory pursuant to the terms set out in Paragraph 21.05(ii) above), Recordati shall bear all costs and expenses reasonably incurred by either Party in connection with the Recall, without prejudice to other ARS' rights under this agreement and under the Applicable Laws.

SECTION IX – FURTHER OBLIGATIONS OF RECORDATI

35. SELLING PRICE REIMBURSEMENT

35.01 Recordati shall use Commercially Reasonable Efforts to obtain price and reimbursement approval for the Product in the Territory.

35.02 In case any further studies are required for pricing and reimbursement purposes in the Territory, Recordati shall bear all costs of such studies.

35.03 The price and reimbursement approval proposed by the Regulatory Authorities shall be considered finally obtained by Recordati only once such price and reimbursement approval is considered adequate according to Recordati's sole judgement.

36. MARKETING OF THE PRODUCT

36.01 ARS acknowledges that Recordati shall be free to Commercialize the Product under either the ARS Trademarks or the Recordati Trademarks.

36.02 Recordati shall use Commercially Reasonable Efforts to:

- (i) act with a view to maximizing the sales of the Product within the Territory;
- (ii) keep ARS informed of any material changes in the Applicable Laws relating to the marketing activity of the Product to End-Users; and
- (iii) refrain to market and/or sell the Product within territories other than the Territory.
- (iv) No later than the date of approval of the Marketing Authorization, to prepare a preliminary non-binding Commercialization plan for the marketing, promotion and pricing of Products during the first [***] after expected First Launching Date in the Territory, which plan shall be reasonable in scope and detail. Such plan will be updated on a yearly basis, and Recordati shall provide updates to ARS regarding Commercialization activities.

36.03 Subject to Applicable Laws, (i) neither Recordati nor its Affiliates or Sublicensees will engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located outside of the Territory or accept orders for the Product from or sell the Product into any country or jurisdiction outside the Territory for its own account, and, if Recordati receives any order for the Product for any country or jurisdiction outside the Territory, it shall refer such orders to ARS, and (ii) neither ARS or its Affiliates or licensees outside the Territory will engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in the Territory or accept orders for the Product from or sell the Product into the Territory for its own account, and, if ARS receives any order for the Product for the Territory, it shall refer such orders to Recordati. Each Party will use reasonable efforts to monitor and prevent exports of the Product from its own territory (the Territory as to Recordati, or outside the Territory as to ARS) for Commercialization in the other Party's territory using methods permitted under Applicable Laws that are commonly used in the industry for such purpose (if any).

37. PRODUCT STORAGE

37.01 Following delivering of the Product pursuant to Clause 20 above, Recordati undertakes to store (or have stored) the Product in a suitable and duly authorized warehouse located in the Territory, properly rotated and under proper storage and security conditions complying with the Specifications and in accordance with the terms and conditions set out in the Technical and Quality Agreement and with the Applicable Laws.

37.02 Recordati shall maintain adequate stocks of the Product, consistent with the Forecast using [***] method of usage.

SECTION X – FURTHER OBLIGATIONS OF ARS

38. UNDERTAKINGS OF ARS

38.01 On the terms and conditions set out in this Agreement, ARS undertakes to:

- (i) provide Recordati with any necessary and available information and documents relating to the Product in ARS' possession and Control to allow Recordati to perform its activities in accordance with this Agreement;
- (ii) update Recordati with all of the relevant scientific, development, Manufacturing, quality and regulatory information on the Product which may become available to ARS;
- (iii) furnish to Recordati the documentation listed in the Technical and Quality Agreement to be provided by ARS;
- (iv) retain a sample of each batch of sold and delivered Product (the **Sample**), in accordance with Applicable Laws, the whole as per the Technical and Quality Agreement;
- (v) make, upon written request of Recordati, the Sample available to Recordati for inspection; it being understood that the retained sample shall be sufficient in size to allow the independent laboratory set out in Paragraph 21.05(ii) below to perform the complete sets of analysis (as described in the Technical and Quality Agreement) to determine whether the Product meets the Specifications;
- (vi) keep on file for the time period set out in the Technical and Quality Agreement the manufacturing records and analytical results pertaining to the Manufacture of each batch of the Product as are required under the Dossier; it being understood that ARS shall make such records available to Recordati (or the Third Party designated by Recordati) for review upon at least [***], and during normal business hours, not more than [***]
- (vii) [***]

SECTION XI – REPRESENTATION AND WARRANTIES

39. REPRESENTATION AND WARRANTIES

39.01 Each Party gives the following representations and warranties to the other Party:

- (i) It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and it has the requisite power and authority to enter into and perform this Agreement;
- (ii) it has obtained all corporate authorizations required to empower it to enter into and perform its obligations under this Agreement, and all governmental statutory, regulatory or other consents, licenses, authorizations, waivers or exemptions required to empower it to enter into this Agreement have been obtained;

- (iii) the entry into and performance of this Agreement does not constitute (a) a breach of any provision of its constitutional documents under the laws or regulations in its jurisdiction of incorporation; (b) a breach of any of the Applicable Laws; or (c) a breach of an agreement binding upon it or upon any of its assets;
- (iv) it is not insolvent or bankrupt under the laws of its jurisdiction of incorporation;
- (v) there are no proceedings in relation to any winding up, bankruptcy or insolvency proceedings concerning it; and
- (vi) this Agreement will, when executed, constitute valid and binding obligations of it, enforceable in accordance with its terms.

39.02 Recordati gives the following representations and warranties to ARS:

- (i) it (directly or through its Affiliates or through the Sublicensees) possesses the necessary governmental licenses, facilities and services to import, market, distribute and sell the Product in the Territory and otherwise perform its obligations under this Agreement, as is appropriate and lawful in the Territory, and neither it nor any of its Affiliates or, to its knowledge, Sublicensees are, or have been, debarred or disqualified by any Regulatory Authority;
- (ii) to the best of its knowledge, the sales of the Product within the Territory do not constitute a breach of the Applicable Laws;
- (iii) it (directly or through its Affiliate or through the Sublicensees) has the requisite expertise, ability, capacity, skills and know-how, including all the qualified and experienced workforce to perform its obligations under this Agreement;
- (iv) there are no legal claims, judgments or settlements against or owed by Recordati or its Affiliates, or pending or, to Recordati's or its Affiliates' knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations;
- (v) it will comply with all Applicable Laws and the terms of this Agreement in its performance of its obligations hereunder;
- (vi) the Product will be handled in compliance with all Applicable Laws, including but not limited to, cGMP standards and/or guidelines and cGDP;
- (vii) the Product will be stored and shipped in compliance with the provision set out Clause 37, all Applicable Laws, including but not limited to, cGMP standards and/or guidelines and cGDP; and
- (viii) in making its decision to enter into this Agreement and to consummate the transactions contemplated hereby, relied on its own independent investigation, analysis and evaluation and on the representation and warranties of ARS.

39.03 ARS gives the following representations and warranties to Recordati:

- (i) ARS has made available to Recordati all material information related to ARS Intellectual Property Rights and Products in ARS' possession or Control, and such information, and all such information provided as of the Effective Date are true, correct and complete in all material respects;
- (ii) as of the Effective Date, it has completed the studies of Strength 1 required by EMA to grant the EU Marketing Authorization for the Strength 1;

- (iii) based upon feedback (the **Feedback**) ARS has received from the *Rapporteur* and the *Co-Rapporteur* in the context of the EU Marketing Authorization application pre-submission meeting held on 10 September 2020 (as reflected in the draft minutes prepared by ARS and sent to *Rapporteur* and Recordati on Monday 14 September 2020 (the **Minutes**)), the submission of the application for the EU Marketing Authorization for the Strength 1 to the EMA can be performed on the legal basis of article 8(3) of the EU Directive 2001/83/EC since the results from the pharmacodynamic studies conducted by ARS and to be included in the Dossier will be considered by EMA as a surrogate for efficacy;
- (iv) it has the right to provide Recordati with the ARS-Know-How set out in this Agreement;
- (v) it has Control to and of the Patents and ARS Intellectual Property Rights free and clear from any encumbrances;
- (vi) it has the right to grant the Licenses to Recordati as set forth in and pursuant to this Agreement;
- (vii) no claim or action has been brought against ARS, or threatened in writing to ARS, by any Third Party alleging that the Patents or ARS Intellectual Property Rights are invalid or unenforceable (and thus are valid, effective and enforceable) and, to ARS's knowledge, no interference, opposition, cancellation or other protest proceeding has been filed against a Patent owned by ARS, and ARS has obtained from all inventors of the Patents owned by ARS effective assignments of all ownership rights of inventors in, to and under such Patents to ARS, all application, registration, maintenance and renewal fees in respect of the Patents have been paid and to ARS's knowledge, all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining such Patents;
- (viii) ARS has not receive any written notice and does not otherwise have knowledge prior to Effective Date that its activities with the Product (or the Manufacture, export, Commercialization thereof) has infringed any patents or other Intellectual Property Rights Controlled by a Third Party;
- (ix) to ARS' knowledge, there are no activities by Third Parties that would constitute infringement or misappropriation of the ARS Intellectual Property Rights;
- (x) it (directly or through its Affiliates or Third Party contractors) has the requisite expertise, ability, capacity, skills and know-how, including all the qualified and experienced workforce and possesses all necessary governmental licenses, facilities and services to perform its obligations under this Agreement, and neither it nor any of its Affiliates or, to its knowledge, its Third Party contractors, are, or have been, debarred or disqualified by any relevant authority;
- (xi) [***];
- (xii) [***];
- (xiii) [***];
- (xiv) [***];
- (xv) [***];

- (xvi) there are no actual, or to ARS' knowledge, threatened enforcement actions by any world-wide local or national authority (including Regulatory Authority) which has jurisdiction over ARS's, ARS' Affiliates' or [***]' operations relating to the Product; and
- (xvii) [***];
- (xviii) in making its decision to enter into this Agreement and to consummate the transactions contemplated hereby, relied on its own independent investigation, analysis and evaluation and on the representation and warranties of Recordati.

39.04 Each Party hereby covenants to the other Party that:

- (i) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (collectively **Anti-Corruption Laws**) that may be applicable to either or both Parties;
- (ii) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;
- (iii) it shall, on request by the other Party, verify in writing that to the best of such Party's knowledge, there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or shall provide details of any exception to the foregoing; and
- (iv) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Paragraph, and upon request of the other Party, upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Paragraph, it being agreed that the costs related to the Third Party auditor to be fully paid by the Party requesting the audit, any auditing activities may not unduly interfere with the normal business operations of the Party subject to such auditing activities, and the audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

39.05 The Parties acknowledge that, the representation and warranties set out in this Clause 39 are the only representation and warranties provided by the Parties under this Agreement and thus no representation and warranties beyond those set out in this Clause 39.

SECTION XII – INDEMNIFICATION – NOTICE OF CLAIM

40. LIMITED LIABILITY

40.01 Neither Party shall be liable to the other Party for any incidental, indirect or special or consequential damages however caused and irrespective of the legal basis thereof, arising out of this Agreement even if it has been advised, knew or should have known of the possibility of such loss or damage or if such loss or damage could have been reasonably foreseen.

40.02 The limitation of Paragraph 40.01 above with respect to a Party's liability shall not apply in cases of (i) such Party's wilful misconduct or gross negligence, (ii) breach of obligations under Clause 47, and (iii) statutory mandatory liability (including, for the avoidance of doubt, personal injury and death). Nothing in Paragraph 40.01 above shall be construed to limit either Party's indemnification obligations with respect to Third Party Claims under Clause 41.

41. INDEMNIFICATION

41.01 ARS undertakes to defend, indemnify and hold Recordati, Recordati's Affiliates, and their respective officers, directors and employees (the **Recordati Representatives**) harmless from, against and in respect of any and all damages, losses, expenses, claims, demands, suits, penalties, judgments or administrative and judicial orders and liabilities (including reasonably counsel fees and expenses) (the **Losses**) incurred by any of them resulting from any claims, actions and proceedings made or instituted by any Third Party (the **Third Party Claims**) to the extent such Losses arise out of: (i) ARS's, its Affiliates' and/or ARS Representatives' gross negligence or wilful misconduct, (ii) ARS's material breach of any representation, warranty or any other obligation under this Agreement or (iii) the handling, storage, Manufacture, export, Commercialization of the Product by ARS or its Affiliates or any other Third Party licensee outside the Territory (excluding any activities by or on behalf of Recordati or its Affiliates or Sublicensees); the whole except to the extent that any such Losses result from Recordati's, its Affiliates and/or Recordati Representatives' gross negligence or wilful misconduct or the material breach by Recordati of any representation, warranty or any other obligation under this Agreement.

41.02 Recordati undertakes to defend, indemnify and hold ARS and ARS's Affiliates, and their respective officers, directors and employees (the **ARS Representatives**) harmless from, against and in respect of any and all Losses incurred by any of them resulting from any Third Party Claims to the extent such Losses arise out of: (i) Recordati's, its Affiliates' and/or Recordati Representatives' gross negligence or wilful misconduct, (ii) Recordati's material breach of any representation, warranty or any other obligation under this Agreement, or (iii) the Recordati's Development Activities, use, handling, storage, Manufacturing, or Commercialization of the Product by Recordati or its Affiliates, Sublicensees; the whole except to the extent that any such Losses result from ARS's, its Affiliates' and/or ARS Representatives' gross negligence or wilful misconduct or the material breach by ARS of any representation, warranty or any other obligation under this Agreement.

42. NOTICE OF CLAIM

42.01 Any Party seeking to be indemnified by virtue of the provisions set out in Clause 41 of this Agreement (**Indemnified Party**) shall notify the Party from which indemnification is sought (**Indemnifying Party**) promptly in writing – and in any event not later than [***] from the date on which the Indemnified Party became aware of the event which could reasonably give rise to the Indemnifying Party's liability under Clause 41 – of any and all respective Third Party Claims; made or instituted against it (including a copy of any related complaint, summons, notice or other instrument); provided that failure to promptly provide such notice within the time period set out above shall not relieve the Indemnifying Party of any of its obligations hereunder except to the extent the Indemnifying Party defences *vis-à-vis* the Third Party Claim are prejudiced by such failure.

42.02 With respect to any Third Party Claim:

- (i) the Indemnified Party shall cause that any such Third Party Claim is diligently and properly defended;

- (ii) the Indemnifying Party shall have the right to participate and, to the maximum extent permitted by the Applicable Laws, join at its cost, through counsel of its choosing, in the defense of the Third Party Claim;
- (iii) the Parties shall, and shall cause their respectively appointed counsel and experts to, actively cooperate with each other in the proper and diligent defense of the Third Party Claim and shall keep each other timely informed of all facts, circumstances and documents relating to the Third Party Claim (it being understood, however, that the Indemnified Party shall have the right to control the litigation strategy); and
- (iv) the Indemnified Party shall not make or accept any settlement of the Third Party Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld or delayed, it being understood that:
 - (a) if the Indemnified Party enters into any settlement of the Third Party Claim without the prior written consent of the Indemnifying Party (acting reasonably), the Indemnifying Party shall not be per se liable *vis-à-vis* the Indemnified Party for the matter giving rise to the Third Party Claim; and
 - (b) if a firm offer is made to the Indemnified Party to settle any matter giving rise to the Third Party Claim which the Indemnifying Party, but not the Indemnified Party, is willing to accept, the Indemnified Party shall be free not to enter into such settlement and to commence or continue litigation, at the Indemnified Party's own expense, but the Indemnifying Party's liability shall be limited to the amount of the proposed settlement.

SECTION XIII – SPECIAL PROVISIONS

43. IP OWNERSHIP; IP RIGHTS INFRINGEMENT LAWSUIT

43.01 The Parties acknowledge and agree that, as between the Parties, all right, title and interest in and to any ARS Intellectual Property Rights shall be owned solely by ARS. All right, title, and interest in and to any inventions made, developed, conceived or reduced to practice by or on behalf of Recordati or any of its Affiliates or Sublicensees in the course of performance of this Agreement based upon the ARS Intellectual Property Rights (or otherwise generated with use of or reference to a Compound or Product, or Confidential Information of ARS), and all Intellectual Property Rights therein (collectively, **New IP**) shall be owned solely by ARS. In connection with the foregoing: (i) Recordati shall promptly disclose in writing to ARS all New IP, (ii) Recordati hereby does, and shall cause its Affiliates and Sublicensees and its and their employees and representatives to, assign and transfer to ARS all right, title, and interest in and to such New IP and agrees to take all further acts reasonably required to evidence such assignment and transfer to ARS; (iii) such New IP shall constitute ARS Intellectual Property Rights for purposes of this Agreement; and (iv) Recordati shall have the royalty-free, fully paid-up right (with the right to sublicense) to use the New IP for the Territory during the Term.

43.02 ARS shall have the sole right, as between ARS and Recordati, in its discretion, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all Patents, at its sole cost and expense and by counsel of its own choice. Upon request of ARS, Recordati shall provide ARS with reasonable assistance and cooperation in connection therewith. ARS shall keep Recordati reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of Patents, including content, timing and jurisdiction of the filing of such Patents.

- 43.03** The Parties shall notify each other in writing of any potential or actual infringement or misappropriation (of which it has or obtains knowledge) in the Territory by any Third Party of the ARS Intellectual Property Rights (or part thereof) and shall provide each other with any available evidence of such infringement or misappropriation in its possession or under its control.
- 43.04** In the event a notice under Paragraph 43.03 above is submitted by either Party, the Parties shall then discuss in good faith the best possible strategy and course of action (and payment of all related costs and expenses), it being understood and agreed that should the Parties not agree with the aforementioned strategy and course of action:
- (i) ARS, shall have the first right (but not the obligation, as between ARS and Recordati) for taking all reasonable steps necessary to enjoin and prevent such infringement or misappropriation of the ARS Intellectual Property Rights, including, without limitation, the institution and maintenance of legal or equitable proceedings, and Recordati shall cooperate with respect thereof, including by way of executing such documents and performing such other acts as may be reasonably required [***];
 - (ii) in the event that ARS chooses not to take any action with respect to such infringement or misappropriation of the ARS Intellectual Property Rights, Recordati shall have the right (but not the obligation) to take any such reasonable steps necessary to enjoin and prevent such infringement or misappropriation, including, without limitation, the institution and maintenance of legal or equitable proceedings, and ARS shall cooperate with respect thereof, including by way of executing such documents and performing such other acts as may be reasonably required [***]; and
 - (iii) in any case, (a) each Party shall have the right to participate in the litigation controlled by the other Party, the whole at its cost and expense, (b) neither Party shall enter into any settlement that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement shall be made without the prior approval of the other Party, acting reasonably (it being understood and agreed that (1) no Party shall have the right to bind the other Party, (2) no Party shall have the obligation to make any admission, (3) no Party shall have the obligation to pay any amount of money, and (4) [***] shall not be obliged to agree to any reduction of the length of any Patent relating to the Product in the Territory); and
 - (iv) except as otherwise agreed by the Parties in writing as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to ARS Intellectual Property Rights shall be used first [***].
- 43.05** Each Party shall promptly notify the other in writing of any allegation by a Third Party that the development, Manufacture or Commercialization of the Product infringes or may infringe any Intellectual Property Right of a Third Party. If a Third Party asserts that any of its Intellectual Property Rights are infringed by the development, Manufacture or Commercialization of the Product in the Territory by Recordati or its Affiliates or Sublicensees, Recordati shall have the right but not the obligation to defend against any such assertions. In the event that Recordati elects not to defend against such Third Party claims within [***] of learning of same, ARS shall have the right, but not the obligation, to defend against such an action. In any event, the other Party shall cooperate fully and shall provide full access to documents, information and witnesses as reasonably requested by the Party defending such action. The Party defending the action will reimburse all Third Party costs incurred in connection with such requested cooperation.

43.06 For clarity, ARS reserves all rights to prepare, file, prosecute (including any interferences, reissue proceedings and re-examinations), maintain, defend and enforce all Intellectual Property Rights owned or controlled by ARS related to the Product outside the Territory.

SECTION XIV –TERM AND TERMINATION OF THIS AGREEMENT

44. TERM

44.01 This Agreement shall become effective as of the Effective Date and shall remain in full force and effect, unless terminated by one of the Parties pursuant to the provisions of Clause 45 below, so long as Recordati, or Recordati's Affiliates or Sublicensees are Commercializing any Product in the Territory (the **Term**).

45. TERMINATION OF THIS AGREEMENT

45.01 Each Party (the **Terminating Party**) shall, without limiting any right under the Applicable Laws, have the right to terminate this Agreement at any time forthwith upon written notice to the other Party (the **Terminated Party**), in any of the following events, in so far as permitted under Applicable Laws:

- (i) if the Terminated Party commits a material breach of this Agreement which is not fully and effectively remedied by the Terminated Party within [***] (or [***] in the event of any payment obligation) from the receipt of the written notice given to such effect by the Terminating Party (the **Cure Period**). If there is a dispute with respect to the existence of a Material Breach or as to whether a Material Breach is capable of being cured (a **Breach Process Dispute**), the Terminated Party may contest the allegation by referring such matter for resolution in accordance with Clause 61 below and the time for the Cure Period will be extended until such time as such dispute is resolved. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder and, if it is finally determined that the Terminated Party committed such Material Breach, then the Terminating Party may terminate the Agreement; or
- (ii) if the Terminated Party is dissolved, wound up or liquidated, whether voluntarily or involuntarily, or it files a voluntary petition in bankruptcy or is declared bankrupt or becomes subject to reorganization or similar procedures, it settles or compounds with its creditors or has a receiver, liquidator or trustee of its assets appointed or it otherwise sells or disposes of all or substantially all of its assets in such insolvency event.

45.02 Recordati may also terminate this Agreement on a country-by-country basis (except if the EU Marketing Authorization is finally rejected by the European Commission as described below in 45.02(i), in which case, Recordati may terminate the agreement in all countries in the EU Territory) at any time forthwith upon written notice given to ARS:

- (i) with respect to the EU Territory, if the EU Marketing Authorization application is finally rejected by the European Commission, and if there is no reasonable basis for approval on resubmission of an application that addresses the deficiencies; or
- (ii) with respect to the UK, if the UK Marketing Authorization application is rejected by the MHRA, and if there is no reasonable basis for approval on resubmission of an application that addresses the deficiencies; or

- (iii) on a country-by-country basis with respect to the Ex-EU Territory if the Marketing Authorization application is rejected by the Regulatory Authority of the relevant country of the Ex-EU Territory, and if there is no reasonable basis for approval on resubmission of an application that addresses the deficiencies.
- 45.03** ARS shall have the right to terminate this Agreement in its entirety upon written notice to Recordati if Recordati or any of its Affiliates directly, or indirectly through any Third Party, (i) commences any interference or opposition proceeding with respect to, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Patent, or (ii) institutes, actively participates as an adverse party in, or otherwise provides material support to, any action, suit or other proceeding to invalidate any Patent or to obtain a ruling that any claim within any Patent is unenforceable or not patentable.
- 45.04** ARS shall have the right to terminate this Agreement in its entirety upon written notice to Recordati if:
- (i) a Sublicensee directly, or indirectly through any Third Party, (a) commences any interference or opposition proceeding with respect to, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Patent, or (b) institutes, actively participates as an adverse party in, or otherwise provides material support to, any action, suit or other proceeding to invalidate any Patent or to obtain a ruling that any claim within any Patent is unenforceable or not patentable; and
- (ii) Recordati does not terminate the agreement with the Sublicensee described in Paragraph 45.04(i) above.
- 46. EFFECTS OF TERMINATION**
- 46.01** Upon this Agreement expiring or being terminated pursuant to one or more of the provision set out in Clause 45 above, ARS, at its own discretion, shall elect to either:
- (i) purchase from Recordati all of the Product that at that time Recordati will have at stock for a price equal to Supply Price actually paid by Recordati to the ARS under the relevant Product Purchase Agreement(s); or
- (ii) allow Recordati – on the same terms and conditions set out in this Agreement – to sell the Product that at that time Recordati will have at stock.
- 46.02** Should ARS exercise the right set out under Paragraph 46.01(i) above, Recordati undertakes to assign and procure the assignment of each and any purchase order and/or tender, and/or agreement for those Products then currently placed from an End-User to Recordati, so as to substitute ARS (or any Third Party indicated by ARS) in such purchase orders and/or tenders and/or agreements, or, as the case may be, perform any action or give the necessary notices to any End-User relating to the termination or expiration of this Agreement.
- 46.03** Upon any termination of this Agreement:
- (i) all rights and obligations of the Parties under this Agreement will terminate except as provided in this Paragraph 46.03 or Paragraph 46.04, and all sublicenses under the ARS Intellectual Property Rights granted by Recordati will automatically terminate, in each case on the effective date of termination;

- (ii) ARS shall notify Recordati within [***] after the effective date of termination whether it wishes to obtain the assignments set forth in Paragraph 46.03(ii), which assignments will be at ARS costs; as promptly as practicable (and in any event within [***]) after such notice, Recordati shall: (I) to the extent not previously provided to ARS, deliver to ARS true, correct and complete copies of all regulatory filings (including Marketing Authorizations and Regulatory Approvals) for the Product in the Territory; (II) effective upon such termination, transfer and assign, or cause to be transferred or assigned, to ARS or its designee (or to the extent not so assignable, take all reasonable actions to make available to ARS or its designee all of the benefits of) all such regulatory filings (including Marketing Authorizations and Regulatory Approvals) for the Product in the Territory, whether held in the name of Recordati or its Affiliate or Sublicensee; and (III) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Paragraph 46.03(ii) to ARS;
 - (iii) Recordati shall, as directed by ARS, either wind-down any ongoing Recordati Development Activities in an orderly fashion or promptly transfer such Recordati Development Activities to ARS or its designee, in compliance with all Applicable Laws; and
 - (iv) except to the extent that a receiving Party obtains or retains the right to use the disclosing Party's Confidential Information, each receiving Party shall promptly destroy, all relevant records and materials in such receiving Party's possession or control containing Confidential Information of the disclosing Party; provided that such receiving Party may keep one copy of such materials solely for the purposes of verifying compliance with this Agreement and/or maintaining regulatory compliance subject to continuing confidentiality obligations.
- 46.04** The use by either Party hereto of a termination right provided for under this Agreement shall [***]. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination and shall not affect continuing rights and/or obligations set forth in Paragraphs 38.01(iv), 38.01(v), 38.01(vi) and Clauses 39, 40, 41, 47, 49, 53, 60 and 61.

SECTION XV – GENERAL PROVISIONS

47. CONFIDENTIALITY

- 47.01** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the receiving Party shall keep confidential, shall not disclose to third persons and shall not use for purposes other than those of this Agreement any Confidential information of the other (disclosing Party) without the prior written consent of the disclosing Party. The receiving Party shall reveal Confidential Information of the disclosing Party to its Affiliates and to its and its Affiliates employees, contractors and other representatives on a strict need to know basis only to persons directly engaged with its activity under this Agreement and shall impose the obligation of secrecy on these persons as well. For clarity, all New IP will be deemed ARS's Confidential Information and ARS shall be considered the disclosing Party and Recordati shall be considered the receiving Party with respect thereto.
- 47.02** The foregoing obligations shall not apply, however, to any part of such information received, which the receiving Party can show by written documentation:
- (i) to have been known to recipient prior to the disclosure by the other Party (provided that this exception shall not apply to Recordati's knowledge of any New IP); or
 - (ii) was known to the public or generally available to the public prior to the date of the disclosure to the recipient by the other Party by the receiving Party; or

- (iii) comes into public domain by publication or otherwise through no breach of this Agreement; or
 - (iv) to have been made known to a recipient without any secrecy obligation from a Third Party having the *bona fide* right to disclose or make available such information;
- 47.03** The receiving Party may disclose Confidential Information of the disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:
- (i) regulatory filings for the Product (for Recordati, only in the Territory) that such Party has a license or right to develop hereunder in a given country or jurisdiction;
 - (ii) [***];
 - (iii) prosecuting or defending litigation arising under this Agreement; and
 - (iv) disclosure that is required by law, provided that a written notification of such disclosure is given and that the recipient, upon request of the disclosing Party (and at the disclosing Party's cost), will reasonably cooperate with the disclosing Party in taking all lawful action against or in complying with such compelled disclosure, provided always that any disclosure shall be only to the extent so required.
- 47.04** As of the Effective Date, the terms of this Clause 47 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.
- 47.05** Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this Clause 47. In addition to all other remedies, a Party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Clause 47.
- 47.06** The obligations under this Clause 47 shall continue to remain valid and in force after the expiration or termination of this Agreement for so long as the information remain confidential and not in the public domain, and in any case for a period not to exceed 5 (five) years.

48. FORCE MAJEURE

Any failure by either Party to comply with its obligations under this Agreement (other than any obligation to make payment when due) shall be excused if and for so long as compliance by such Party is hindered, prevented, or delayed by a Force Majeure event. The Parties shall notify each other immediately, report the expected duration and the extent of such events or circumstances, and shall discuss how to proceed further. The Party affected by the Force Majeure event shall be obligated to make Commercially Reasonable Effort, to limit the disruption caused by the Force Majeure.

49. INSURANCE

- 49.01** For the entire duration of this Agreement and for [***] thereafter, ARS and Recordati undertake to maintain appropriate insurance coverage, including commercial general liability insurance, which adequately covers each Parties' obligations under this Agreement, as well as adequate products liability and property insurance, which insurances shall afford limits of not less than Euro [***] per occurrence and per Calendar Year in the aggregate. For general liability, and not less than Euro [***] per occurrence and per Calendar Year in the aggregate for product liability.
- 49.02** Each Party if requested by the other Party will provide such other Party with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability.

SECTION XVI – MISCELLANEOUS

50. ENTIRE AGREEMENT

- 50.01** This Agreement constitutes the entire agreement between the Parties with respect to the subject matter thereof, and supersedes all prior representations, negotiations and understandings between the Parties, whether in writing or otherwise. Neither Party shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, that will be binding (or purport to be binding) on the other.
- 50.02** Without prejudice to Paragraph 50.01 above, all Product Purchase Agreements are entered in reliance of the fact that this Agreement and all Product Purchase Agreements form a single agreement between the Parties in respect of the subject matter thereof, and that the Parties would not otherwise have entered into a Product Purchase Agreement.

51. AMENDMENTS

This Agreement may only be amended or modified with the written consent of the Parties. Any Party may, as to itself, waive in writing the performance of any provision of this Agreement intended for its benefit.

52. PARTIAL INVALIDITY

In the event that any provision of this Agreement or the application of any provision hereof is declared to be illegal, invalid or otherwise unenforceable by a court of competent jurisdiction, such provision shall be reformed, if possible, or otherwise deleted, and the remainder of this Agreement shall not be affected except to the extent necessary to reform such illegal, invalid or unenforceable provision unless reforming or deleting the provision held invalid shall substantially impair the benefits of the remaining portion of this Agreement.

53. NOTICES

Any communication pursuant to this Agreement shall be carried out in writing and shall be considered effectively and validly executed provided that it is addressed by international courier (return receipt requested) as follows:

- to ARS: 3525 Del Mar Heights Rd.
San Diego, CA 92130, USA
Attn. of Chief Executive Officer;
- to Recordati: Raheens East, Ringaskiddy,
Co Cork, P43 KD30, Ireland
Attn. of Managing Director;

or to a different address that each of the Parties may communicate to the other in writing after the date hereof, it being understood that the above mentioned addresses or any addresses communicated in writing in the future are to be considered as the legal addresses of the Parties for any purpose concerning this Agreement, including legal notifications, settlement procedures and/or arbitration.

54. NO ASSIGNMENT

Without prejudice to the provision set out in Paragraph 3.03, neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned or delegated by a Party to any Person without the previous written consent of the other Party, such consent not to be unreasonably withheld or delayed; except that (i) [***]. This Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assignees. Any assignment or transfer in violation of this Clause 54 shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

55. WAIVER

The tolerance of either Party of any breach of the provisions set out in this Agreement by the other Party shall not be construed as a waiver or variation of the relevant breached provisions, or to the right to require the full performance of all the obligations of the other Party on the term and conditions hereunder.

56. INDEPENDENT CONTRACTORS

The Parties are independent contractors, and this Agreement will not establish any relationship of partnership, joint venture, employment, franchise, or agency between the Parties.

57. COSTS AND EXPENSES

All costs and expenses, including, without limitation, fees and disbursements of legal counsel, financial, accounting and other advisors incurred in connection with this Agreement and the transactions contemplated by this Agreement shall be paid by the Party incurring such costs and expenses.

58. COUNTERPARTS

This Agreement may be executed in several counterparts, all of which together shall constitute one agreement binding on all Parties hereto, notwithstanding that all the Parties have not signed the same counterpart. The Parties agree that this Agreement may be exchanged by facsimile, pdf or other electronic means, which upon request of a Party shall be followed up with originals.

59. ANNOUNCEMENT

The Parties agree that in case they will estimate their joint best interest to make a public announcement concerning their relationship under this Agreement, they will agree to issue a joint or separate press releases in a form and substance reasonably acceptable to both, provided however, that such press release shall not include financial or other patently confidential aspects concerning the subject matter hereof. The Parties will agree on the text of such press releases. Notwithstanding the forgoing, the Parties agree that on the Effective Date each Party may separately release the announcements attached hereto under **Annex 8**.

60. GOVERNING LAW

This Agreement and any non-contractual obligations arising out of or in connection with this Agreement shall be governed by, and interpreted in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded.

61. DISPUTE RESOLUTION

- 61.01** The Parties recognize that disputes as to matters (i) arising under, or relating to, this Agreement or (ii) either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Clause 61 to resolve any such dispute if and when it arises.
- 61.02** Except as otherwise provided in Paragraph 33.06, if an unresolved dispute as to matters arising under or relating to this Agreement or either Party's rights and obligations hereunder arises, either Party may refer such dispute to the Chief Executive Officers (or the Senior Executive of Recordati appointed for the purpose) of the respective Parties, who shall meet in person or by telephone within [***] after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of such Chief Executive Officers (or the Senior Executive of Recordati appointed for the purpose) within such [***] period (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with Paragraph 61.03.
- 61.03** Any dispute between the Parties which cannot be amicably resolved between the Parties as provided in Paragraph 61.02 shall be finally settled by binding arbitration pursuant to this Paragraph 61.03, except for any dispute, controversy or claim that concerns (a) the validity, enforceability or infringement of a patent, trademark or copyright or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.
- (i) The arbitration shall be conducted under the Arbitration Rules of the International Chamber of Commerce as then in effect by a panel of [***] arbitrators appointed in accordance with said rules, none of whom shall be a current or former employee or director, or a then-current stockholder, of either Party, their respective Affiliates or any Sublicensee. If either Party intends to commence binding arbitration of such dispute, such Party will provide written notice to the other Party informing the other Party of such intention and the issues to be resolved. Within [***] after the receipt of such notice, the other Party may, by written notice to the Party initiating binding arbitration, add additional issues to be resolved.
 - (ii) The seat of the arbitration shall be New York, New York. The arbitrators shall resolve the dispute on the basis of the substantive law chosen by the Parties under Clause 60 above. The arbitration award rendered in any such arbitration will be final and not appealable and may be executed by any court of competent jurisdiction. All proceedings of the arbitration, including arguments and briefs, shall be conducted in English.
 - (iii) It is the intention of the Parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than [***] after selection of the arbitrators, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within [***] from such meeting. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

- (iv) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non- compensatory damages. The award shall be in writing and shall describe the basis for the award and the arbitrators' decision(s). The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a Party in connection with the arbitration be paid by the other Party. Each Party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.
- (v) Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

SECTION XVIII – ANNEXES

62. ANNEXES

The following Annexes are attached to this Agreement:

Annex 1	EU Territory;
Annex 2	Ex-EU Territory;
Annex 3	Patents;
Annex 4	Paediatric Development;
Annex 5	Remaining Strength 1 Studies;
Annex 6	Supply Price;
Annex 7	Annual Report Example;
Annex 8	Announcements.

[Remainder of page intentionally left blank]

In witness whereof, each of the Parties has caused this Agreement to be initialled on each page and signed by its duly authorized representative as of the date and in the place specified herein below.

Cork, 21 September 2020

San Diego, 21 September 2020

/s/ Cédric Ripert

/s/ Richard Lowenthal

Recordati Ireland, Ltd
Mr. Cédric Ripert
Title: Managing Director

ARS Pharmaceuticals, Inc.
Mr. Richard Lowenthal
Title: President & Chief Executive Officer

Annex 1
EU Territory

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark*
Estonia
Finland

France**
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg

Malta
The Netherlands
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden

* including Faroe Islands

** including DOM-TOM

Annex 2
Ex-EU Territory

EFTA	Other Europe	CIS	Middle East	Africa
Iceland	Albania	Armenia	Afghanistan	Algeria
Lichtenstein	Andorra	Azerbaijan	Bahrain	Benin
Norway	Bosnia-Herzegovina	Belarus	Egypt	Burkina Faso
Switzerland	Georgia	Kazakhstan	Iran	Burundi
	Monaco	Kyrgyzstan	Iraq	Cameroon
	Montenegro	Moldova	Israel	Central African Rep.
	North Macedonia	Russia	Jordan	Chad
	Ukraine	Tajikistan	Kuwait	Congo
	San Marino	Uzbekistan	Lebanon	Dem. Rep. Congo
	Serbia		Oman	Djibouti
	Vatican City		Pakistan	Equatorial Guinea
			Palestine	Ivory Coast
			Qatar	Lybia
			Saudi Arabia	Madagascar
			Syria	Mali
			Turkey	Mauritius
			United Arab Emirates	Morocco
			Yemen	Niger
				Rwanda
				Senegal
				Seychelles
				Togo
				Tunisia

For the sake of clarity, the United Kingdom (UK) is part of the Territory definition.



ARS Pharmaceuticals and Recordati Announce Exclusive License for the Rights in Europe and additional countries for Neffy™ (ARS-1; epinephrine nasal spray)

Agreement will give access to millions at risk for severe allergic reaction to new pain-free delivery method for epinephrine and will help in efforts to gain regulatory approval for ARS-1 (known as Neffy™ in the U.S.) around the world

SAN DIEGO SEPTEMBER 21, 2020—ARS Pharmaceuticals (ARS) announced that it has entered into an exclusive licensing agreement with Recordati for marketing rights in the European Union, Iceland, Liechtenstein, Norway, Switzerland, United Kingdom, Russia/CIS, Turkey, Middle East and French-speaking African countries, for ARS-1 (known as Neffy™ in the United States), an epinephrine nasal spray. This agreement will allow ARS, a pharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions potentially leading to anaphylaxis, to continue the important work of gaining regulatory approval in the United States and globally by providing additional capital through licensing milestones and future royalties on sales.

“We are thrilled that Recordati has recognized the importance of this new delivery technology for epinephrine that will provide an improved therapy for the millions of people in Europe living with life-threatening allergies. With their strong track-record in specialty medicines, we are excited to work with the team at Recordati, to help deliver a new, easier to dose, pain-free way to treat severe allergic reactions and prevent progression to anaphylaxis,” said Richard Lowenthal, President and Chief Executive Officer of ARS Pharmaceuticals. “The agreement with Recordati is critical in our continued journey towards Neffy™ (ARS-1) approval in the United States and Worldwide.”

Recordati will receive exclusive rights to develop, register and commercialize ARS-1 (known as Neffy™ in the United States) in 93 countries including Europe in return for an upfront and subsequent payments based on successful achievement of regulatory and commercial milestones. ARS Pharmaceuticals will manufacture and supply ARS-1 (known as Neffy™ in the United States) to Recordati as part of the agreement, and receive tiered royalties based on net sales.

Because of its innovative delivery method, Neffy™ (ARS-1) has the potential to be a much more effective treatment in preventing severe allergic reactions than currently available. Its needle-free, small and easy-to-use delivery system may help eliminate anxiety and overcome hesitation that is common with injectable epinephrine. The marketing authorization application for the 1 mg dose, for patients 30kg or greater, is expected to be filed in the EU by the end of 2020. A dosage strength of 0.65 mg is under development for children weighing between 15kg and 30kg and is expected to be filed shortly after the initial approval.

In Europe, based on epidemiology data about 4% of the general population have experienced an anaphylactic episode. Overall annual net sales of epinephrine auto-injectors in Europe are around \$120 million USD based on IQVIA prescription data, representing less than 10% of the eligible population. According to the European Anaphylaxis Registry, less than 15% of anaphylaxis episodes are self-treated with an auto-injector. The introduction of Neffy™ (ARS-1) would be a welcome new tool to safely, quickly and painlessly administer lifesaving epinephrine.

About ARS Pharmaceuticals, Inc.

ARS Pharmaceuticals is dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis. The Company is developing Neffy™ (ARS-1), an intranasal epinephrine spray with a unique absorption technology that could be easy-to-use, needle-free, convenient and more reliable for patients and loved ones at-risk of severe allergic reactions to food, medications and insect bites that could lead to life-threatening anaphylaxis. For more, visit www.ars-pharma.com.

About Recordati

Recordati, established in 1926, is an international pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of more than 4,300, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations throughout the whole of Europe, Russia, Turkey, North Africa, the United States of America, Canada, Mexico, some South American countries, Japan and Australia. An efficient field force of medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses for its territories. Recordati is committed to the research and development of new specialties with a focus on treatments for rare diseases. Consolidated revenue for 2019 was € 1,481.8 million, operating income was € 465.3 million and net income was € 368.9 million.

Contact: Margaret Long
margaret.long@porternovelli.com
571-445-4428

RECORDATI LICENSES AN INNOVATIVE EPINEPHRINE NASAL SPRAY IN DEVELOPMENT FOR ANAPHYLAXIS PREVENTION

Milan, 21 September, 2020—Recordati announces the signing of an exclusive license agreement with ARS Pharmaceuticals, a private U.S. company, for the commercialization in the European Union, Iceland, Liechtenstein, Norway, Switzerland, United Kingdom, Russia/CIS, Turkey, Middle East and French-speaking African countries, of ARS-1, an epinephrine nasal spray in late-stage development for the emergency treatment of severe allergic reactions that can lead to anaphylaxis. Under the terms of the agreement an upfront payment is due by Recordati upon signature of the contract and further milestone payments are linked to the regulatory process and commercial performance.

Anaphylaxis is a severe, generalized allergic reaction, characterized by life-threatening breathing or cardiovascular problems and usually associated with skin and mucosal changes. The trigger is exogenous and can be associated with food, insect bites or other allergenic substances. ARS-1 is a liquid formulation of epinephrine associated with Intravail®, an absorption enhancer, contained in a disposable, mono-dose nasal spray device. This innovative formulation represents a new route of administration compared to existing products, increasing patient compliance and fulfilling an unmet medical need. Easy-to-use and needle-free, this solution may eliminate the anxiety and hesitation associated with using an injection device. With use at the first signs of allergic response, it could provide patients and their families the preventive solution to anaphylactic progression.

The marketing authorization application for the 1 mg dose of the product is expected to be filed in the EU by the end of 2020. Furthermore, a dosage strength of 0.65 mg is under development for pediatric patients.

“We are very pleased that ARS Pharmaceuticals has granted Recordati the exclusive license to market its innovative product for the prevention of severe allergic reactions in Europe, Russia, the Middle East and other countries”, stated Andrea Recordati CEO. “This effective innovative formulation of a product for the prevention of life-threatening allergic reactions reinforces our Specialty and Primary care pipeline and provides further diversification to our portfolio in an area where medical needs are not fully satisfied.”

Recordati, established in 1926, is an international pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECL.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of more than 4,300, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations throughout the whole of Europe, including Russia, Turkey, North Africa, the United States of America, Canada, Mexico, some South American countries, Japan and Australia. An efficient field force of medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses for its territories. Recordati is committed to the research and development of new specialties with a focus on treatments for rare diseases. Consolidated revenue for 2019 was € 1,481.8 million, operating income was € 465.3 million and net income was € 368.9 million.

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Statements contained in this release, other than historical facts, are “forward-looking statements” (as such term is defined in the Private Securities Litigation Reform Act of 1995). These statements are based on currently available information, on current best estimates, and on assumptions believed to be reasonable. This information, these estimates and assumptions may prove to be incomplete or erroneous, and involve numerous risks and uncertainties, beyond the Company’s control. Hence, actual results may differ materially from those expressed or implied by such forward-looking statements. All mentions and descriptions of Recordati products are intended solely as information on the general nature of the company’s activities and are not intended to indicate the advisability of administering any product in any particular instance.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.**

MANUFACTURING AGREEMENT

BY AND BETWEEN

RENAISSANCE LAKEWOOD, LLC

AND

ARS PHARMACEUTICALS, INC.

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This Manufacturing Agreement (the “Agreement”) is made as of this 9th day of September, 2020 (the “Effective Date”) by and between ARS Pharmaceuticals, Inc., a corporation organized under the laws of the State of California with its principal office located at [***], (hereinafter referred to as “COMPANY”) and Renaissance Lakewood, LLC, a limited liability corporation organized under the laws of the State of Delaware with a place of business at 1200 Paco Way, Lakewood, New Jersey, 08701 (hereinafter “RENAISSANCE”).

WITNESSETH:

WHEREAS, COMPANY is engaged in the development, manufacture, and commercialization of certain pharmaceutical products; and

WHEREAS, RENAISSANCE owns and has a broad spectrum of technologies for the development, formulation, testing, control, manufacture, filling and distribution of pharmaceutical products; and

WHEREAS, COMPANY and RENAISSANCE have entered into that certain Research & Development Services Agreement, dated as of [***] (“R&D Agreement”), pursuant to which, among other things, RENAISSANCE has developed a formulation of a certain Product (as hereinafter defined); and

WHEREAS, COMPANY desires to engage RENAISSANCE to manufacture and supply the Product to COMPANY for its commercial uses, and RENAISSANCE desires to do so.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter expressed, the parties agree as follows:

I—DEFINITIONS

“Acknowledgement” has the meaning set forth in Section 2.6(a) hereof.

“Act” means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder.

“Additional Development” has the meaning set forth in Section 10.1 hereof.

“Administrative Expenses” means, in the context of any Product [***].

“Affiliate” means, with respect to either party, any Person controlling, controlled by or under common control with such party, for so long as such relationship exists. For the purposes of this definition, “control” means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such party, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such party (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Law of the country of incorporation or domicile), as applicable.

“Agreement” has the meaning set forth in the Preamble hereof.

“Annual Product Review” means an analysis conducted by RENAISSANCE personnel on a yearly basis, consistent with 21 C.F.R. § 211.180 and any comparable regulation in the Primary Territory, which examines a multitude of subject matter areas, including production review and changes in processes, raw materials, API, Packaging and shipping components, unit volume, production, and other similar such issues.

“API” means, Epinephrine, which is the active pharmaceutical ingredient that is contained in the Product, as more fully defined in Schedule A.

“Applicable Law” means all laws, ordinances, rules, rulings, directives and regulations of any Regulatory Authority: (a) applicable to the Manufacture, distribution and/or sale of Product; or (b) governing the parties; as the context requires under this Agreement, including, (i) all applicable federal, state and local laws and regulations; (ii) the Act (iii) cGMP; and (iv) any other requirements by any Regulatory Authority. For the avoidance of doubt “Applicable Law” when used in this Agreement in relation to RENAISSANCE compliance obligations includes the items set forth in clause (i)-(iv) only for the Primary Territory and not the Secondary Territory or any other country, but with regard to COMPANY includes any country in which it sells Product.

“Background IP” has the meaning set forth in Section 7.1 hereof.

“Batch” means a defined quantity of Product that is Manufactured in a single Manufacturing run in accordance with the Specifications.

“Batch Documentation” has the meaning set forth in Section 5.2 hereof.

“Certificate of Analysis” has the meaning set forth in Section 5.2 hereof.

“Certificate of Compliance” has the meaning set forth in Section 5.2 hereof.

“Change Control Request” or “CCR” means the primary record in RENAISSANCE’s record keeping system in which the overall details of a change are captured, monitored and approved by COMPANY.

“Commercially Reasonable Efforts” means [***].

“Common Technical Document” means the document assembling all the quality, safety and efficacy information in a common format developed by the EMA, the FDA, and the Japanese Ministry of Health, Labour and Welfare; in each case, any successor agency thereto, maintained by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

“COMPANY” has the meaning set forth in the Preamble hereof.

“COMPANY Inventions” has the meaning set forth in Section 7.2 hereof.

“COMPANY Material” has the meaning set forth in Section 2.2(a) hereof and includes [***].

“Confidential Information” has the meaning set forth in Section 9.1(a) hereof.

“Disclosing Party” has the meaning set forth in Section 9.1(a) hereof.

“Effective Date” has the meaning set forth in the Preamble hereof.

“EMA” means the European Medicines Agency and any successor agency or authority having substantially the same function in the European Union.

“Extraordinary Matters” has the meaning set forth in Section 11.5 hereof.

“E.U.” means the European Union as it is comprised from time to time and the United Kingdom so long it remains subject to Applicable Law of the E.U. and the EMA.

“E.U. and Other Country Initial Term” has the meaning set forth in Section 4.1 hereof.

“E.U. and Other Country Renewal Term” has the meaning set forth in Section 4.1 hereof.

“E.U. and Other Country Term” has the meaning set forth in Section 4.1 hereof.

“E.U. Launch Date” means the first Launch Date for the first Product for any country in the E.U.

“Facility” means the facility of RENAISSANCE located at 1200 Paco Way, Lakewood, New Jersey, 08701, where Product will be Manufactured and stored by RENAISSANCE.

“FDA” means the United States Food and Drug Administration, or any successor agency or authority having substantially similar function in the United States.

“Forecasted Needs” means COMPANY’s estimate of Product to be ordered from RENAISSANCE for the [***] beginning with the [***] in which such estimate is provided.

“Force Majeure” means causes beyond the control of a party, which are not attributable to any legal violation, breach or default by such party, including acts of God, acts, regulations, or laws of any government, epidemics, pandemics, civil commotion, strikes, shortages of raw materials, terrorism, unavailability of necessary equipment, substantial damage to or destruction of production facilities or material by fire, earthquake or storm, and failure of public utilities or common carriers.

“Good Manufacturing Practices” or “cGMP” means the current good manufacturing practices and standards applicable to the manufacture of Product as provided for (and as amended from time to time) in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations 21 C.F.R. § 210 and 211 in relation to the production of finished pharmaceutical Product and any corresponding practices and standards under U.S. and E.U. Applicable Law , subject to any arrangements, additions, clarifications, and the respective roles and responsibilities agreed from time to time between the parties.

“Initial Term” has the meaning set forth in Section 4.1 hereof.

“Inventions” has the meaning set forth in Section 7.2(a) hereof.

“Label”, or “Labeling” means all labels and other written, printed, or graphic matter: (i) upon Product or any container or wrapper utilized with Product or (ii) accompanying Product.

“Launch Date” means, with respect to any Product in any country in the Territory, the first day of the month following RENAISSANCE’s initial invoicing of Product to COMPANY designated for sale in such country, which Product has been Manufactured by RENAISSANCE and released for commercial use under this Agreement.

“Manufacture”, “Manufactured” or “Manufacturing” means any steps, processes and activities necessary to produce Product, including, the manufacturing, processing, formulation, fill/finish, handling, labeling, packaging, inspection, quality control testing, release or storage of Product, but excluding any storage or distribution of Product or validation activity prior to release of that Product.

“Manufacturing Fee” means the fee paid by COMPANY to RENAISSANCE for services required to Manufacture Product under this Agreement. [***].

“Maximum Purchase Order Quantity” has the meaning set forth in Section 2.6(a) hereof.

“Minimum Order Quantities or (MOQ)” means [***].

[***]

“Other Countries” means the countries listed in Schedule E.

“Packaging” means all primary containers, cartons, shipping cases, inserts or any other like material used in packaging, or accompanying Product in accordance with applicable Specifications, including executed Batch records.

“Partner” means COMPANY’s commercialization partner.

“Partner Trade Dress” means Partner’s Packaging to be used in relation to Product in the Territory, which includes Partner’s Trademarks.

“PDUFA” has the meaning set forth in Section 6.2 hereof.

“Permitted Recipients” has the meaning set forth in Section 9.1(b) hereof.

“Person” means any natural person, partnership, limited liability company, corporation, trust, joint venture, joint stock company, association, unincorporated organization, government or agency or political subdivision thereof, or other entity, whether acting in an individual, fiduciary or other capacity.

“Primary Territory” means the E.U. and the U.S.

“Prior CDA” has the meaning set forth in Section 9.1(a) hereof.

“Product” means each product listed in Schedule B to be Manufactured, by RENAISSANCE hereunder.

“Project Protocol” means a precise and detailed plan that is mutually agreed and executed by RENAISSANCE and COMPANY, which describes the nature and scope of out-of-scope services to be rendered and fees to be charged, which may include Additional Development.

“Purchase Commitment” has the meaning set forth in Section 2.1(a) hereof.

“QBR” has the meaning set forth in Section 5.7 hereof.

“Quality Agreement” has the meaning set forth in Section 5.1 hereof.

“R&D Agreement” has the meaning set forth in the Preamble hereof.

“Receiving Party” has the meaning set forth in Section 9.1(a) hereof.

“Regulatory Approval” means, with respect to a particular Product, all approvals, licenses, registrations or authorizations necessary for the development or commercialization in the Territory of such Product (including applicable approvals of Labeling, price and reimbursement for such Product in the Territory), including approval of any New Drug Approval (NDA) or Abbreviated New Drug Application (ANDA) by the FDA or of any Marketing Authorization Application (MAA) by the EMA or any other applicable Regulatory Authority in the E.U.

“Regulatory Authority” means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental agency with authority over the development, manufacture or commercialization (including Regulatory Approvals) of any Product; in each case, with regard to RENAISSANCE, only in the Primary Territory, including the FDA and the EMA.

“Regulatory Filing” means any and all filings or applications submitted to a Regulatory Authority with respect to any Product (together with supporting documentation), submitted via the Common Technical Document or otherwise.

“Rejected Product” has the meaning set forth in Section 2.7(a) hereof.

“RENAISSANCE” has the meaning set forth in the Preamble hereof.

“RENAISSANCE Fault” has the meaning set forth in Section 2.7(c) hereof.

“RENAISSANCE Inventions” has the meaning set forth in Section 7.1 hereof.

“RENAISSANCE Material” has the meaning set forth in Section 2.2(b) hereof.

“RENAISSANCE Product Warranty” has the meaning set forth in Section 6.1 hereof.

“Renewal Term” has the meaning set forth in Section 4.1 hereof.

“Representatives” means, with respect to a party and its Affiliates, their employees, agents, accountants, attorneys, consultants, subcontractors and other representatives.

“Required Lead Time” has the meaning set forth in Section 2.6(c) hereof.

“Requirements” means COMPANY’s actual requirements for Product, which will reflect any instances where its requirements are reduced due to (i) [***], (ii) [***], or (iii) [***].

“Safety Data Sheet” or “SDS” means written or printed material concerning a hazardous chemical, which is prepared in accordance with the regulations promulgated by the Occupational Safety & Health Administration or any successor entity thereto.

“Secondary Territory” means United Kingdom (upon it no longer being subject to Applicable Law of the E.U. and the EMA) and the Other Countries.

“Specifications” means, with respect to a Product, all written product, regulatory, manufacturing, quality control and quality assurance procedures, processes, practices, standards, instructions and specifications provided by COMPANY to RENAISSANCE in writing, including [***] in accordance with Article VIII), including RENAISSANCE’s Acceptable Quality Limits, applicable to the Manufacture, storage and shipment of Product as set forth in the applicable Regulatory Approval.

“Standard Cost(s)” means the [***] cost to [***] of materials plus [***].

“Standard Operating Procedures” or “SOPs” means detailed, written instructions to achieve uniformity of the performance of a specific process, which may cover more than one task or area covered by cGMP regulations. SOPs are considered to be supplemental to master batch records, specification documents and standard methods of analysis. Specific instructions provided in master batch records, specification documents and standard methods of analysis will supersede instructions in SOPs (unless otherwise stipulated in the applicable SOP document).

“Stock Keeping Unit” or “SKU” means a unique number assigned to a finished product.

“Supply Failure” has the meaning set forth in Section 2.1(b) hereof.

“Technical and Development Services” means the services provided by RENAISSANCE technical and development personnel to customers of RENAISSANCE with respect to the evaluation, sourcing, qualification, development, manufacture and/or testing of new equipment, products or other items which may become projects hereunder separate from the Manufacture of Product.

“Target E.U. Launch Date” means [***], the target Launch Date for the first Product in the E.U.

“Target U.S. Launch Date” means [***], the target Launch Date for the first Product in the U.S.

“Technical and Development Hourly Rate” means the standard, reasonable hourly rate charged by RENAISSANCE for Technical and Development Services at the time such Technical and Development Services are provided, which hourly rate is \$[***] per hour as of the Effective Date.

“Term” has the meaning set forth in Section 4.1 hereof.

“Territory” means, collectively, the Primary Territory and the Secondary Territory.

“Third Party” means any Person other than RENAISSANCE and COMPANY and their respective Affiliates.

“Total Price per Unit of Product” means, with respect to a unit of a Product, the sum of its [***].

“Trademarks” means, with regard to any country in the Territory, all marks, logos, trademarks and brand names designated by a party to commercialize Product in such country.

“U.S.” means the United States of America, its territories, commonwealths and possessions, including, but not limited to, the District of Columbia, Commonwealth of Puerto Rico, the U.S. Virgin Islands, the Marshall Islands and Guam.

“U.S. Initial Term” has the meaning set forth in Section 4.1 hereof.

“U.S. Renewal Term” has the meaning set forth in Section 4.1 hereof.

“U.S. Term” has the meaning set forth in Section 4.1 hereof.

“U.S. Termination Event” means the occurrence of any of the following events: (i) COMPANY has not submitted its first Regulatory Filing for any Product in the U.S. on or before June 30, 2022, (ii) the authorization and approval to distribute or sell Product in the U.S. is not granted or before the Target U.S. Launch Date, (iii) the authorization and approval representing more than [***] units of Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (iv) COMPANY at its sole discretion determines to cease commercializing all Product in the U.S.

“U.S. Launch Date” means the first Launch Date for the first Product in the U.S.

II—PRODUCT MANUFACTURE AND SUPPLY

2.1 Manufacture and Purchase

(a) General Provisions

Subject to the terms and conditions of this Agreement (including Section 2.1(b)), RENAISSANCE agrees that it will Manufacture for, and provide to, COMPANY, and COMPANY agrees that during the Initial Term it will order from RENAISSANCE pursuant to Section 2.6, not less than (i) [***] of the COMPANY’s aggregate annual Requirements in the E.U.; and (ii) [***] of the COMPANY’s annual, aggregate Requirements in the U.S. (the “Purchase Commitment”). COMPANY shall pay RENAISSANCE for Product according to Sections 2.8 and 2.9. RENAISSANCE shall Manufacture Product and perform its obligations hereunder in accordance with U.S. and E.U. Applicable Law, the Specifications, the Quality Agreement, and this Agreement, and shall use [***] to Manufacture Product in sufficient quantity to meet COMPANY’s Forecasted Needs for the length of this Agreement. [***].

(b) Volume Commitment and Duration

The Purchase Commitment is subject to RENAISSANCE maintaining its ability to supply COMPANY's Requirements, and if RENAISSANCE [***] or is unable to supply COMPANY's Requirements of Product for a period exceeding [***] (a "Supply Failure"), then the Purchase Commitment will be suspended, provided that upon the resumption of RENAISSANCE's ability to supply COMPANY's Requirements [***], the Purchase Commitment will be reinstated.

[***].

[***].

2.2 Supply of Materials

(a) Materials Supplied by COMPANY

If COMPANY is to supply any material for Manufacture of Product as set forth under this Section 2.2, such material shall be described in Schedule C ("COMPANY Material"). COMPANY shall notify RENAISSANCE, in writing of any changes or amendments to Schedule C. COMPANY shall provide RENAISSANCE with COMPANY Material [***] expense along with Certificates of Analysis and SDSs relating to such COMPANY Material in accordance with Section 2.4 at a minimum of [***] prior to RENAISSANCE's scheduled production of Product requiring such COMPANY Material and in sufficient amounts for RENAISSANCE's Manufacture of Product, but not to exceed the greater of (i) quantities necessary to support [***] of the most recently-supplied Forecasted Needs, and (ii) any [***]. In addition, COMPANY Material in excess of [***] of the most recently-supplied Forecast Needs shall be either subject to storage fees in accordance with Schedule D or returned to COMPANY, [***]. All COMPANY Material shall be shipped to RENAISSANCE [***]. In the event COMPANY ships or causes to ship

such COMPANY Material [***], [***] shall invoice [***] for the cost of the freight [***], which invoice shall be paid [***] promptly upon receipt. COMPANY shall be responsible for the quality of all COMPANY Material. COMPANY shall be responsible for the payment of [***] and [***] incident to [***] of COMPANY Material delivered to RENAISSANCE. For each lot of COMPANY Material supplied by COMPANY, RENAISSANCE shall [***] as agreed to in the Specifications unless COMPANY has made arrangements in writing for [***]. In the event that any COMPANY Material requires RENAISSANCE to [***] that is not included in the Specifications, RENAISSANCE will [***] and may charge COMPANY for those services at the [***]. COMPANY shall deliver all COMPANY Material so that it is received by RENAISSANCE with not less than [***] of shelf life remaining at the time of receipt. RENAISSANCE shall have the right to reject any [***] COMPANY Material which does not meet the Specifications in accordance with Section 2.3. To the extent required by Applicable Law, COMPANY is responsible for auditing the facilities of the COMPANY Material, and COMPANY agrees to provide RENAISSANCE, upon RENAISSANCE's request, a current copy of the audit report of these facilities, subject to COMPANY's confidentiality obligations to the relevant Third Parties. RENAISSANCE warrants that it will maintain, for the benefit of COMPANY, complete and accurate records of the inventory of all such COMPANY Material. RENAISSANCE will provide to COMPANY a [***] report of the ending [***] inventory balance of each type of COMPANY Material stored at RENAISSANCE. [***]. RENAISSANCE will use the first-expiring, first-out method of inventory management for COMPANY Material. RENAISSANCE shall not transfer, distribute or release any COMPANY Material to any Third Party without the COMPANY's prior written consent, except to its Representatives conducting activities on behalf of RENAISSANCE, provided that such any such Representative is bound by written agreements or are otherwise bound to retain and use the COMPANY Material only in the manner permitted under this Agreement and are subject to non-use, confidentiality and intellectual property obligations not less stringent than those provided for in Article IX and Article VII, respectively. RENAISSANCE will only use COMPANY Material as authorized under this Agreement. Risk of loss and damage to COMPANY Material shall remain with [***] (i) in the case of [***], at all times, and (ii) in the case of all other [***] Material, until [***] Material is delivered to RENAISSANCE following which [***] will bear all risk of loss or damage to [***] Material until such [***] Material is returned to [***] or delivered to [***] as part of a completed Product.

(b) Materials Supplied by RENAISSANCE

RENAISSANCE shall be responsible for the supply of all materials, other than the COMPANY Material, necessary for the Manufacture of Product (“RENAISSANCE Material”). [***].

(c) Packaging and Labeling

COMPANY shall provide RENAISSANCE with Specifications (including art proofs) for Packaging and Labeling, and RENAISSANCE shall [***] in accordance with the Specifications. As between the parties, prior to the applicable Launch Date, [***] shall be responsible for obtaining labeler codes, drug listings and the National Drug Code (NDCs), or the equivalents of the same in non-U.S. parts of the Territory, for use in connection with the sale of Product.

(d) Additional Charges

COMPANY shall be responsible for any additional charges [***], and incurred in the procurement of any materials and/or Packaging and Labeling components (as detailed in the immediately preceding sub-sections (a), (b) and (c)) required for the Manufacture of Product [***].

2.3 Materials Testing

All materials (including COMPANY Material and RENAISSANCE Material) and Packaging components shall, when received by RENAISSANCE, be submitted to analysis and evaluation in accordance with RENAISSANCE’s SOPs to determine whether or not such materials meet the Specifications. The cost of all such analyses and evaluations shall be borne by [***], except as otherwise expressly provided in Section 2.2. RENAISSANCE agrees to maintain and, if necessary, make available records of all such analyses and evaluations. If RENAISSANCE

determines that any COMPANY Material does not meet the Specifications, RENAISSANCE shall promptly notify COMPANY thereof, and COMPANY shall have the right to conduct such analysis and evaluation (or engage a Third Party to conduct such analysis and evaluation), subject to Section 2.7(d). COMPANY hereby acknowledges and agrees that RENAISSANCE's sole and exclusive obligations with regard to the quality of COMPANY Material are set forth in this Section 2.3 and the Quality Agreement and that, provided RENAISSANCE has complied with its obligations under this Section 2.3 and the Quality Agreement, RENAISSANCE will not be responsible for any Product defects caused by COMPANY Material.

2.4 Safety Data Sheets

Prior to RENAISSANCE's receipt and testing, and as a condition precedent to any testing or formulation work by RENAISSANCE pursuant to this Agreement, COMPANY shall provide SDSs to RENAISSANCE for finished Product, COMPANY Material and all components necessary for the Manufacture of Product, excluding RENAISSANCE Material. RENAISSANCE shall presume any components or Product requiring disposal to be hazardous, unless otherwise provided in the SDS information provided.

2.5 Commencement of Manufacturing for New Products

Not later than [***] prior to the estimated delivery date of a new Product (or an SKU of an existing Product), COMPANY agrees to notify RENAISSANCE of its delivery requirements for such new Product (or SKU of an existing Product). COMPANY shall provide Forecasted Needs covering the [***] period subsequent to the first Launch Date for such new Product for each country in the Territory in order to ensure timely delivery of Product for the initial sales and marketing campaign. Firm orders shall be issued for the first [***] of the COMPANY's Forecasted Needs [***].

2.6 Purchase Orders

(a) Purchase of Product

Product shall be ordered by COMPANY by the issuance of [***]. RENAISSANCE will accept all purchase orders submitted by COMPANY in accordance with this Section 2.6, provided that (i) the total number of Batches does exceed [***] (B) [***], and (ii) [***] (the "Maximum

Purchase Order Quantity”). Promptly following receipt of a purchase order (and in no event later than [***] following such receipt), RENAISSANCE shall [***].

(b) Forecasted Needs

COMPANY shall provide RENAISSANCE with a written, non-binding [***] projection as to its Forecasted Needs, specifying the number of Batches on a Product-by-Product and [***] basis. Such Forecasted Needs shall be updated by COMPANY [***] on or before the [***] of each calendar [***] on a rolling [***]. It is understood and agreed that with respect to all Forecasted Needs issued to RENAISSANCE by COMPANY pursuant to the terms hereof, the Forecast Needs for the first [***] thereof are not subject to modification and shall [***]. COMPANY shall issue a purchase order to RENAISSANCE for such quantity of Product concurrent with the delivery of such Forecasted Needs. RENAISSANCE may initiate production of Product up to [***] prior to the requested delivery date in order to accommodate fluctuations in production demands, provided that RENAISSANCE will set a target to release each Batch within [***] after filling. The remaining [***] of the Forecasted Needs shall be utilized by RENAISSANCE for purposes of planning material acquisition on behalf of COMPANY and RENAISSANCE production planning. RENAISSANCE agrees to [***]

Any such material which is subsequently rendered in excess of that required to support up to [***] of COMPANY's Forecasted Needs may be subject to [***] and [***], and RENAISSANCE may require [***] of such RENAISSANCE Material.

(c) Required Lead Time

COMPANY shall issue written purchase orders for Product to RENAISSANCE at least [***] prior to the requested delivery dates (the "Required Lead Time"), provided that COMPANY hereby acknowledges and agrees that for RENAISSANCE to accept any purchase order in excess of the Maximum Purchase Order Quantity (which acceptance is subject to Section 2.6(a)), a longer lead time may be necessary.

(d) Contents of Purchase Orders

COMPANY's purchase orders shall designate the desired quantities of Product, delivery destination, and delivery dates. The terms and conditions of this Agreement shall be controlling over any conflicting terms and conditions stated in COMPANY's purchase order or RENAISSANCE's invoice, Acknowledgement or other standardized document, unless the parties mutually agree in writing therein.

2.7 Rejected Product

(a) Rejection of Product by COMPANY

Prior to shipment, all Product shall be submitted to inspection and evaluation in accordance with RENAISSANCE's SOP and the terms and conditions of this Agreement to determine whether or not said Product meets the Specifications. COMPANY may [***] ("Rejected Product"). COMPANY shall promptly, but in no event later than [***] after its receipt of any shipment of Product and related Batch Documentation (as described in Section 5.2), notify RENAISSANCE in writing of COMPANY's [***], and any claim relating to the [***] and, failing such notification, shall be deemed to have accepted [***]; provided that, COMPANY may revoke [***] and [***] any Product contained in such [***] within [***] of receipt thereof for any [***] and COMPANY notifies RENAISSANCE thereof within [***] after such [***] is discovered. Such notice to RENAISSANCE shall specify why the [***] failed to [***]. COMPANY shall grant to RENAISSANCE the right to [***].

(b) Refunds or Replacement of Rejected Product

As to any Rejected Product (including phases of or complete Batches of bulk product) for which [***] has responsibility for costs pursuant to Section 2.7(c) below, [***] shall, at [***] election (i) refund [***] for the amount paid by [***] for such Rejected Product, or (ii) replace such Rejected Product promptly within the shortest practical time. The amount refunded and/or replacement cost for any Batch of Rejected Product shall be reasonably allocated as set forth in Section 2.7(c). Upon [***] election, [***] shall make arrangements with [***] for the return or disposal of Rejected Product in accordance with Applicable Law.

(c) Responsibility for Costs

For each validation Batch produced by RENAISSANCE [***], [***] shall bear [***] of all costs directly related to and invoiced for such validation Batch, [***], which shall be conducted and managed by [***] in accordance with Applicable Law. With respect to Rejected Product resulting from [***], [***]; in each case rendering the Rejected Product unmarketable (collectively, “[***] Fault”), then [***] shall bear [***] of the [***]. In the event a Rejected Product results other than [***] Fault (including [***]) rendering the Product unmarketable, [***] shall bear the [***]. Destruction of Rejected Product shall be in accordance with Applicable Law. The party conducting the destruction shall also provide to the other party all manifests and other applicable evidence of proper destruction as may be required by Applicable Law.

(d) Resolution of Conflict

In the event of: (i) a conflict between the parties with respect to the conclusions to be drawn from any test results or (ii) a difference of opinion between the parties regarding the [***] with respect to any Product in such Batch, in each of clause (i) or (ii) that is not resolved by the parties within [***] following [***], a sample of such Rejected Product shall be submitted by [***] to an independent laboratory or recognized industry expert mutually agreed in writing by the parties for testing against the Specifications and any other mutually agreed tests, utilizing the methods set out in the Specifications or as otherwise mutually agreed by the parties. The fees and expenses of such laboratory testing shall be borne [***], unless otherwise agreed to by the parties.

(e) Product Recall

Each party will immediately inform the other in writing if it believes one or more Batches should be subject to recall from distribution, withdrawal or some other field action. To the extent permitted by Applicable Law and public safety, the parties will confer before initiating any recall or other field action; provided that [***].

In the event (i) any Regulatory

Authority issues a request, directive or administrative order that Product be recalled, (ii) a court of competent jurisdiction orders a Product recall, or (iii) COMPANY reasonably determines that any Product should be recalled, the parties shall take all appropriate corrective actions which are reasonable under the circumstances. [***] shall initially bear the cost thereof and shall carry out the recall in accordance with best industry practices. In the event that such recall results [***] from [***], [***] shall be responsible for the [***] of the recall, [***], as well as for the [***]. The parties shall each maintain traceability records as are sufficient and as may be necessary to permit a recall.

2.8 Product Price

(a) Manufacturing Fee

Each initial Manufacturing Fee to be paid by COMPANY to RENAISSANCE is listed in Schedule B. On the first day of [***] of each [***] following the Effective Date, the applicable Manufacturing Fee for property designated for commercial sale in the U.S. (as shown in Schedule B, Table 1) [***] be adjusted by the change in the most recently published monthly Producer Price Index for Pharmaceutical Preparation Manufacturing PCU 325412, issued by the Bureau of Labor Statistics, U.S. Department of Labor (“PPI”), or comparable successor index, in [***] of the preceding [***] as compared to the [***] of the most recently-completed [***], provided that (i) the increase during the period commencing on the Effective Date and ending on the first U.S. Launch Date may not exceed [***] during any [***] period, and (ii) the total increase for the remainder of the Initial Term may not exceed [***]. The Manufacturing Fee for Product designated for commercial sale in the E.U. and the Other Countries will not be subject to adjustment during the Initial Term.

The Manufacturing Fee for any new Product not initially included in Schedule B shall be negotiated in good faith, and RENAISSANCE and COMPANY shall arrive at a mutual agreement with respect to the Manufacturing Fee prior to the time of first production.

(b) Materials Fee

The estimated Materials Fee to be paid by COMPANY to RENAISSANCE is listed in Schedule B and will be reset [***] prior to the commencement of Manufacturing Product to be sold on the Launch Date for that Product. Thereafter, the Materials Fee for that Product will be adjusted [***] at the beginning of each [***] and Schedule B shall be amended accordingly based on [***]. In the event, however, that the total underlying costs of Materials Fee for a Product increases or decreases during any [***] by more than [***]. The Materials Fee for any new Product not initially included in Schedule B shall be established by mutual agreement of the parties prior to the time of first production.

(c) Taxes

COMPANY agrees that the [***] and [***] will be exclusive of, and that [***] shall bear, all taxes, whether direct or indirect [***], levies, and duties ([***]) as may be imposed on the sale of Product under this Agreement [***], and [***] shall be responsible for the timely payment of such amounts to such governmental body or authority.

2.9 Payment

Payment for all deliveries of Product and services shall be made in U.S. Dollars (USD), net [***] after the date of RENAISSANCE's invoice therefor. Invoices shall be generated upon [***] of Product from RENAISSANCE. Total invoice price shall be equal to [***], plus any other additional amounts listed in Schedule B. Payment shall be made by check, wire transfer, electronic fund transfer or through other instrument accepted by RENAISSANCE. Payment by wire or electronic fund transfer should be made to the following:

2.10 Late Payment

Without prejudice to any other remedies, including the rights to claim for further damages, any undisputed amount not paid by COMPANY within the applicable time set forth in Section 2.9 shall be subject to a late fee of [***] of total invoice which shall be added [***] for late payments. RENAISSANCE, [***], has the right to discontinue COMPANY's credit on future orders and to put a hold on any production or shipment of Product if COMPANY's [***]. Such hold on production or shipment shall not constitute a breach of this Agreement by RENAISSANCE. In the event credit is discontinued, a [***] material deposit paid by COMPANY to RENAISSANCE will be required prior to RENAISSANCE ordering materials, a [***] Manufacturing Fee deposit will be required prior to RENAISSANCE manufacturing any Product and the balance of the invoice must be paid in full prior to shipment.

2.11 Recordkeeping

RENAISSANCE will prepare, and shall cause its Affiliates or any permitted subcontractors to prepare, in English, records of documents, information, data and materials used or generated under this Agreement in a professional manner so as to permit COMPANY to review such records without disclosing to COMPANY any Third Party confidential or proprietary information. Representatives of COMPANY shall, upon reasonable notice to RENAISSANCE, have access to and shall be permitted to review all such records during the Term and during the applicable retention period thereof. Upon COMPANY's request, RENAISSANCE shall provide to COMPANY a copy of any or all such records.

2.12 Expansion into Secondary Territory

COMPANY will initially be selling Product only in the Primary Territory, but COMPANY may later elect to sell Product in the Secondary Territory. In the event that COMPANY wishes to commence sale of Product in any country of the Secondary Territory, COMPANY [***] provide RENAISSANCE reasonable advance notice that COMPANY wishes to schedule an audit of the Regulatory Authority for that country, and RENAISSANCE will allow and support that audit. Within [***] after receiving the results of that audit, including any additional modifications to its Manufacturing and quality controls that will be required to comply with that audit, RENAISSANCE will advise COMPANY of the costs associated with making the required modifications, which shall be paid for by [***] if the COMPANY elects to proceed with the expansion. [***] agrees to reimburse RENAISSANCE for all of its expenses, at the [***], for all time spent by RENAISSANCE regarding any request by COMPANY to sell Product in any country of the Secondary Territory [***]. Further, regardless of any expansion into a country of the Secondary Territory, COMPANY hereby acknowledges and agrees that RENAISSANCE makes no representations and warranties regarding its compliance with Applicable Law in any jurisdictions other than the Primary Territory and will charge for any future inspections conducted by any Regulatory Authority other than the FDA and the EMA pursuant to Section 5.5.

2.13 Expansion Outside the Territory.

COMPANY hereby acknowledges and agrees that COMPANY may not sell Product outside of the Territory. In the event that COMPANY wishes to expand the Territory beyond its scope on the Effective Date, COMPANY shall provide RENAISSANCE reasonable advance notice that COMPANY wishes to schedule an audit of the Regulatory Authority from that jurisdiction, and RENAISSANCE will allow and support that audit. Within [***] after receiving the results of that audit, including any additional modifications to its Manufacturing and quality controls that will be required to comply with that audit, RENAISSANCE will advise COMPANY whether RENAISSANCE will implement the modifications provided for in the audit report, which RENAISSANCE may determine in its sole discretion. If RENAISSANCE elects to implement such modifications such that the Territory may be expanded, RENAISSANCE shall notify COMPANY of that determination and the costs associated with making the required modifications, which shall be paid for by [***] if COMPANY elects to proceed with the expansion. COMPANY also agrees to reimburse RENAISSANCE for all of its expenses, at the [***], for all time spent by RENAISSANCE regarding any request by COMPANY

to expand the Territory [***]. Further, regardless of any Territory expansion, COMPANY hereby acknowledges and agrees that RENAISSANCE makes no representations and warranties regarding its compliance with Applicable Law in any jurisdictions other the Primary Territory and will charge for any future inspections conducted by any Regulatory Authority other than the FDA and the EMA pursuant to Section 5.5.

III—DELIVERY AND RISK OF LOSS

3.1 Delivery

Delivery of Product shall be in accordance with COMPANY instructions; provided that COMPANY instructions comply with Applicable Law. At COMPANY's request, (a) RENAISSANCE shall hold Product in RENAISSANCE's warehouse for up to [***], and (b) RENAISSANCE may, in its sole discretion, hold such Product for more than [***] provided that (i) RENAISSANCE may [***] in accordance with Schedule D attached hereto; and (ii) [***]. At the time of release, RENAISSANCE shall to the extent applicable provide to COMPANY all reasonably required shipping and import/export documentation.

3.2 Delivery Terms

The delivery terms of Product shall be [***]. Title to, and risk of loss for, Product shall transfer from RENAISSANCE to COMPANY when [***]. [***] shall bear all risk of loss, delay, or damage in transit, as well as cost of freight and insurance.

3.3 Claims

The weights and tares set forth in RENAISSANCE's invoice shall govern unless incorrect. Claims relating to quantity, weight and loss or damage to any Product sold under this Agreement shall be waived by COMPANY unless made within (i) [***] of receipt of Product by COMPANY or its designee with respect to Product designated for commercial sale in the E.U. and the Other Countries, and (ii) [***] of receipt of Product by COMPANY with respect to all other Product.

4.1 Term

The initial term of this Agreement shall commence on the Effective Date hereof and will continue (a) for Product designated for commercial sale in in the U.S. until the earlier of the fifth (5th) anniversary of the (i) Target U.S. Launch Date and (ii) the initial U.S. Launch Date (the "U.S. Initial Term"), and (b) for Product designated for commercial sale in the E.U. and the Other Countries, the earlier of the fifth (5th) anniversary of (i) the Target E.U. Launch Date and (ii) the initial E.U. Launch Date (the "E.U. and Other Country Initial Term" and with the U.S. Initial Term, each an "Initial Term"); in each case, unless sooner terminated pursuant to Section 4.2. Thereafter, each of the U.S. Initial Term and the E.U. and Other Country Initial Term shall automatically renew for periods of twenty-four (24) months (each a "U.S. Renewal Term" and an "E.U. and Other Country Renewal Term" respectively and each a "Renewal Term" and collectively with each Initial Term, the "U.S. and Term and "E.U. and Other Country Term" and collectively, the "Term"), unless either party shall give notice to the other to the contrary not later than twenty-four (24) months prior to the expiration of the Initial Term or the then-current Renewal Term. For clarity, each of the U.S. Term and the E.U. and Other Country Term may be independently or collectively renewed pursuant to this Section 4.1.

4.2 Early Termination

This Agreement may be terminated at any time upon the occurrence of any of the following events:

- (a) Either party shall have the right to terminate this Agreement upon written notice, if the other party commits a material breach or material default in the performance or observance of any of its obligations under this Agreement and such material breach or material default is not cured within [***] after receipt by such party of written notice from the non-breaching party specifying the material breach or material default. The party allegedly in default may cure the asserted breach or pursue the dispute resolution process specified in Section 12.6 within the notice period.
- (b) If either party applies for or consents to the appointment of a receiver, trustee or liquidator for all or a substantial part of its assets; admits in writing its inability to pay its debts generally as they mature; makes a general assignment for the benefit of creditors; is adjudicated a bankrupt; submits a petition or an answer seeking an arrangement with creditors; takes advantage of any insolvency law except as a creditor; submits an answer admitting the material allegations of a petition in bankruptcy or insolvency proceeding; has an order, judgment or decree entered by any court of competent jurisdiction approving a petition seeking reorganization of such party or appointing a receiver, trustee or liquidator for such party, or for all or a substantial part of any of its assets and such order, judgment or decree shall continue unstayed and in effect for a period of ninety (90) consecutive days; files a voluntary petition of bankruptcy or fails to remove an involuntary petition in bankruptcy filed against it within ninety (90) days of the filing thereof, the other party may terminate this Agreement immediately upon providing written notice to the first party.

- (c) This Agreement may be terminated by either party on a Product-by-Product basis on immediate notice if the manufacture, distribution or sale of any of Product in the Territory would materially contravene any Applicable Law; provided, however, no termination shall occur if the manufacture, distribution or sale of such the Product can be brought into compliance with such Applicable Law within ninety (90) days following the notice of non-compliance or violation.
- (d) Either party shall have the right to terminate this Agreement in the U.S. upon ten (10) days' prior written notice to the other party upon the occurrence of a U.S. Termination Event. If, at the time of such U.S. Termination Event, COMPANY has obtained a marketing authorization in the E.U., then the parties will negotiate in good faith for a thirty (30) day period following such U.S. Termination Event to restructure the commercial terms of this Agreement for it to apply only to the E.U. and the Other Counties (or any sub-set thereof); provided further that if the parties cannot agree on such restructured terms (or if COMPANY has not then obtained a marketing authorization in the E.U.) then this Agreement will terminate as to the entire Territory.
- (e) Either party may terminate this Agreement in the case of a Force Majeure Event pursuant to the terms and conditions set forth in Section 12.4.
- (f) Further to this Section 4.2, a violation by either party of a trade control law and/or an anti-corruption law, including the U.S. Foreign Corrupt Practices Act, shall be grounds for immediate termination of this Agreement by the non-offending party upon written notice given to the offending party.

4.3 Effects of Termination

In the event of any expiration or termination of this Agreement, (a) COMPANY shall reimburse RENAISSANCE for: [***] and other amounts set forth in Schedule B and (b) RENAISSANCE shall promptly deliver to COMPANY all COMPANY Material and [***].

4.4 Survival

Any expiration or termination of this Agreement shall not relieve either party of any obligation accruing prior to such termination or expiration. Sections [***] and Articles [***] (including all of their Sections) shall survive the expiration or termination of this Agreement for any reason.

V—CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE

5.1 Quality and Safety Data Exchange Agreement

Not less than [***] before the [***], the parties shall enter into a mutually agreeable Quality Agreement (the “Quality Agreement”), in accordance with RENAISSANCE’ SOP’s and in conformity with any Regulatory Authority requirements and Applicable Law setting forth the parties’ obligations with regard to quality matters and Product complaints and adverse drug experiences. Until a Quality Agreement is entered into between the parties, this Agreement, in conjunction with all applicable Regulatory Authority requirements and Applicable Law, shall govern the parties’ responsibilities with respect to procedures impacting the identity, strength, quality, purity and all other aspects of the Product.

5.2 Batch Documentation

In accordance with Applicable Law and the Quality Agreement, RENAISSANCE shall [***]. COMPANY hereby acknowledges and agrees that reporting or documentation not expressly required under this Agreement may be subject to additional, reasonable charge by RENAISSANCE.

5.3 Stability Testing and Retention Samples

RENAISSANCE shall perform stability testing in accordance with RENAISSANCE’s SOPs, or as separately agreed to in accordance with this Agreement, the Quality Agreement, or a CCR, for each Batch. During each year during the Term, RENAISSANCE will provide to COMPANY the Annual Product Review for the Batches Manufactured during the applicable review period within

[***] following the closing date of the annual reporting period. If COMPANY elects to perform its own stability testing on Product, COMPANY agrees to provide RENAISSANCE with a copy of the results from such testing on an annual basis. RENAISSANCE shall keep such samples and records in respect of Product as is required by Applicable Law for such period of time as may be required by Applicable Law, subject an agreement on fees for this service to be set forth in the applicable Project Protocol not to exceed [***]. Upon the termination of this Agreement, at the sole discretion of COMPANY, RENAISSANCE shall, either dispose of such samples and records or ship such samples and records to COMPANY, at COMPANY's written request [***].

5.4 Validation Work or Additional Testing

It is understood by the parties that the responsibility for any validation work relating the activities hereunder shall be the sole responsibility of COMPANY. If COMPANY desires for RENAISSANCE to conduct any validation work or additional testing in connection with the Product, RENAISSANCE and COMPANY shall enter into a specific written Project Protocol establishing methodology and pricing for such services, not to exceed [***]. It is understood between the parties that if RENAISSANCE is required by any Regulatory Authority to perform validation studies or additional testing in order to continue Manufacturing Product in accordance with Applicable Law, and RENAISSANCE and COMPANY cannot reach an agreement on a written Project Protocol, then RENAISSANCE shall be under no obligation to continue to Manufacture the affected Product.

5.5 Regulatory Inspection

RENAISSANCE will permit any Regulatory Authority to conduct inspections of the Facility as such Regulatory Authority may request, [***], and will cooperate with Regulatory Authorities with respect to the inspections and any related matters, in each case that is related to each Product hereunder. RENAISSANCE will give COMPANY prior notice, to the extent practicable, of any such inspections and will permit COMPANY (and/or its Representatives) to assist in the preparation for such inspections. RENAISSANCE will coordinate with COMPANY where practicable to enable COMPANY to be [***] the Facility while the inspection is being conducted. In addition, COMPANY may be present at the inspection (i) if the Regulatory Authority conducting the inspection requests in writing that COMPANY be present at the inspection or (ii) to respond to any specific question or issue agreed to in advance by the respective quality teams if such specific question or issue is raised by the Regulatory Authority during the inspection. In

addition, RENAISSANCE shall as soon as practicable (and in any event within [***] following receipt of notice thereof) advise COMPANY if the Regulatory Authority requests or requires information or changes regarding or impacting any Product or if RENAISSANCE receives any correspondence from the Regulatory Authority regarding or impacting any Product or that would materially affect RENAISSANCE's ability to meet its obligations under this Agreement and provide COMPANY copies of such correspondence, redacted as necessary to protect Third-Party confidential information. In addition, COMPANY shall promptly inform RENAISSANCE of any correspondence from the applicable Regulatory Authority regarding any Product that would materially affect COMPANY's or RENAISSANCE's ability to meet its obligations under this Agreement and provide RENAISSANCE copies of such correspondence, redacted as necessary to protect Third-Party confidential information. Each party shall notify the other promptly of any materially adverse inspections by the Regulatory Authorities which pertain to the Product or to the Facility, or any occurrences or information that arise out of any activities that have or could reasonably be expected to have adverse regulatory compliance or reporting consequences concerning any Product or which might otherwise be reasonably expected to adversely affect the supply by RENAISSANCE of Product to COMPANY. Each party will provide to the other party upon request all information reasonably necessary to enable the requesting party to respond to any request of a Regulatory Authority regarding any Product under this Agreement. RENAISSANCE will discuss with COMPANY any Regulatory Authority correspondence regarding or impacting any Product or that would materially affect RENAISSANCE's ability to meet its obligations under this Agreement and will consider in good faith incorporating any COMPANY comments into its responses to such correspondence.

5.6 Regulatory Filings

COMPANY shall bear sole responsibility for all Regulatory Approvals, Regulatory Filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies necessary to sell and distribute any Product in the Territory. COMPANY further warrants that, except for any approvals, permits or authorizations with respect to the Facility or the operation of the business of RENAISSANCE, its Affiliates and their respective subcontractors, COMPANY has obtained or will obtain prior to the first Launch Date any and all necessary approvals from all applicable Regulatory Authorities necessary to Manufacture and distribute any Product under this Agreement.

Upon RENAISSANCE's reasonable request, COMPANY agrees to provide RENAISSANCE with copies of any sections of NDA's, ANDA's, 510(k)'s or other Regulatory Filings and Regulatory Authority correspondence applicable to Product Manufactured by RENAISSANCE, and copies of any changes in or updates of same, in each case, to the extent necessary or reasonably useful for RENAISSANCE to perform its obligations hereunder. Upon COMPANY's request and at COMPANY's expense, RENAISSANCE will promptly provide COMPANY with information and data in RENAISSANCE's possession or control that is necessary for obtaining or maintaining Regulatory Approval for each Product in the Territory, including information relating to the Facility. RENAISSANCE will cooperate with COMPANY's Representatives with respect to its obligations to submit or report information to the Regulatory Authority for any Product pursuant to Applicable Law.

5.7 Access to RENAISSANCE’s Facilities

During the Term and through the valid shelf life of the last shipment of Product, COMPANY shall have the right, subject to the confidentiality obligations contained in this Agreement and providing RENAISSANCE with reasonable prior notification, to access the Facility during normal business hours, for the [***] purpose of auditing RENAISSANCE’s compliance with Applicable Law. Furthermore, such audits shall be limited in frequency to [***] (unless for cause) for [***] maximum of [***] COMPANY Representatives all of whom shall be subject to the confidentiality obligations not less restrictive than those set forth in this Agreement. COMPANY shall be responsible for its own costs in connection with the audit or inspection permitted under this Section 5.7. In addition, RENAISSANCE will permit COMPANY Representatives [***] to visit the Facility or participate virtually [***] in order to participate in [***] quality and business reviews (each a “QBR”) for the purpose of reviewing and evaluating metrics, data and other information related to Product quality during the prior quarter. [***].

VI – REPRESENTATIONS AND WARRANTIES

6.1 RENAISSANCE Product Warranty

RENAISSANCE represents and warrants that all Product Manufactured and supplied pursuant to this Agreement will (i) have been [***], and (ii) be free and clear from any security interest, lien or other encumbrance (the “RENNAISSANCE Product Warranty”).

6.2 No Debarment; RENAISSANCE Permits; User Fees

RENAISSANCE represents and warrants that neither it, its Affiliates nor any of their Representatives that are performing any activities under this Agreement has been debarred under Article 306 of the Act, 21 U.S.C. §335a(a) or (b) its successor provisions, or any equivalent foreign or local law, rule or regulation, and neither appears on the United States Food and Drug debarment list. RENAISSANCE represents and warrants that neither it, its Affiliates nor any of their Representatives that are performing any activities under this Agreement has committed any crime or conduct that could result in such debarment or exclusion from any governmental healthcare program. RENAISSANCE represents and warrants that, [***], no investigations, claims or proceedings with respect to any such crimes or conduct are pending or threatened against it, its Affiliates or any of their Representatives that are performing any activities under this Agreement. In addition, RENAISSANCE covenants that it will not [***] any person if, [***], such a person (i) is under investigation by the FDA for debarment or is presently debarred by the FDA Article 306 of the Act, 21 U.S.C. §335a(a) or (b) or its successor provisions, or any equivalent foreign or local law, rule or regulation, or (ii) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions. RENAISSANCE agrees and undertakes to promptly notify COMPANY if it, its Affiliates or any of their Representatives that are performing any activities under this Agreement becomes debarred or proceedings have been initiated against either of them with respect to debarment, whether such debarment or initiation of proceedings occurs during or after the Term.

RENAISSANCE shall obtain and maintain all permits and licenses (including but not limited to all appropriate DEA licenses) with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which RENAISSANCE Manufactures Product. As between the parties, COMPANY shall be responsible for all other Regulatory Approvals, Regulatory Filings, and necessary approvals from all applicable Regulatory Authorities necessary to Manufacture and distribute all Product supplied to it under this Agreement.

Each party agrees that any user fees or the equivalent thereof under Applicable Law currently in effect or future enactments thereof associated with any intended Regulatory Filing or Regulatory Approval in the Territory shall, as between the parties, be the [***]. COMPANY shall comply with the Prescription Drug User Fee Act (Public Law 112-144, Title I) (“PDUFA”) and [***] with RENAISSANCE and [***] RENAISSANCE in complying with PDUFA.

6.3 Conformity with Applicable Law; COMPANY-Furnished Equipment

RENAISSANCE represents and warrants that [***].

6.4 Compliance of Packaging and Labeling with Applicable Law

COMPANY warrants that all Labeling copy and artwork approved, designated or supplied by COMPANY shall be in compliance with Applicable Law. Compliance with Applicable Law concerning Packaging and Labeling shall be [***]; provided that [***] such Packaging and Labeling as provided in Section 2.2(c).

6.5 Mutual Warranties

Each party hereby represents and warrants to the other party that (a) it is duly organized and validly existing under the laws of the jurisdiction of its organization and has full corporate or limited liability company power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder; (c) this Agreement is legally binding upon it and enforceable in accordance with its terms and conditions; and (d) the execution, delivery and performance of this Agreement by it do not conflict with any agreement, instrument or understanding, oral or written, to which it is a party, or to which it is bound, and it shall not enter into any agreement, instrument or understanding, oral or written, that conflicts with its rights and obligations under this Agreement.

6.6 No Additional Warranties

RENAISSANCE AND COMPANY MAKE NO REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, PRODUCT LABELING OR PACKAGING, EXCEPT AS EXPRESSLY DETAILED IN THIS AGREEMENT. ALL OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR FOR NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHT, ARE HEREBY DISCLAIMED.

VII – INTELLECTUAL PROPERTY

7.1 Background Intellectual Property

Each party shall own and retain all intellectual property rights (a) owned or controlled by such party prior to the Effective Date, or (b) developed or acquired by or on behalf of such party outside of this Agreement (“Background IP”).

7.2 Inventions

- (a) RENAISSANCE shall own all data, work product, results, reports, inventions, improvements, developments, technologies and information, and all intellectual property rights in any of the foregoing, that are developed, conceived, invented, or first reduced to practice by or on behalf of RENAISSANCE or its Affiliates in the performance of activities under this Agreement (“Inventions”), that (i) are [***] applicable to manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products and devices, and (ii) are not [***] any COMPANY Background IP, COMPANY Confidential Information, COMPANY Materials or any Product (“RENAISSANCE Inventions”). [***].
- (b) COMPANY will own all Inventions other than RENAISSANCE Inventions (collectively, “COMPANY Inventions”). RENAISSANCE hereby assigns to COMPANY all of its right, title and interest in and to any COMPANY Inventions. RENAISSANCE agrees to, and shall cause its Affiliates and their Representatives to, execute such documents and take such other actions as COMPANY may reasonably request to evidence and perfect the foregoing assignment and COMPANY’s rights in and to the COMPANY Inventions.

7.3 License Grants

- (a) COMPANY hereby grants to RENAISSANCE a limited, royalty-free, non-exclusive license under COMPANY Background IP and COMPANY Inventions solely to perform its obligations under this Agreement.
- (b) RENAISSANCE hereby grants to COMPANY an irrevocable, perpetual, fully paid-up, non-exclusive license under RENAISSANCE Background IP and RENAISSANCE Inventions to the extent necessary to make, use, sell and otherwise exploit any Product.

7.4 No Implied Licenses

Except as expressly set forth herein, no right or license is granted under this Agreement by either party to the other party, whether by implication, estoppel or otherwise.

7.5 Trademarks and Trade Names

- (a) Each party hereby acknowledges that it does not have, and shall not acquire any interest in any of the other party’s Trademarks, unless otherwise expressly agreed; except however, that COMPANY hereby grants to RENAISSANCE the right to use the Partner Trade Dress for the sole and exclusive purpose of performing its obligations under this Agreement (and hereby represents and warrants to RENAISSANCE that it has the authority to grant such license).

(b) Each party agrees not to use any trade names or trademarks of the other party, except as specifically authorized in writing by the other party in writing, both as to the names or marks which may be used and as to the manner and prominence of use.

7.6 [***]

[***].

VIII – CHANGES TO PROCESS OR PRODUCT

8.1 Changes by the Parties

If either party at any time requests a change to any Product to the other party, the parties shall promptly discuss in good faith the scope and cost adjustments, if any, with respect to such change. If the parties agree to such change, including the scope and cost allocations therefor, (a) such change shall be [***] reviewed and agreed upon in writing by both RENAISSANCE and COMPANY; (b) the parties shall adjust the [***], if necessary, and Schedule B shall be amended accordingly; and (c) [***].

8.2 Changes or Fees by Regulatory Authorities

The parties agree that any changes required by a Regulatory Authority or by Applicable Law shall be incorporated into the Product, subject to the prior written approval of COMPANY, [***], via a CCR prior to such incorporation. Any actual or potential additional Product costs, fees or expenses, [***] shall be the [***]. At the time of such incorporation, such changes shall become part of the Specifications. If RENAISSANCE is required by Regulatory Authority to perform validation studies for purposes of validating new manufacturing process or cleaning procedures or new material and finished Product assay procedures with respect to Product in order to continue to engage in the Manufacture of said Product for COMPANY, such studies shall be conducted in accordance with Section 5.4. Any costs to RENAISSANCE resulting from the operation of this Section 8.2 shall be [***] and subject to the terms and conditions set forth in Section 2.9.

8.3 Obsolete Inventory and Raw Material

Any inventory procured or developed by RENAISSANCE specifically for the Manufacture of Product, [***] at the [***]. At such time and as instructed by COMPANY, RENAISSANCE will either destroy such obsolete

inventory or raw materials or ship such obsolete inventory or raw materials to COMPANY. [***] shall bear [***] of all shipping and destruction costs related to such obsolete inventory or raw materials. Any such destruction shall be in accordance with Applicable Law, and each party shall also provide the other party with all manifests and other applicable evidence of proper destruction as may be requested by the other party or required by Applicable Law. If RENAISSANCE does not receive disposition instructions from COMPANY within [***] from date of notification, obsolete inventory [***] shall be subject to [***] or destruction at RENAISSANCE's discretion.

IX—CONFIDENTIAL INFORMATION

9.1 Confidential Information

(a) Definition of Confidential Information

“Confidential Information” means any information provided by or on behalf of a party (the “Disclosing Party”) to the other party (the “Receiving Party”), its Affiliates or their Representatives under the Mutual Confidentiality Agreement between the parties entered into on January 12, 2017 (the “Prior CDA”), the R&D Agreement or this Agreement, whether prior to, on, or after the Effective Date. In addition, (a) all RENAISSANCE Background IP and RENAISSANCE Inventions shall be deemed to be the Confidential Information of RENAISSANCE; (b) all COMPANY Background IP and COMPANY Inventions shall be deemed to be the Confidential Information of COMPANY and (c) the terms of this Agreement and all communications between the parties and their Affiliates relating to the subject matters of this Agreement shall be deemed to be Confidential Information of both parties.

(b) Obligations of Confidentiality

During the Term and for [***] thereafter, Receiving Party shall (a) not disclose Disclosing Party's Confidential Information to any Person except as to the Representatives of Receiving Party and its Affiliates, who need to know such Confidential Information in order to perform, or assist Receiving Party in the performance of, its obligations under this Agreement (collectively, "Permitted Recipients"), provided that any such Permitted Recipient is subject to confidentiality obligations not less restrictive than those set forth in this Article IX; (b) not disclose Disclosing Party's Confidential Information for any purpose other than the purpose of exercising or performing, or assisting in the exercise or performance of, a party's rights or obligations under this Agreement; and (c) take, and shall cause the Permitted Recipients to whom it discloses Disclosing Party's Confidential Information to take, at least such precautions as it normally takes with its own confidential and proprietary information to prevent unauthorized disclosure of Disclosing Party's Confidential Information, but in no event less than reasonable precautions. Receiving Party shall be responsible for any breach of this Article IX by any of its Affiliates or Permitted Recipients, and shall promptly notify Disclosing Party of any breaches of this Article IX.

(c) Exceptions

Any other provisions hereof to the contrary notwithstanding, it is expressly understood and agreed by the parties hereto that the obligations of confidence and non-use herein assumed shall not apply to any information which Receiving Party can demonstrate with competent written evidence:

- (a) is at the time of disclosure, or thereafter so becomes, a part of the public domain (other than as a result of, directly or indirectly, any breach of confidentiality or other act or omission by Receiving Party or its Permitted Recipients); or
- (b) was otherwise in Receiving Party's lawful possession prior to disclosure as shown by its contemporaneous written record (provided that this exception shall not apply to any COMPANY Inventions generated by or on behalf of RENAISSANCE hereunder); or
- (c) is hereafter disclosed to Receiving Party without any obligations of confidentiality by a Third Party that is not in violation of an obligation of confidentiality relative to said information; or
- (d) is independently developed by or on behalf of Receiving Party without any use of or reference to any Confidential Information of Disclosing Party or breach of this Agreement; or
- (e) is by mutual agreement of the parties released from a confidential status.

(d) Authorized Disclosure

Notwithstanding the foregoing, Receiving Party may make disclosures of Disclosing Party's Confidential Information in the following instances:

(a) to comply with Applicable Law or as required by an order of a governmental agency, legislative body or court of competent jurisdiction, provided that Receiving Party: (i) provides Disclosing Party with prompt written notice of such requirement, (ii) cooperates with Disclosing Party at Disclosing Party's expense in connection with Disclosing Party's reasonable and lawful actions to obtain confidential treatment for such Confidential Information, and (iii) limits such disclosure of Confidential Information to the fullest extent permitted under applicable law. Any Confidential Information that is disclosed pursuant to this paragraph shall remain confidential for all other purposes;

(b) in Regulatory Filings, including filings, applications and submissions to Regulatory Authorities;

(c) disclosure to Receiving Party's Affiliates, to actual or potential (sub)licensees, or collaborators, and to Receiving Party's and its Affiliates' Representatives who have a need to know such information in order for Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential (sub)licensee, collaborator, or Representative is bound by similar terms of confidentiality and non-use as set forth in this Article IX, and such Receiving Party shall be liable for any breach thereof by such Affiliates, actual or potential (sub)licensees, collaborators, or Representatives; and

(d) disclosure to any Third Party in connection with due diligence or similar investigations by such Third Party, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party needs to know such Confidential Information and is bound by reasonable obligations of confidentiality and non-use and such Receiving Party shall be liable for any breach thereof by such Third Party.

(e) Return of Confidential Information

Upon the written request of Disclosing Party, Receiving Party will promptly return the Confidential Information of Disclosing Party to Disclosing Party or, if Disclosing Party directs, destroy all Confidential Information of Disclosing Party disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for Receiving Party (i) may retain one (1) copy which may be maintained by Receiving Party for its legal files for compliance and regulatory purposes, and (ii) need not destroy electronic archives and backups made in the ordinary course of business where it would be commercially impracticable to do so including information included in minutes of the board of directors and committees thereof, subject in either case to its obligations of confidentiality herein.

9.2 Publicity

Except as permitted in this Article IX, neither party shall issue any press release or other public statement disclosing the existence of or relating to this Agreement without the prior written consent of the other party, which consent shall not be unreasonably withheld, conditioned or delayed. However, COMPANY shall have sole discretion over the issuance of any press release or public statement regarding the commercial launch of the Product, so long as RENAISSANCE is not named in such release or statement.

9.3 Security Filings

The parties acknowledge that either or both parties or their Affiliates may be obligated to file under applicable law a copy of this Agreement with governmental authorities, including, the U.S. Securities and Exchange Commission. Each party and its Affiliates shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available. In the event of any such filing, such party will provide the other party with a copy of this Agreement marked to show provisions for which such party or its Affiliate intends to seek confidential treatment and shall reasonably consider and incorporate the other party's timely comments thereon to the extent consistent with the legal requirements, with respect to the filing party or Affiliate, governing disclosure of material agreements and material information that must be publicly filed.

9.4 Injunctive Relief

Each party hereby acknowledges the unique and proprietary nature of the other party's Confidential Information and agrees that damages at law may be an inadequate remedy for any breach of Receiving Party's obligations under this Agreement, and that Disclosing Party may suffer great and irreparable injury as a consequence of such breach. Accordingly, Receiving Party agrees that Disclosing Party will be entitled to seek such temporary, preliminary and permanent injunctive relief as may be necessary to remedy or limit such breach, including specific performance of such obligations and an order enjoining Receiving Party from the continuation of, or from any threatened, breach of such obligations. The rights set forth in this Section 9.4 shall be in addition to, and not in lieu of, any other rights which Disclosing Party may have at law or in equity.

10.1 Additional Development

From time to time, COMPANY may request, in writing, that RENAISSANCE [***] (collectively, “Additional Development”) on behalf of COMPANY. If RENAISSANCE

agrees to perform such Additional Development, RENAISSANCE shall so notify COMPANY within [***] of its receipt of COMPANY’s request. To the extent that RENAISSANCE agrees to perform any Additional Development hereunder for COMPANY, RENAISSANCE shall only be obligated to act in good faith and to use reasonable efforts to accomplish the desired results as outlined in a mutually agreed upon Project Protocol issued under this Agreement. Nothing herein shall obligate RENAISSANCE to achieve any specific results with respect to Additional Development and RENAISSANCE makes no warranties or representations with respect thereto or that it will be able to achieve the desired results.

10.2 Project Protocol

Should RENAISSANCE agree to perform any Additional Development, RENAISSANCE shall submit a written development proposal in the form of a Project Protocol to COMPANY identifying RENAISSANCE’s best estimate of the costs for such Additional Development. This estimate shall include [***]. If this estimate is acceptable to COMPANY, and COMPANY so notifies RENAISSANCE by approving the Project Protocol in writing, RENAISSANCE shall begin working on the Additional Development as outlined in the Project Protocol. It is understood between the parties that during any development project unforeseen circumstances may evolve, including termination of any further activity due to unacceptable results, significant reevaluation due to marginal results, etc. RENAISSANCE will promptly notify COMPANY of any such unforeseen circumstances before proceeding at which time either COMPANY or RENAISSANCE may terminate the Additional Development project or mutually agree to amend or completely revise the Project Protocol. In the case where the Additional Development project is terminated or revised, COMPANY will be obligated to pay for [***].

10.3 Costs

Material costs involved will be billed to COMPANY at RENAISSANCE’s [***]. The foregoing development costs shall be paid to RENAISSANCE regardless of whether RENAISSANCE is able to accomplish the results which COMPANY requested. All invoices shall be paid by COMPANY in accordance with Section 2.9.

XI - INDEMNIFICATION

11.1 Indemnification by RENAISSANCE

RENAISSANCE shall indemnify, defend and hold harmless, COMPANY, its Affiliates and their respective directors, officers, employees and agents from and against any and all liabilities, damages, claims, demands, losses, costs, or expenses (including reasonable out-of-pocket attorney's fees) resulting from any Third Party claims made or suits brought against COMPANY, its Affiliates or their respective directors, officers, employees and agents, which arise from RENAISSANCE's (a) [***], (b) violation of [***], or (c) [***]. Notwithstanding the foregoing, RENAISSANCE's obligations under this Section 11.1 shall not apply to the extent that any such liabilities are the result of COMPANY's [***], violation of [***] or [***].

11.2 Insurance by RENAISSANCE

Until the later of (a) the termination or expiration of this Agreement, or (b) the date when the shelf life of all Product Manufactured has expired, RENAISSANCE shall maintain in full force and effect the following insurance: Product Liability coverage in the minimum amount of [***] per occurrence with an annual aggregate amount of [***]; Workers Compensation coverage in accordance with all applicable statutory requirements, and Employers Liability coverage of [***] per accident/disease/injury; General Liability coverage, including Contractual Liability coverage, with limits of [***] per occurrence and [***] in the annual aggregate. The limits required may be satisfied through a combination of both primary and excess casualty programs. RENAISSANCE shall provide to COMPANY evidence of the foregoing insurance upon COMPANY's request, which evidence may be in the form of an original policy or a certificate of insurance issued by the insurance broker.

11.3 Indemnification by COMPANY

COMPANY shall indemnify, defend, and hold harmless, RENAISSANCE and its Affiliates and their respective directors, officers, employees and agents from and against any and all liabilities, damages, claims, demands, losses, costs or expenses (including reasonable out-of-pocket attorney's fees) resulting from any Third Party claims made or suits brought against RENAISSANCE, its Affiliates or their respective directors, officers, employees and agents, which arise from COMPANY's (a) sale, promotion, marketing, distribution or use of any Product delivered by RENAISSANCE to COMPANY under this Agreement, including product liability, strict liability or infringement with the intellectual property rights of any Third Party, (b) gross negligence or willful misconduct, (c) violation of Applicable Law, or (d) breach of this Agreement. Notwithstanding the foregoing, COMPANY's obligations under this Section 11.3 shall not apply to the extent that any such liabilities are the result of RENAISSANCE's gross negligence, willful misconduct, violation of Applicable Law or breach of this Agreement.

11.4 Insurance by COMPANY

Until the later of (a) the termination or expiration of this Agreement, or (b) the date when the shelf life of all Product Manufactured has expired, COMPANY shall maintain in full force and effect: Commercial General Liability insurance covering bodily injury and property damage, premises liability and personal/advertising injury in an amount not less than [***] per occurrence with an annual aggregate amount of not less than [***]; Product Liability coverage and Contractual Liability coverage in an amount not less than [***] per occurrence with an annual aggregate amount of not less than [***]. Such evidence of insurance coverage can be in the form of the original policy or a Certificate of Insurance. Upon RENAISSANCE's request, COMPANY shall provide evidence of the foregoing insurance coverage to:

[***]

11.5 Disclaimer

EXCEPT WITH RESPECT TO EACH PARTY'S [***] (THE "EXTRAORDINARY MATTERS"), NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY [***] OF ANY KIND, [***], INCLUDING ANY [***] OR [***], IN CONNECTION WITH OR ARISING OUT OF THE PERFORMANCE OF THIS AGREEMENT, WHETHER ALLEGED AS A BREACH OF CONTRACT OR TORTIOUS CONDUCT, INCLUDING NEGLIGENCE, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ADDITION, WITH RESPECT TO ALL CLAIMS MADE BY COMPANY AGAINST RENAISSANCE UNDER THIS AGREEMENT, (I) WITH RESPECT TO THE [***], THE TOTAL LIABILITY OF [***] TO [***] SHALL NOT EXCEED [***] AND (II) WITH RESPECT TO ALL OTHER MATTERS, SHALL NOT EXCEED [***].

11.6 Conditions of Indemnification

If either party seeks indemnification from the other party under Sections 11.1 or 11.3 hereof, it (a) shall promptly give notice to the other party of any such claim or suit threatened, made or filed against it which forms the basis for such claim of indemnification, provided that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure, (b) shall permit the indemnifying party to control the defense or settlement of such claim or suit, and (c) shall cooperate fully with the indemnifying party in the defense of all such claims or suits. No settlement or compromise shall be binding on a party hereto without its prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed. The indemnified party shall have the right to join, but not control, at its own expense and with counsel of its choice, the defense of any claim or suit that has been assumed by the indemnifying party.

XII - GENERAL PROVISIONS

12.1 Notices

Any notice, request or other document to be given hereunder to any party shall be in writing and delivered personally, sent by certified mail, postage prepaid, by email transmission with confirmation of receipt, or sent by a commercially recognized overnight courier, provided a receipt is required,

If to RENAISSANCE:

Renaissance Lakewood, LLC

With a copy to:

Renaissance Lakewood, LLC.

If to COMPANY:

ARS Pharmaceuticals Inc.
Attn: Richard Lowenthal, MSc MBA,
CEO and President
Email:
With Copy to:

Any notice, if sent properly addressed, postage prepaid, shall be deemed made [***] after the date of mailing as indicated on the registered mail receipt, or [***] after the date of entrusting to express courier service or on the date of delivery or transmission (if delivered or sent during ordinary business hours, otherwise on the next business day) if hand-delivered or sent by email transmission.

12.2 Entire Agreement; Amendment

The parties hereto acknowledge that this Agreement, together with the Quality Agreement and including all Schedules to this Agreement, sets forth the entire agreement and understanding of the parties and supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof, including the Prior CDA, and shall supersede any conflicting portions of RENAISSANCE's quotation, acknowledgment and invoice forms and COMPANY's purchase order and other written forms. For clarity, the parties agree that the R&D Agreement shall continue in full force and effect in accordance with its terms. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by the party against whom enforcement is sought. To the extent that the obligations of RENAISSANCE contained in this Agreement conflict with the Quality Agreement, the Quality Agreement will prevail with respect to quality control documents and procedures only; otherwise, the obligations contained in this Agreement will govern and control, including with respect to all financial obligations and financial exposures of the parties.

12.3 Waiver

No waiver by either party of any default shall be effective unless in writing, nor shall any such waiver operate as a waiver of any other default or of the same default on a future occasion.

12.4 Force Majeure

Each party shall be excused from the performance of its obligations hereunder in the event performance of this Agreement is prevented by Force Majeure and such excuse shall continue as long as the condition constituting such Force Majeure continues; provided that the affected party shall promptly notify the non-affected of the Force Majeure condition and shall exert Commercially Reasonable Efforts to eliminate, cure or overcome any such causes; and further provided that the affected party shall continue to perform to the extent feasible in view of such Force Majeure event. If such Force Majeure event shall continue for a period of six (6) months or more, then the non-affected party shall have the right to terminate this Agreement upon written notice to the affected party.

12.5 Assignment

This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the parties and may not be assigned or transferred by either party without the prior written consent of the other; provided however, that a party may assign this Agreement or any part hereof to one of its Affiliates, or in connection with a merger, reorganization, consolidation, change in control, or sale of the assets of the business to which this Agreement relates, without the other party's consent. No such assignment shall release the original party hereto from its duties and obligations under this Agreement and any purported assignment, transfer, or attempt to assign or transfer any interest or right hereunder by any party, except in compliance with this Section 12.5, shall be null, void and of no effect.

12.6 Governing Law, Waiver of Trial by Jury and Consent to Jurisdiction

- (a) THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF DELAWARE, APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO THE CONFLICTS OF LAW PRINCIPLES OF SUCH STATE.
- (b) Any dispute arising between the parties in connection with this Agreement shall first be presented to the respective senior executives of the parties for their consideration and resolution. If the parties' executives cannot resolve such dispute within [***], then either party may commence an action, suit or proceeding in the Delaware Chancery Court, or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in any other state court in the State of Delaware or in the United States District Court for the District of Delaware.
- (c) Each party hereby waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement or any transaction contemplated hereby. Each party (i) certifies that no representative, agent or attorney of any other party has represented, expressly or otherwise, that such other party would not, in the event of litigation, seek to enforce the foregoing waiver and (ii) acknowledges that it and the other party have been induced to enter into this Agreement by, among other things, the mutual waivers and certifications in this Section 12.6.

- (d) Each of party irrevocably submits to the exclusive jurisdiction of the Delaware Chancery Court, any other state court in the State of Delaware, and the United States District Court for the District of Delaware, and any appellate court thereof, for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby, and each party irrevocably and unconditionally agrees that all claims in respect of any such suit, action or other proceeding may be heard and determined in such courts. Each of party further agrees that service of any process, summons, notice or document by U.S. registered mail to such party's respective address set forth in Section 12.1 shall be effective service of process for any action, suit or proceeding in Delaware with respect to any matters to which it has submitted to jurisdiction in this Section 12.6. Each party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in any court referred to in Section 12.6(b) and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

12.7 Severability

If any term or provision of this Agreement is invalid, illegal or incapable of being enforced by any applicable law or public policy, all other terms or provisions of this Agreement shall nonetheless remain in full force and effect so long as the economic and legal substance of the transactions contemplated by this Agreement are not affected in any manner materially adverse to any party. Upon such determination that any term or other provision of this Agreement is invalid, illegal or incapable of being enforced, the parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated by this Agreement are consummated as originally contemplated to the fullest extent possible.

12.8 Licenses and Permits

Each party shall, at its sole cost and expense, maintain in full force and affect all necessary licenses, permits, and other authorizations required by Applicable Law in order to carry out its duties and obligations hereunder.

12.9 Delegation to Affiliates

Each party shall have a right to delegate certain of its obligations under this Agreement to its Affiliates, provided that such party shall remain fully responsible for any such obligations so delegated. Any breach of any of such party's obligations (including representations and warranties) under this Agreement by such Affiliate shall be deemed a breach by the delegating party, and the other party may proceed directly against the delegating party without any obligation to first proceed against such Affiliate.

12.10 Headings, Interpretation

The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. The word “or” when used in this Agreement is not exclusive and shall be deemed to include the word “and” (e.g., “and/or”). The word “extent” in the phrase “to the extent” shall mean the degree to which a subject or other thing extends, and such phrase shall not mean simply “if”. All terms defined in this Agreement shall have their defined meanings when used in any certificate or other document made or delivered pursuant hereto, unless otherwise defined therein. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth therein), (ii) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (iii) all references herein to Articles, Sections or Schedules shall be construed to refer to Articles, Sections or Schedules of this Agreement and (iv) the headings contained in this Agreement or any Schedule and in the table of contents to this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. Any capitalized terms used in any Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement. In the event of an ambiguity or a question of intent or interpretation, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

12.11 Counterparts

This Agreement may be executed in one or more counterparts, all of which, when taken together, shall be considered one and the same agreement, and shall become effective when one or more such counterparts have been signed by each of the parties and delivered to the other party. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means shall be effective as delivery of a manually executed counterpart of this Agreement.

12.12 Independent Contractor

In performing its obligations hereunder, RENAISSANCE shall act as an independent contractor. The parties agree that no joint venture, partnership, employment, or agency relationship exists as a result of the negotiation and execution of this Agreement and that neither party is granted any right or authority hereunder to assume or create any obligation, express or implied, or to make any representation, warranties or guarantees, except as are expressly granted or made in this Agreement

12.13 Export/Import Laws and Regulations

This Agreement is subject to any restrictions concerning the import or export of Product, API, chemical or Packaging components (or related technical information or data) to or from the United States as well as the laws and regulations of any other country involved in the import or export of such Product, API, chemical or Packaging components (or related technical information or data). COMPANY acknowledges that it shall be solely and exclusively responsible for the preparation of all import and export documentation and compliance with all import and export laws of the United States as well as the laws and regulations of any other country involved in the import or export of such Product, API, chemical or Packaging components (or related technical information or data); except as otherwise agreed by the parties in writing. COMPANY shall not take any action to identify or otherwise name RENAISSANCE as the importer or exporter of record for any of the aforementioned items. COMPANY shall cooperate with RENAISSANCE as reasonably necessary to permit RENAISSANCE to comply with the laws and regulations of the United States and any other country relating to the control of import or export of Product, API, chemical or Packaging components (or related technical information or data).

[Remainder of page intentionally left blank; signature page follows.]

IN WITNESS WHEREOF, the parties hereto have each caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

ARS PHARMACEUTICALS, INC.

RENAISSANCE LAKEWOOD, LLC

By: /s/ Richard Lowenthal
Its: CEO and President

By: /s/ Serge Maltais
Its: President and CEO

EFTA
Iceland
Lichtenstein
Norway
Switzerland

Asia
Japan

Other
Albania
Andorra
Bosnia-Herzegovina
Georgia
Monaco
Montenegro

North Macedonia
Ukraine
San Marino
Serbia
Vatican City

CIS
Armenia
Azerbaijan
Belarus
Kazakhstan
Kyrgyzstan
Moldova

Russia
Tajikistan
Uzbekistan

Middle East
Afghanistan
Bahrain
Egypt
Iran
Iraq
Israel

Jordan
Kuwait
Lebanon
Oman
Pakistan
Palestine
Qatar
Saudi Arabia
Syria
Turkey
United Arab
Emirates
Yemen

Africa
Algeria
Benin
Burkina Faso
Burundi
Cameroon
Central African
Rep.
Chad
Congo
Dem. Rep. Congo
Djibouti
Equatorial Guinea
Ivory Coast
Lybia
Madagascar
Mali
Mauritius
Morocco

Niger
Rwanda
Senegal
Seychelles
Togo
Tunisia

ARS PHARMACEUTICALS, INC.
EXECUTIVE EMPLOYMENT AGREEMENT

for

RICHARD E. LOWENTHAL

This Executive Employment Agreement (this “**Agreement**”) is made and entered into effective as of September 14, 2018 (the “**Effective Date**”), by and between Richard E. Lowenthal (“**Executive**”) and ARS Pharmaceuticals, Inc. (the “**Company**”).

1. Employment by the Company.

1.1 Position. Executive shall serve as the Company’s Chief Executive Officer (“**CEO**”) and President, reporting to the Company’s Board of Directors (the “**Board**”). During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts and substantially all of Executive’s business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities all in conformity with the Company’s policies applicable to senior executives and general employment policies. For so long as Executive remains the CEO of the Company, Executive shall serve on the Board, without additional compensation and upon ceasing being CEO of the Company for any reason, Executive shall, if requested by the Board, resign from the Board.

1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of CEO and President and such other duties as are assigned to Executive by the Board. Executive’s primary office location shall be the Company’s office located in San Diego, California, and Executive will travel as reasonably required by the Company for business purposes.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company and applicable California law, except that when the terms of this Agreement differ from or are in conflict with the Company’s general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. Executive shall receive a base salary at the annual rate of \$400,000, less standard payroll deductions and withholdings and payable in accordance with the Company’s regular payroll schedule.

2.2 Incentive Compensation. Subject to Board approval, the Company intends to establish an annual incentive compensation plan as soon as practicable following the execution of this Agreement. Once established, the details of the annual incentive compensation plan, including the applicable terms and conditions of such plan and Executive’s eligibility to participate in such plan, will be provided to Executive.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion.

4. Expenses. The Company shall pay or reimburse Executive, on a monthly basis, for reasonable travel, entertainment, promotional and other expenses incurred by Executive in the performance of his business-related obligations under this Agreement (collectively “**Expenses**”). To be eligible for reimbursement of any Expenses under this Agreement, Executive must submit timely detailed expense reports, receipts or other satisfactory evidence of payment for appropriate review within 30 days of incurring such expense. The Company shall reimburse Executive promptly, but in no event later than thirty (30) days after Executive submits an expense report in accordance with the preceding sentence.

5. Confidential Information Obligations.

5.1 Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement, Executive agrees to continue to abide by the Company’s Employee Confidential Information and Inventions Assignment Agreement (the “**Confidential Information Agreement**”) that he previously executed. In addition, Executive agrees to abide by the Company’s policies and procedures, as may be modified from time to time within the Company’s discretion.

5.2 Third-Party Agreements and Information. Executive represents and warrants that Executive’s employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive’s duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive’s employment by the Company, except as expressly authorized by that third party. During Executive’s employment by the Company, Executive will use in the performance of Executive’s duties only information that is generally known and used by persons with training and experience comparable to Executive’s own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive’s work for the Company.

6. Outside Activities and Non-Competition During Employment.

6.1 Outside Activities. It is understood that Executive is also founder and owner of Pacific-Link Consulting Inc. (“**PLC**”) and is permitted to serve in an executive and/or director capacity with PLC so long as such activities do not interfere with the full-time performance of Executive’s duties hereunder or present a conflict of interest with the Company or its affiliates. Subject to the restrictions set forth herein and the Confidential Information Agreement, and only with prior written disclosure to and consent of the Board, Executive may engage in other types of business or public activities; provided that the Board may rescind such

consent, if the Board determines, in its sole discretion, that such other activities compromise or threaten to compromise the Company's or its affiliates' business interests or conflict with Executive's duties to the Company or its affiliates.

6.2 Non-Competition During Employment. Throughout Executive's employment with the Company, Executive will not, without the express written consent of the Board, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venturer, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

7. Termination of Employment; Severance Benefits.

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause (as defined below) or advance notice.

7.2 Termination Without Cause or Resignation for Good Reason. In the event Executive's employment with the Company is terminated by the Company without Cause (and other than as a result of Executive's death or disability) or Executive resigns for Good Reason, such termination or resignation constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), and provided that Executive satisfies the Release Requirement in Section 8 below, and remains in compliance with the terms of this Agreement and the Confidential Information Agreement, the Company shall provide Executive with the following "**Severance Benefits**":

7.2.1 Severance Payments. Severance pay in the form of continuation of Executive's final base salary for a period of twelve (12) months following termination, subject to required payroll deductions and tax withholdings (the "**Severance Payments**"). Subject to Section 9 below, the Severance Payments shall be made on the Company's regular payroll schedule in effect following Executive's termination date; provided, however that any such payments that are otherwise scheduled to be made prior to the Release Effective Date (as defined below) shall instead accrue and be made on the first administratively practicable payroll date following the Release Effective Date. For such purposes, Executive's final base salary will be calculated prior to giving effect to any reduction in base salary that would give rise to Executive's right to resign for Good Reason.

7.2.2 Stock Vesting. The vesting of all outstanding Stock Awards (as defined below) granted to Executive following the Effective Date held by Executive shall be accelerated such that the amount of shares vested under such Stock Awards shall equal that number of shares that would have been vested if Executive had continued to render services to the Company for twelve (12) continuous months after the date of Executive's termination of employment. "**Stock Awards**" shall mean any rights granted by the Company to Executive

following the Effective Date with respect to the common stock of the Company, including, without limitation, stock options, stock appreciation rights, restricted stock, stock bonuses and restricted stock units.

7.2.3 Health Care Continuation Coverage Payments.

(i) **COBRA Premiums.** If Executive timely elects continued coverage under COBRA, the Company will pay Executive's COBRA premiums to continue Executive's coverage (including coverage for Executive's eligible dependents, if applicable) ("**COBRA Premiums**") through the period starting on the termination date and ending twelve (12) months after the termination date (the "**COBRA Premium Period**"); provided, however, that the Company's provision of such COBRA Premium benefits will immediately cease if during the COBRA Premium Period Executive becomes eligible for group health insurance coverage through a new employer or Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

(ii) **Special Cash Payments in Lieu of COBRA Premiums.** Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, on the first day of each calendar month following the termination date, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including the amount of COBRA premiums for Executive's eligible dependents), subject to applicable tax withholdings (such amount, the "**Special Cash Payment**"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

7.3 Termination for Cause; Resignation Without Good Reason; Death or Disability. Executive will not be eligible for, or entitled to any severance benefits, including (without limitation) the Severance Benefits listed in Section 7.2 above, if (i) Executive's employment terminates for any reason prior to the first year anniversary of the Effective Date; (ii) the Company terminates Executive's employment for Cause, (iii) Executive resigns Executive's employment without Good Reason, or (iv) Executive's employment terminates due to Executive's death or disability.

8. Conditions to Receipt of Severance Benefits. To be eligible for the Severance Benefits pursuant to Section 7.2 above, Executive must satisfy the following release requirement (the "**Release Requirement**"): return to the Company a signed and dated general release of all known and unknown claims in a termination agreement acceptable to the Company (the "**Release**") within the applicable deadline set forth therein, but in no event later than forty-five (45) calendar days following Executive's termination date, and permit the Release to become effective and irrevocable in accordance with its terms (such effective date of the Release, the "**Release Effective Date**"). No Severance Benefits will be provided hereunder prior to the Release Effective Date. Accordingly, if Executive refuses to sign and deliver to the Company an

executed Release or signs and delivers to the Company the Release but exercises Executive's right, if any, under applicable law to revoke the Release (or any portion thereof), then Executive will not be entitled to any severance, payment or benefit under this Agreement.

9. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month and one day period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 9 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the Company determines that any severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A, for purposes of determining the schedule for payment of the severance benefits, the effective date of the Release will not be deemed to have occurred any earlier than the sixtieth (60th) date following the Separation From Service, regardless of when the Release actually becomes effective. In addition to the above, to the extent required to comply with Section 409A and the applicable regulations and guidance issued thereunder, if the applicable deadline for Executive to execute (and not revoke) the applicable Release spans two calendar years, payment of the applicable severance benefits shall not commence until the beginning of the second calendar year. To the extent required to avoid accelerated taxation and/or tax penalties under Code Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not effect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Agreement will be exempt from or comply with Code Section 409A and makes no undertaking to preclude Code Section 409A from applying to any such payment.

10. Definitions.

10.1 Cause. For the purposes of this Agreement, “Cause” means the occurrence of any one or more of the following: (i) Executive’s conviction of or plea of guilty or *nolo contendere* to any felony or any crime of moral turpitude; (ii) Executive’s continued failure or refusal to follow lawful instructions of the Board or lawful policies and regulations of the Company; (iii) Executive’s continued failure to faithfully and diligently perform the assigned duties of Executive’s employment with the Company; (iv) Executive’s violation of a fiduciary duty or duty or loyalty owed to the Company or its affiliates; (v) unprofessional, unethical, immoral or fraudulent conduct by Executive that materially discredits the Company or its affiliates, or is materially detrimental to the reputation, character and standing of the Company or its affiliates; or (vi) Executive’s material breach of this Agreement, the Confidential Information Agreement, or any written Company policies. An event described in Section 10.1(ii) through Section 10.1(vi) herein shall not be treated as “Cause” until after Executive has been given written notice of such event, failure, conduct or breach and Executive fails to cure such event, failure, conduct or breach within 30 calendar days from such written notice; provided, however, that such 30 calendar day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured.

10.2 Good Reason. For purposes of this Agreement, Executive shall have “Good Reason” for resignation from employment with the Company if any of the following actions are taken by the Company without Executive’s prior written consent: (i) a material reduction in Executive’s base salary, unless pursuant to a salary reduction program applicable generally to the Company’s senior executives; or (ii) a material reduction in Executive’s duties (including responsibilities and/or authorities), provided, however, that a change in job position (including a change in title) or reporting line shall not be deemed a “material reduction” in and of itself unless Executive’s new duties are materially reduced from the prior duties. In order for Executive to resign for Good Reason, each of the following requirements must be met: (iii) Executive must provide written notice to the Board within 30 calendar days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive’s resignation, (iv) Executive must allow the Board at least 30 calendar days from receipt of such written notice to cure such event, (v) such event is not reasonably cured within such 30 calendar day period (the “Cure Period”), and (vi) Executive must resign from all positions Executive then holds with the Company and its affiliates not later than 30 calendar days after the expiration of the Cure Period.

11. Dispute Resolution. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive’s employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive’s employment with the Company, or the termination of Executive’s employment with the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California by JAMS, Inc. (“JAMS”) or its successors by a single arbitrator. ***Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.*** Any

such arbitration proceeding will be governed by JAMS' then applicable rules and procedures for employment disputes, which will be provided to Executive upon request. Questions of whether a claim is subject to arbitration under this Agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. In any such arbitration, the arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those which would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. In the event of any such arbitration, the arbitrator shall (as opposed to may) award the prevailing party his or its costs of arbitration including but not limited to reasonable attorney's fees; arbitration forum and arbitrator fees; travel expenses; expert fees and such other usual and customary costs incurred in an arbitration.

12. General Provisions.

12.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

12.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

12.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

12.4 Complete Agreement. This Agreement, together with the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company's and Executive's agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes and replaces any other agreements or promises made to Executive by anyone concerning Executive's employment terms, compensation or benefits, whether oral or written. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Board, with the exception of those changes expressly reserved to the Company's discretion in this Agreement.

12.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

12.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

12.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

12.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

[Signature Page Follows

IN WITNESS WHEREOF, this Agreement shall be effective as of the Effective Date.

ARS PHARMACEUTICALS, INC.

By: /s/ Pratik Shah

Pratik Shah

On Behalf of the Board of Directors

EXECUTIVE

/s/ Richard E. Lowenthal

RICHARD E. LOWENTHAL

[SIGNATURE PAGE TO EMPLOYMENT AGREEMENT]

ARS PHARMACEUTICALS, INC.
EXECUTIVE EMPLOYMENT AGREEMENT

for
KATHY SCOTT

This Executive Employment Agreement (this “**Agreement**”) is made and entered into effective as of February 7, 2022 (the “**Effective Date**”), by and between Kathleen Scott (“**Executive**”) and ARS Pharmaceuticals, Inc. (the “**Company**”).

1. Employment by the Company.

1.1 Position. Executive’s employment with the Company shall begin on February 16, 2022 or such date as otherwise agreed to by Executive and the Company (such actual date Executive’s employment begins, the “**Start Date**”). Executive shall serve as the Company’s Chief Financial Officer, reporting to the Company’s Chief Executive Officer. From the Start Date until March 15, 2022 or such other date as mutually agreed in writing between the Company and the Chief Executive Officer (“**Transition Period**”), Executive shall be employed on a part-time basis with a 50% time commitment to the Company. Following the Transition Period, Executive shall be employed on a full-time basis with a 100% time commitment to the Company. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities all in conformity with the Company’s policies applicable to senior executives and general employment policies.

1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of Chief Financial Officer and such other duties as are assigned to Executive by the Company’s Chief Executive Officer. Executive’s primary work location shall be the Company’s office located in San Diego, California, and Executive will travel as reasonably required by the Company for business purposes.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company and applicable state law, except that when the terms of this Agreement differ from or are in conflict with the Company’s general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. During the Transition Period, Executive shall receive an initial base salary at the annual rate of \$195,000 (the “**Base Salary**”) reflecting a 50% part-time commitment. Following the Transition Period, once Executive becomes employed on a full-time basis with the Company, then Executive’s Base Salary shall be increased to an annual rate of \$390,000. Executive’s Base Salary shall be subject to standard payroll deductions and withholdings and payable in accordance with the Company’s regular payroll schedule.

2.2 Annual Bonus. During Executive’s employment, Executive will be

1.

eligible for an annual discretionary bonus, subject to applicable payroll deductions and withholdings, and prorated for the number of days Executive remains continuously employed in a calendar year (the “**Annual Bonus**”). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company’s Board of Directors (the “**Board**”) and/or the Compensation Committee thereof in its discretion based upon the achievement of Company corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board. Executive must continue to be employed through the date the Annual Bonus is paid in order to earn such bonus.

2.3 Equity Grant; Change in Control. Subject to approval by the Board, and pursuant to the Company’s 2018 Equity Incentive Plan (the “**Plan**”), the Company shall grant Executive an option to purchase 700,000 shares of the Company’s common stock at the fair market value as determined by the Board as of the date of grant (the “**Option**”). The Option will be subject to the terms and conditions of the Plan and Executive’s grant agreement. Executive’s grant agreement will include a four year vesting schedule, under which 25 percent of Executive’s shares will vest after twelve months of employment, with the remaining shares vesting monthly thereafter, until either the Option is fully vested or Executive’s employment ends, whichever occurs first. In the event of a Change in Control during Executive’s Continuous Service (as such terms are defined in the Plan), then 100% of the shares underlying the Option will automatically accelerate and become exercisable.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion.

4. Expenses. The Company shall pay or reimburse Executive, on a monthly basis, for reasonable travel, entertainment, promotional and other expenses incurred by Executive in the performance of Executive’s business-related obligations under this Agreement (collectively “**Expenses**”). To be eligible for reimbursement of any Expenses under this Agreement, Executive must submit timely detailed expense reports, receipts or other satisfactory evidence of payment for appropriate review within 30 days of incurring such expense. The Company shall reimburse Executive promptly, but in no event later than thirty (30) days after Executive submits an expense report in accordance with the preceding sentence.

5. Confidential Information Obligations.

5.1 Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement, Executive agrees to execute and abide by the Company’s Employee Confidential Information and Inventions Assignment Agreement (the “**Confidential Information Agreement**”) attached hereto as **Exhibit A**. In addition, Executive agrees to abide by the Company’s policies and procedures, as may be modified from time to time within the Company’s discretion.

5.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the performance of Executive's duties only information that is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

6. Outside Activities and Non-Competition During Employment.

6.1 Outside Activities. Except with the prior written consent of the Company's Chief Executive Officer, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor; provided that Executive may participate in the Permitted Outside Activities listed in **Exhibit B** hereto in accordance with the terms and conditions set forth therein. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

6.2 Non-Competition During Employment. Throughout Executive's employment with the Company, Executive will not, without the express written consent of the Chief Executive Officer, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venture, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

7. Termination of Employment; Severance Benefits.

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause (as defined below) or advance notice.

7.2 Termination Without Cause or Resignation for Good Reason. In the event Executive's employment with the Company is terminated by the Company without Cause (and other than as a result of Executive's death or disability) or Executive resigns for Good Reason, such termination or resignation constitutes a "separation from service" (as defined under

Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a “**Separation from Service**”), and provided that Executive satisfies the Release Requirement in Section 8 below, and remains in compliance with the terms of this Agreement and the Confidential Information Agreement, the Company shall provide Executive with the following “**Severance Benefits**”:

7.2.1 Severance Payments. Severance pay in the form of continuation of Executive’s final Base Salary for a period of twelve (12) months following termination, subject to required payroll deductions and tax withholdings (the “**Severance Payments**”). Subject to Section 9 below, the Severance Payments shall be made on the Company’s regular payroll schedule in effect following Executive’s termination date; provided, however that any such payments that are otherwise scheduled to be made prior to the Release Effective Date (as defined below) shall instead accrue and be made on the first administratively practicable payroll date following the Release Effective Date. For such purposes, Executive’s final Base Salary will be calculated prior to giving effect to any reduction in Base Salary that would give rise to Executive’s right to resign for Good Reason.

7.2.2 Stock Vesting. The vesting of all outstanding Stock Awards (as defined below) granted to Executive following the Effective Date held by Executive shall be accelerated such that the amount of shares vested under such Stock Awards shall equal that number of shares that would have been vested if Executive had continued to render services to the Company for twelve (12) continuous months after the date of Executive’s termination of employment. “**Stock Awards**” shall mean any rights granted by the Company to Executive following the Effective Date with respect to the common stock of the Company, including, without limitation, stock options, stock appreciation rights, restricted stock, stock bonuses and restricted stock units.

7.2.3 Health Care Continuation Coverage Payments.

(i) COBRA Premiums. If Executive timely elects continued coverage under COBRA, the Company will pay Executive’s COBRA premiums to continue Executive’s coverage (including coverage for Executive’s eligible dependents, if applicable) (“**COBRA Premiums**”) through the period starting on the termination date and ending twelve (12) months after the termination date (the “**COBRA Premium Period**”); provided, however, that the Company’s provision of such COBRA Premium benefits will immediately cease if during the COBRA Premium Period Executive becomes eligible for group health insurance coverage through a new employer or Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer’s group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

(ii) Special Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive’s dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, on the first day of each calendar month

following the termination date, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including the amount of COBRA premiums for Executive's eligible dependents), subject to applicable tax withholdings (such amount, the "**Special Cash Payment**"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

7.3 Termination for Cause; Resignation Without Good Reason; Death or Disability. Executive will not be eligible for, or entitled to any severance benefits, including (without limitation) the Severance Benefits listed in Section 7.2 above, if (i) Executive's employment terminates for any reason prior to the first to occur of (A) the first anniversary of the date of this Agreement or (B) the consummation of a Change in Control, (ii) the Company terminates Executive's employment for Cause, (iii) Executive resigns Executive's employment without Good Reason, or (iv) Executive's employment terminates due to Executive's death or disability.

8. Conditions to Receipt of Severance Benefits. To be eligible for the Severance Benefits pursuant to Section 7.2 above, Executive must satisfy the following release requirement (the "**Release Requirement**"): return to the Company a signed and dated general release of all known and unknown claims in a termination agreement acceptable to the Company (the "**Release**") within the applicable deadline set forth therein, but in no event later than forty-five (45) calendar days following Executive's termination date, and permit the Release to become effective and irrevocable in accordance with its terms (such effective date of the Release, the "**Release Effective Date**"). No Severance Benefits will be provided hereunder prior to the Release Effective Date. Accordingly, if Executive refuses to sign and deliver to the Company an executed Release or signs and delivers to the Company the Release but exercises Executive's right, if any, under applicable law to revoke the Release (or any portion thereof), then Executive will not be entitled to any severance, payment or benefit under this Agreement.

9. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month and one day

period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 9 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the Company determines that any severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A, for purposes of determining the schedule for payment of the severance benefits, the effective date of the Release will not be deemed to have occurred any earlier than the sixtieth (60th) date following the Separation From Service, regardless of when the Release actually becomes effective. In addition to the above, to the extent required to comply with Section 409A and the applicable regulations and guidance issued thereunder, if the applicable deadline for Executive to execute (and not revoke) the applicable Release spans two calendar years, payment of the applicable severance benefits shall not commence until the beginning of the second calendar year. To the extent required to avoid accelerated taxation and/or tax penalties under Code Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not effect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Agreement will be exempt from or comply with Code Section 409A and makes no undertaking to preclude Code Section 409A from applying to any such payment.

10. Definitions.

10.1 Cause. For the purposes of this Agreement, "**Cause**" means the occurrence of any one or more of the following: (i) Executive's conviction of or plea of guilty or *nolo contendere* to any felony or any crime of moral turpitude; (ii) Executive's continued failure or refusal to follow lawful instructions of the Company or lawful policies and regulations of the Company; (iii) Executive's continued failure to faithfully and diligently perform the assigned duties of Executive's employment with the Company; (iv) Executive's violation of a fiduciary duty or duty or loyalty owed to the Company or its affiliates; (v) unprofessional, unethical, immoral or fraudulent conduct by Executive that materially discredits the Company or its affiliates, or is materially detrimental to the reputation, character and standing of the Company or its affiliates; or (vi) Executive's material breach of this Agreement, the Confidential Information Agreement, or any written Company policies. An event described in Section 10.1(ii) through Section 10.1(vi) herein shall not be treated as "Cause" until after Executive has been given written notice of such event, failure, conduct or breach and Executive fails to cure such event, failure, conduct or breach within 30 calendar days from such written notice; provided, however, that such 30 calendar day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured.

10.2 Good Reason. For purposes of this Agreement, Executive shall have "**Good Reason**" for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent: (i) a material reduction in Executive's Base Salary, unless pursuant to a salary reduction program applicable

generally to the Company's senior executives; or (ii) a material reduction in Executive's duties (including responsibilities and/or authorities), provided, however, that a change in job position (including a change in title) or reporting line shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from the prior duties. In order for Executive to resign for Good Reason, each of the following requirements must be met: (iii) Executive must provide written notice to the Company within 30 calendar days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, (iv) Executive must allow the Company at least 30 calendar days from receipt of such written notice to cure such event, (v) such event is not reasonably cured within such 30 calendar day period (the "Cure Period"), and (vi) Executive must resign from all positions Executive then holds with the Company and its affiliates not later than 30 calendar days after the expiration of the Cure Period.

11. Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise between Executive and the Company, both Executive and the Company mutually agree that pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by applicable law, Executive and the Company will submit solely to final, binding and confidential arbitration any and all disputes, claims, or causes of action arising from or relating to: **(i)** the negotiation, execution, interpretation, performance, breach or enforcement of this Agreement; or **(ii)** Executive's employment with the Company (including but not limited to all statutory claims); or **(iii)** the termination of Executive's employment with the Company (including but not limited to all statutory claims). **BY AGREEING TO THIS ARBITRATION PROCEDURE, BOTH EXECUTIVE AND THE COMPANY WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTES THROUGH A TRIAL BY JURY OR JUDGE OR THROUGH AN ADMINISTRATIVE PROCEEDING.** The arbitrator shall have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration under this Section and to determine any procedural questions which grow out of such disputes, claims or causes of action and bear on their final disposition. All claims, disputes, or causes of action under this Section, whether by Executive or the Company, must be brought solely in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences in this Section are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. Any arbitration proceeding under this Section shall be presided over by a single arbitrator and conducted by JAMS, Inc. ("**JAMS**") in San Diego, California, or as otherwise agreed to by Executive and the Company, under the then applicable JAMS rules for the resolution of employment disputes (available upon request and also currently available at <http://www.jamsadr.com/rules-employment-arbitration/>). Executive and the Company both have the right to be represented by legal counsel at any arbitration proceeding, at each party's own expense. The arbitrator shall: **(i)** have the authority to compel adequate discovery for the resolution of the dispute; **(ii)** issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and **(iii)** be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the amount of court fees that would be required of Executive if the dispute were decided in a court of

law. This Section shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the “**Excluded Claims**”). In the event Executive intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Nothing in this Section is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any final award in any arbitration proceeding hereunder may be entered as a judgment in the federal and state courts of any competent jurisdiction and enforced accordingly.

12. General Provisions.

12.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

12.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

12.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

12.4 Complete Agreement. This Agreement, together with the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company’s and Executive’s agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes and replaces any other agreements or promises made to Executive by anyone concerning Executive’s employment terms, compensation or benefits, whether oral or written. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company, with the exception of those changes expressly reserved to the Company’s discretion in this Agreement.

12.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

12.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

12.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

12.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement shall be effective as of the Effective Date

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal

Richard Lowenthal
Chief Executive Officer

EXECUTIVE

/s/ Kathleen Scott

Kathleen Scott

[SIGNATURE PAGE TO EMPLOYMENT AGREEMENT]

Exhibit A

Employee Confidential Information and Inventions Assignment Agreement

(separately attached)

Exhibit B
Permitted Outside Activities

The Company agrees that, during my employment, I may engage in outside services and activities (the “**Permitted Outside Activities**”):

- Member of Board of Directors of Dermata Therapeutics, and other private or public company board positions that do not interfere or conflict with the performance of my duties and obligations to the Company.
- Completing the shut down process of Neurana Pharmaceuticals, Inc.

As a condition to the Company’s consent to my participation in such outside activities during my employment with the Company, I hereby represent, warrant and agree that:

1. I agree that, at all relevant times during my employment with the Company, my employment duties to the Company shall take precedence over the Permitted Outside Activities, and such Permitted Outside Activities shall not interfere or conflict with the performance of my duties and obligations to the Company.
2. I understand and agree that, during my employment with the Company, the Company shall have the discretion to determine whether my time commitment to such Permitted Outside Activities conflicts with my duties to the Company and to reasonably request changes to such outside time commitment by providing advance notice to me.
3. I will not use for any outside party’s benefit (or that of any other third parties), any information relating to or arising out of my employment with or work on behalf of the Company. I will not utilize the funds, personnel, facilities, equipment, materials or other resources of the Company in performing the Permitted Outside Activities.
4. I will not incorporate any of the Company’s intellectual property, confidential information or proprietary information into the Permitted Outside Activities. Likewise, I will not incorporate any outside party’s intellectual property, confidential information or proprietary information into my work for the Company.
5. Without limiting the Company’s other rights and remedies, I agree that the Company’s consent to my participation in such outside activities may be immediately withdrawn if the Company determines, in its sole discretion, that such activities compromise or threaten to compromise the Company’s or its affiliates’ business interests or conflict with my duties or obligations to the Company or its affiliates, or upon breach of any of the foregoing statements.

Accepted and agreed:

Kathleen Scott

ARS PHARMACEUTICALS, INC.
EXECUTIVE EMPLOYMENT AGREEMENT
for
DR. SARINA TANIMOTO

This Executive Employment Agreement (this “**Agreement**”) is made and entered into effective as of September 14, 2018 (the “**Effective Date**”), by and between Dr. Sarina Tanimoto (“**Executive**”) and ARS Pharmaceuticals, Inc. (the “**Company**”).

1. Employment by the Company.

1.1 Position. Executive shall serve as the Company’s Chief Medical Officer (“**CMO**”), reporting to the Company’s Chief Executive Officer. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts, on a part-time (30%) basis, to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities all in conformity with the Company’s policies applicable to senior executives and general employment policies.

1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of CMO and such other duties as are assigned to Executive by the Company’s Chief Executive Officer or the Company’s Board of Directors (the “**Board**”). Executive’s primary office location shall be the Company’s office located in San Diego, California, and Executive will travel as reasonably required by the Company for business purposes.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company and applicable California law, except that when the terms of this Agreement differ from or are in conflict with the Company’s general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. Executive shall receive a base salary at the annual rate of \$120,000, less standard payroll deductions and withholdings and payable in accordance with the Company’s regular payroll schedule.

2.2 Incentive Compensation. Subject to Board approval, the Company intends to establish an annual incentive compensation plan as soon as practicable following the execution of this Agreement. Once established, the details of the annual incentive compensation plan, including the applicable terms and conditions of such plan and Executive’s eligibility to participate in such plan, will be provided to Executive.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion.

4. Expenses. The Company shall pay or reimburse Executive, on a monthly basis, for reasonable travel, entertainment, promotional and other expenses incurred by Executive in the performance of his business-related obligations under this Agreement (collectively “**Expenses**”). To be eligible for reimbursement of any Expenses under this Agreement, Executive must submit timely detailed expense reports, receipts or other satisfactory evidence of payment for appropriate review within 30 days of incurring such expense. The Company shall reimburse Executive promptly, but in no event later than thirty (30) days after Executive submits an expense report in accordance with the preceding sentence.

5. Confidential Information Obligations.

5.1 Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement, Executive agrees to continue to abide by the Company’s Employee Confidential Information and Inventions Assignment Agreement (the “**Confidential Information Agreement**”) that he previously executed. In addition, Executive agrees to abide by the Company’s policies and procedures, as may be modified from time to time within the Company’s discretion.

5.2 Third-Party Agreements and Information. Executive represents and warrants that Executive’s employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive’s duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive’s employment by the Company, except as expressly authorized by that third party. During Executive’s employment by the Company, Executive will use in the performance of Executive’s duties only information that is generally known and used by persons with training and experience comparable to Executive’s own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive’s work for the Company.

6. Outside Activities and Non-Competition During Employment.

6.1 Outside Activities. Subject to the restrictions set forth herein and the Confidential Information Agreement, and only with prior written disclosure to and consent of the Board, Executive may engage in other types of business or public activities; provided that the Board may rescind such consent, if the Board determines, in its sole discretion, that such other activities compromise or threaten to compromise the Company’s or its affiliates’ business interests or conflict with Executive’s duties to the Company or its affiliates.

6.2 Non-Competition During Employment. Throughout Executive's employment with the Company, Executive will not, without the express written consent of the Board, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venturer, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

7. Termination of Employment; Severance Benefits.

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause (as defined below) or advance notice.

7.2 Termination Without Cause or Resignation for Good Reason. In the event Executive's employment with the Company is terminated by the Company without Cause (and other than as a result of Executive's death or disability) or Executive resigns for Good Reason, such termination or resignation constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), and provided that Executive satisfies the Release Requirement in Section 8 below, and remains in compliance with the terms of this Agreement and the Confidential Information Agreement, the Company shall provide Executive with the following "**Severance Benefits**":

7.2.1 Severance Payments. Severance pay in the form of continuation of Executive's final base salary for a period of twelve (12) months following termination, subject to required payroll deductions and tax withholdings (the "**Severance Payments**"). Subject to Section 9 below, the Severance Payments shall be made on the Company's regular payroll schedule in effect following Executive's termination date; provided, however that any such payments that are otherwise scheduled to be made prior to the Release Effective Date (as defined below) shall instead accrue and be made on the first administratively practicable payroll date following the Release Effective Date. For such purposes, Executive's final base salary will be calculated prior to giving effect to any reduction in base salary that would give rise to Executive's right to resign for Good Reason.

7.2.2 Stock Vesting. The vesting of all outstanding Stock Awards (as defined below) granted to Executive following the Effective Date held by Executive shall be accelerated such that the amount of shares vested under such Stock Awards shall equal that number of shares that would have been vested if Executive had continued to render services to the Company for twelve (12) continuous months after the date of Executive's termination of employment. "**Stock Awards**" shall mean any rights granted by the Company to Executive following the Effective Date with respect to the common stock of the Company, including, without limitation, stock options, stock appreciation rights, restricted stock, stock bonuses and restricted stock units.

7.2.3 Health Care Continuation Coverage Payments.

(i) COBRA Premiums. If Executive timely elects continued coverage under COBRA, the Company will pay Executive's COBRA premiums to continue Executive's coverage (including coverage for Executive's eligible dependents, if applicable) ("**COBRA Premiums**") through the period starting on the termination date and ending twelve (12) months after the termination date (the "**COBRA Premium Period**"); provided, however, that the Company's provision of such COBRA Premium benefits will immediately cease if during the COBRA Premium Period Executive becomes eligible for group health insurance coverage through a new employer or Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

(ii) Special Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, on the first day of each calendar month following the termination date, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including the amount of COBRA premiums for Executive's eligible dependents), subject to applicable tax withholdings (such amount, the "**Special Cash Payment**"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

7.3 Termination for Cause; Resignation Without Good Reason; Death or Disability. Executive will not be eligible for, or entitled to any severance benefits, including (without limitation) the Severance Benefits listed in Section 7.2 above, if (i) Executive's employment terminates for any reason prior to the first year anniversary of the Effective Date; (ii) the Company terminates Executive's employment for Cause, (iii) Executive resigns Executive's employment without Good Reason, or (iv) Executive's employment terminates due to Executive's death or disability.

8. Conditions to Receipt of Severance Benefits. To be eligible for the Severance Benefits pursuant to Section 7.2 above, Executive must satisfy the following release requirement (the "**Release Requirement**"): return to the Company a signed and dated general release of all known and unknown claims in a termination agreement acceptable to the Company (the "**Release**") within the applicable deadline set forth therein, but in no event later than forty-five (45) calendar days following Executive's termination date, and permit the Release to become effective and irrevocable in accordance with its terms (such effective date of the Release, the "**Release Effective Date**"). No Severance Benefits will be provided hereunder prior to the Release Effective Date. Accordingly, if Executive refuses to sign and deliver to the Company an executed Release or signs and delivers to the Company the Release but exercises Executive's right, if any, under applicable law to revoke the Release (or any portion thereof), then Executive will not be entitled to any severance, payment or benefit under this Agreement.

9. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month and one day period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 9 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the Company determines that any severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A, for purposes of determining the schedule for payment of the severance benefits, the effective date of the Release will not be deemed to have occurred any earlier than the sixtieth (60th) date following the Separation From Service, regardless of when the Release actually becomes effective. In addition to the above, to the extent required to comply with Section 409A and the applicable regulations and guidance issued thereunder, if the applicable deadline for Executive to execute (and not revoke) the applicable Release spans two calendar years, payment of the applicable severance benefits shall not commence until the beginning of the second calendar year. To the extent required to avoid accelerated taxation and/or tax penalties under Code Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not effect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Agreement will be exempt from or comply with Code Section 409A and makes no undertaking to preclude Code Section 409A from applying to any such payment.

10. Definitions.

10.1 Cause. For the purposes of this Agreement, "Cause" means the occurrence of any one or more of the following: (i) Executive's conviction of or plea of guilty or *nolo contendere* to any felony or any crime of moral turpitude; (ii) Executive's continued failure or refusal to follow lawful instructions of the Board or lawful policies and regulations of the

Company; (iii) Executive's continued failure to faithfully and diligently perform the assigned duties of Executive's employment with the Company; (iv) Executive's violation of a fiduciary duty or duty of loyalty owed to the Company or its affiliates; (v) unprofessional, unethical, immoral or fraudulent conduct by Executive that materially discredits the Company or its affiliates, or is materially detrimental to the reputation, character and standing of the Company or its affiliates; or (vi) Executive's material breach of this Agreement, the Confidential Information Agreement, or any written Company policies. An event described in Section 10.1(ii) through Section 10.1(vi) herein shall not be treated as "Cause" until after Executive has been given written notice of such event, failure, conduct or breach and Executive fails to cure such event, failure, conduct or breach within 30 calendar days from such written notice; provided, however, that such 30 calendar day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured.

10.2 Good Reason. For purposes of this Agreement, Executive shall have "**Good Reason**" for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent: (i) a material reduction in Executive's base salary, unless pursuant to a salary reduction program applicable generally to the Company's senior executives; or (ii) a material reduction in Executive's duties (including responsibilities and/or authorities), provided, however, that a change in job position (including a change in title) or reporting line shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from the prior duties. In order for Executive to resign for Good Reason, each of the following requirements must be met: (iii) Executive must provide written notice to the Board within 30 calendar days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, (iv) Executive must allow the Board at least 30 calendar days from receipt of such written notice to cure such event, (v) such event is not reasonably cured within such 30 calendar day period (the "**Cure Period**"), and (vi) Executive must resign from all positions Executive then holds with the Company and its affiliates not later than 30 calendar days after the expiration of the Cure Period.

11. Dispute Resolution. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with the Company, or the termination of Executive's employment with the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California by JAMS, Inc. ("**JAMS**") or its successors by a single arbitrator. ***Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.*** Any such arbitration proceeding will be governed by JAMS' then applicable rules and procedures for employment disputes, which will be provided to Executive upon request. Questions of whether a claim is subject to arbitration under this Agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. In any such arbitration, the arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would

otherwise be permitted by law; and (ii) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those which would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. In the event of any such arbitration, the arbitrator shall (as opposed to may) award the prevailing party his or its costs of arbitration including but not limited to reasonable attorney's fees; arbitration forum and arbitrator fees; travel expenses; expert fees and such other usual and customary costs incurred in an arbitration.

12. General Provisions.

12.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

12.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

12.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

12.4 Complete Agreement. This Agreement, together with the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company's and Executive's agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes and replaces any other agreements or promises made to Executive by anyone concerning Executive's employment terms, compensation or benefits, whether oral or written. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Board, with the exception of those changes expressly reserved to the Company's discretion in this Agreement.

12.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

12.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

12.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

12.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement shall be effective as of the Effective Date

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal

Richard Lowenthal
Chief Executive Officer

EXECUTIVE

/s/ Sarina Tanimoto

Dr. Sarina Tanimoto

[SIGNATURE PAGE TO EMPLOYMENT AGREEMENT]

ARS PHARMACEUTICALS, INC.
AMENDMENT NO. 1 TO
EXECUTIVE EMPLOYMENT AGREEMENT
for
DR. SARINA TANIMOTO

This **AMENDMENT NO. 1 TO EXECUTIVE EMPLOYMENT AGREEMENT** (this “*First Amendment*”) is made and entered into as of September 1, 2021 (the “*Effective Date*”) by and between ARS Pharmaceuticals, Inc. (the “*Company*”), and Dr. Sarina Tanimoto (the “*Executive*”) (the Company and Executive are hereinafter sometimes individually referred to as a “*Party*” and together referred to as the “*Parties*”).

WHEREAS, Executive and the Company previously entered into that certain Executive Employment Agreement dated as of September 18, 2018 (the “*Employment Agreement*”); and

WHEREAS, Executive and the Company have agreed to amend certain terms of the Employment Agreement in accordance with the terms hereof.

NOW THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth, the adequacy and sufficiency of which is hereby acknowledged, the Company and Executive agree as follows:

1. Section 1.1 of the Employment Agreement. Effective as of the Effective Date, Section 1.1 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“**Position.** Executive shall serve as the Company’s Chief Medical Officer (“*CMO*”), reporting to the Company’s Chief Executive Officer. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts, on a full-time (100%) basis, to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities all in conformity with the Company’s policies applicable to senior executives and general employment policies.”

2. Section 2.1 of the Employment Agreement. Effective as of the Effective Date, Section 2.1 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“**Base Salary.** Executive shall receive a base salary at the annual rate of \$409,000, less standard payroll deductions and withholdings and payable in accordance with the Company’s regular payroll schedule.”

3. Section 6.1 of the Employment Agreement. Effective as of the Effective Date, Section 6.1 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

“Outside Activities. It is understood that Executive is also founder and owner of Pacific- Link Consulting Inc. (“**PLC**”) and is permitted to serve in an executive and/or director capacity with PLC so long as such activities do not interfere with the full-time performance of Executive’s duties hereunder or present a conflict of interest with the Company or its affiliates. Subject to the restrictions set forth herein and the Confidential Information Agreement, and only with prior written disclosure to and consent of the Board, Executive may engage in other types of business or public activities; provided that the Board may rescind such consent, if the Board determines, in its sole discretion, that such other activities compromise or threaten to compromise the Company’s or its affiliates’ business interests or conflict with Executive’s duties to the Company or its affiliates.”

4. Acknowledgments. Executive expressly consents to the revised compensation, terms and benefits under this First Amendment. In consideration of the compensation, terms and benefits provided to Executive by this First Amendment and as part of Executive’s continued employment, Executive agrees and acknowledges that there are no circumstances as of the date of this First Amendment that constitute, and nothing contemplated in this First Amendment shall be deemed for any purpose to be or to create, an involuntary termination without Cause or a Good Reason resignation right, including for purposes of Section 7.2 of the Employment Agreement, or any other severance or change in control plan, agreement or policy maintained by the Company. Executive further hereby expressly waives any claim or right Executive may have (if any) to assert that this First Amendment, or any other condition or occurrence, forms the basis for a without Cause termination or Good Reason resignation for any purpose, including for purposes of Section 7.2 of the Employment Agreement, or any other severance or change in control plan, agreement or policy maintained by the Company.

5. Effect of Amendment. Except as modified herein, the terms and conditions of the Employment Agreement shall remain unchanged and in full force and effect.

6. Governing Law. This First Amendment shall be governed by the laws of the State of California, without regard to any conflicts of law principles thereof that would call for the application of the laws of any other jurisdiction.

7. Counterparts. This First Amendment may be executed in counterparts which shall be deemed to be part of one original, and facsimile and electronic image copies of signatures (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000) or other transmission method shall be equivalent to original signatures.

[Signature Page Follows]

IN WITNESS WHEREOF, each of the Parties has executed this First Amendment as of the date first above written.

COMPANY:

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal

Richard Lowenthal
Chief Executive Officer

EXECUTIVE:

/s/ Sarina Tanimoto

Dr. Sarina Tanimoto

ARS PHARMACEUTICALS, INC.
EXECUTIVE EMPLOYMENT AGREEMENT

for
ERIC KARAS

This Executive Employment Agreement (this “**Agreement**”) is made and entered into effective as of February 16, 2022 (the “**Effective Date**”), by and between Eric Karas (“**Executive**”) and ARS Pharmaceuticals, Inc. (the “**Company**”).

1. Employment by the Company.

1.1 Position. Executive’s employment with the Company shall begin on April 1, 2022 or such date as otherwise agreed to by Executive and the Company (such actual date Executive’s employment begins, the “**Start Date**”). Executive shall serve as the Company’s Chief Commercial Officer, reporting to the Company’s Chief Executive Officer. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts and full-time attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities all in conformity with the Company’s policies applicable to senior executives and general employment policies.

1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of Chief Commercial Officer and such other duties as are assigned to Executive by the Company’s Chief Executive Officer. It is recognized that the Executive resides in, and will primarily work remotely from, his home office in Chester Springs, Pennsylvania; provided that Executive shall be expected to travel to the Company’s office located in San Diego, California and to engage in other travel as reasonably required by the Company for business purposes.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company and applicable state law, except that when the terms of this Agreement differ from or are in conflict with the Company’s general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. Executive shall receive a base salary at the annual rate of \$410,000, less standard payroll deductions and withholdings and payable in accordance with the Company’s regular payroll schedule.

2.2 Annual Bonus. During Executive’s employment, Executive will be eligible for an annual discretionary bonus, subject to applicable payroll deductions and withholdings, and prorated for the number of days Executive remains continuously employed in a calendar year (the “**Annual Bonus**”). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company’s Board of Directors (the “**Board**”) and/or the Compensation Committee thereof in its discretion

based upon the achievement of Company corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board. Executive must continue to be employed through the date the Annual Bonus is paid in order to earn such bonus.

2.3 Equity Grant; Change in Control. Subject to approval by the Board, and pursuant to the Company's 2018 Equity Incentive Plan (the "**Plan**"), the Company shall grant Executive an option to purchase 520,000 shares of the Company's common stock at the fair market value as determined by the Board as of the date of grant (the "**Option**"). The Option will be subject to the terms and conditions of the Plan and Executive's grant agreement. Executive's grant agreement will include a four year vesting schedule, under which 25 percent of Executive's shares will vest after twelve months of employment, with the remaining shares vesting monthly thereafter, until either the Option is fully vested or Executive's employment ends, whichever occurs first.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion.

4. Expenses. The Company shall pay or reimburse Executive, on a monthly basis, for reasonable travel, entertainment, promotional and other expenses incurred by Executive in the performance of Executive's business-related obligations under this Agreement (collectively "**Expenses**"). To be eligible for reimbursement of any Expenses under this Agreement, Executive must submit timely detailed expense reports, receipts or other satisfactory evidence of payment for appropriate review within 30 days of incurring such expense. The Company shall reimburse Executive promptly, but in no event later than 30 days after Executive submits an expense report in accordance with the preceding sentence.

5. Confidential Information Obligations.

5.1 Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement, Executive agrees to execute and abide by the Company's Employee Confidential Information and Inventions Assignment Agreement (the "**Confidential Information Agreement**") attached hereto as **Exhibit A**. In addition, Executive agrees to abide by the Company's policies and procedures, as may be modified from time to time within the Company's discretion.

5.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the

performance of Executive's duties only information that is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

6. Outside Activities and Non-Competition During Employment.

6.1 Outside Activities. Except with the prior written consent of the Company's Chief Executive Officer, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

6.2 Non-Competition During Employment. Throughout Executive's employment with the Company, Executive will not, without the express written consent of the Chief Executive Officer, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venture, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

7. Termination of Employment; Severance Benefits.

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause (as defined below) or advance notice.

7.2 Termination Without Cause or Resignation for Good Reason. In the event Executive's employment with the Company is terminated by the Company without Cause (and other than as a result of Executive's death or disability) or Executive resigns for Good Reason, such termination or resignation constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), and provided that Executive satisfies the Release Requirement in Section 8 below, and remains in compliance with the terms of this Agreement and the Confidential Information Agreement, the Company shall provide Executive with the following "**Severance Benefits**":

7.2.1 Severance Payments. Severance pay in the form of continuation of Executive's final base salary for a period of twelve (12) months following termination, subject to required payroll deductions and tax withholdings (the "**Severance Payments**"). Subject to Section 9 below, the Severance Payments shall be made on the Company's regular payroll

schedule in effect following Executive's termination date; provided, however that any such payments that are otherwise scheduled to be made prior to the Release Effective Date (as defined below) shall instead accrue and be made on the first administratively practicable payroll date following the Release Effective Date. For such purposes, Executive's final base salary will be calculated prior to giving effect to any reduction in base salary that would give rise to Executive's right to resign for Good Reason.

7.2.2 Stock Vesting. The vesting of all outstanding Stock Awards (as defined below) granted to Executive following the Effective Date held by Executive shall be accelerated such that the amount of shares vested under such Stock Awards shall equal that number of shares that would have been vested if Executive had continued to render services to the Company for twelve (12) continuous months after the date of Executive's termination of employment. "**Stock Awards**" shall mean any rights granted by the Company to Executive following the Effective Date with respect to the common stock of the Company, including, without limitation, stock options, stock appreciation rights, restricted stock, stock bonuses and restricted stock units.

7.2.3 Health Care Continuation Coverage Payments.

(i) COBRA Premiums. If Executive timely elects continued coverage under COBRA, the Company will pay Executive's COBRA premiums to continue Executive's coverage (including coverage for Executive's eligible dependents, if applicable) ("**COBRA Premiums**") through the period starting on the termination date and ending twelve (12) months after the termination date (the "**COBRA Premium Period**"); provided, however, that the Company's provision of such COBRA Premium benefits will immediately cease if during the COBRA Premium Period Executive becomes eligible for group health insurance coverage through a new employer or Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

(ii) Special Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, on the first day of each calendar month following the termination date, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including the amount of COBRA premiums for Executive's eligible dependents), subject to applicable tax withholdings (such amount, the "**Special Cash Payment**"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

7.3 Termination Without Cause or Resignation for Good Reason Relating to Change in Control; Double-Trigger Acceleration. If, within twelve (12) months following a Change in Control (as defined in the Plan), Executive's employment with the Company is terminated by the Company without Cause (and other than as a result of Executive's death or

disability) or Executive resigns for Good Reason, such termination or resignation constitutes a Separation from Service, and provided that Executive satisfies the Release Requirement in Section 8 below, and remains in compliance with the terms of this Agreement and the Confidential Information Agreement, then 100% of the shares underlying the Option will automatically accelerate and become exercisable (the “**Double-Trigger Acceleration**”). For the avoidance of doubt, the Double-Trigger Acceleration under this subsection is conditioned upon the actual consummation of a Change in Control.

7.4 Termination for Cause; Resignation Without Good Reason; Death or Disability. Executive will not be eligible for, or entitled to any severance benefits, including (without limitation) the Severance Benefits listed in Section 7.2 or the Double-Trigger Acceleration listed in Section 7.3, if (i) Executive’s employment terminates for any reason prior to the first to occur of (A) the first year anniversary of the Effective Date or (B) the consummation of a Change in Control; (ii) the Company terminates Executive’s employment for Cause, (iii) Executive resigns Executive’s employment without Good Reason, or (iv) Executive’s employment terminates due to Executive’s death or disability.

8. Conditions to Receipt of Severance Benefits and Double-Trigger Acceleration. To be eligible for the Severance Benefits pursuant to Section 7.2 and the Double-Trigger Acceleration pursuant to Section 7.3 above, Executive must satisfy the following release requirement (the “**Release Requirement**”): return to the Company a signed and dated general release of all known and unknown claims in a termination agreement acceptable to the Company (the “**Release**”) within the applicable deadline set forth therein, but in no event later than forty-five (45) calendar days following Executive’s termination date, and permit the Release to become effective and irrevocable in accordance with its terms (such effective date of the Release, the “**Release Effective Date**”). No Severance Benefits or Double-Trigger Acceleration will be provided hereunder prior to the Release Effective Date. Accordingly, if Executive refuses to sign and deliver to the Company an executed Release or signs and delivers to the Company the Release but exercises Executive’s right, if any, under applicable law to revoke the Release (or any portion thereof), then Executive will not be entitled to any severance, payment or benefit under this Agreement.

9. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive’s right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive’s Separation from Service to be a “specified employee” for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be

“deferred compensation”, then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month and one day period measured from the date of Executive’s Separation from Service with the Company, (ii) the date of Executive’s death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 9 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the Company determines that any severance benefits provided under this Agreement constitutes “deferred compensation” under Section 409A, for purposes of determining the schedule for payment of the severance benefits, the effective date of the Release will not be deemed to have occurred any earlier than the sixtieth (60th) date following the Separation From Service, regardless of when the Release actually becomes effective. In addition to the above, to the extent required to comply with Section 409A and the applicable regulations and guidance issued thereunder, if the applicable deadline for Executive to execute (and not revoke) the applicable Release spans two calendar years, payment of the applicable severance benefits shall not commence until the beginning of the second calendar year. To the extent required to avoid accelerated taxation and/or tax penalties under Code Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not effect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Agreement will be exempt from or comply with Code Section 409A and makes no undertaking to preclude Code Section 409A from applying to any such payment.

10. Section 280G.

If any payment or benefit Executive will or may receive from the Company or otherwise (a “**280G Payment**”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “**Excise Tax**”), then any such 280G Payment pursuant to this Agreement or otherwise (a “**Payment**”) shall be equal to the Reduced Amount. The “**Reduced Amount**” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the “**Reduction Method**”) that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the “**Pro Rata Reduction Method**”).

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are “deferred compensation” within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change in control transaction triggering the Payment shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within 15 calendar days after the date on which Executive’s right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other reasonable time as requested by Executive or the Company.

If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section so that no portion of the remaining Payment is subject to the Excise Tax). For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first paragraph of this Section, Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence

11. Definitions.

11.1 Cause. For the purposes of this Agreement, “Cause” means the occurrence of any one or more of the following: (i) Executive’s conviction of or plea of guilty or *nolo contendere* to any felony or any crime of moral turpitude; (ii) Executive’s continued failure or refusal to follow lawful instructions of the Company or lawful policies and regulations of the Company; (iii) Executive’s continued failure to faithfully and diligently perform the assigned duties of Executive’s employment with the Company; (iv) Executive’s violation of a fiduciary duty or duty or loyalty owed to the Company or its affiliates; (v) unprofessional, unethical, immoral or fraudulent conduct by Executive that materially discredits the Company or its

affiliates, or is materially detrimental to the reputation, character and standing of the Company or its affiliates; or (vi) Executive's material breach of this Agreement, the Confidential Information Agreement, or any written Company policies. An event described in Section 11.1(ii) through Section 11.1(vi) herein shall not be treated as "Cause" until after Executive has been given written notice of such event, failure, conduct or breach and Executive fails to cure such event, failure, conduct or breach within 30 calendar days from such written notice; provided, however, that such 30 calendar day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured.

11.2 Good Reason. For purposes of this Agreement, Executive shall have "**Good Reason**" for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent: (i) a material reduction in Executive's base salary, unless pursuant to a salary reduction program applicable generally to the Company's senior executives; or (ii) a material reduction in Executive's duties (including responsibilities and/or authorities), provided, however, that a change in job position (including a change in title) or reporting line shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from the prior duties. In order for Executive to resign for Good Reason, each of the following requirements must be met: (iii) Executive must provide written notice to the Company within 30 calendar days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, (iv) Executive must allow the Company at least 30 calendar days from receipt of such written notice to cure such event, (v) such event is not reasonably cured within such 30 calendar day period (the "**Cure Period**"), and (vi) Executive must resign from all positions Executive then holds with the Company and its affiliates not later than 30 calendar days after the expiration of the Cure Period.

12. Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise between Executive and the Company, both Executive and the Company mutually agree that pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by applicable law, Executive and the Company will submit solely to final, binding and confidential arbitration any and all disputes, claims, or causes of action arising from or relating to: (i) the negotiation, execution, interpretation, performance, breach or enforcement of this Agreement; or (ii) Executive's employment with the Company (including but not limited to all statutory claims); or (iii) the termination of Executive's employment with the Company (including but not limited to all statutory claims). **BY AGREEING TO THIS ARBITRATION PROCEDURE, BOTH EXECUTIVE AND THE COMPANY WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTES THROUGH A TRIAL BY JURY OR JUDGE OR THROUGH AN ADMINISTRATIVE PROCEEDING.** The arbitrator shall have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration under this Section and to determine any procedural questions which grow out of such disputes, claims or causes of action and bear on their final disposition. All claims, disputes, or causes of action under this Section, whether by Executive or the Company, must be brought solely in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences in this Section are found to violate applicable law or

are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. Any arbitration proceeding under this Section shall be presided over by a single arbitrator and conducted by JAMS, Inc. (“JAMS”) in Philadelphia, Pennsylvania, or as otherwise agreed to by Executive and the Company, under the then applicable JAMS rules for the resolution of employment disputes (available upon request and also currently available at <http://www.jamsadr.com/rules-employment-arbitration/>). Executive and the Company both have the right to be represented by legal counsel at any arbitration proceeding, at each party’s own expense. The arbitrator shall: **(i)** have the authority to compel adequate discovery for the resolution of the dispute; **(ii)** issue a written arbitration decision, to include the arbitrator’s essential findings and conclusions and a statement of the award; and **(iii)** be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. This Section shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the “**Excluded Claims**”). In the event Executive intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. Nothing in this Section is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any final award in any arbitration proceeding hereunder may be entered as a judgment in the federal and state courts of any competent jurisdiction and enforced accordingly.

13. General Provisions.

13.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

13.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

13.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

13.4 Complete Agreement. This Agreement, together with the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company’s and Executive’s agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those

expressly contained herein, and it supersedes and replaces any other agreements or promises made to Executive by anyone concerning Executive's employment terms, compensation or benefits, whether oral or written. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company, with the exception of those changes expressly reserved to the Company's discretion in this Agreement.

13.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

13.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

13.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

13.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

13.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the Commonwealth of Pennsylvania.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement shall be effective as of the Effective Date

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal

Richard Lowenthal
Chief Executive Officer

EXECUTIVE

/s/ Eric Karas

Eric Karas

[SIGNATURE PAGE TO EMPLOYMENT AGREEMENT]

Exhibit A

Employee Confidential Information and Inventions Assignment Agreement

(separately attached)

ARS PHARMACEUTICALS, INC.
EXECUTIVE EMPLOYMENT AGREEMENT
For Justin Chakma

This Executive Employment Agreement (this “**Agreement**”) is made and entered into effective as of June 1st, 2019 (the “**Effective Date**”), by and between Justin Chakma (“**Executive**”) and ARS Pharmaceuticals, Inc. (the “**Company**”).

1. Employment by the Company.

1.1 Position. Executive shall serve as the Company’s Chief Business Officer (“**CBO**”), reporting to the Company’s Chief Executive Officer. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts, on a full-time (100%) basis, to the business of the Company, except for vacation periods and periods of illness or other incapacities all in conformity with the Company’s policies applicable to senior executives and general employment policies and laws.

1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of CBO and such other reasonable duties as are assigned to Executive by the Company’s Chief Executive Officer or the Company’s Board of Directors (the “**Board**”). Executive’s primary office location shall be the Company’s office located in San Diego, California, and Executive will travel as reasonably required by the Company for business purposes.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company and applicable California law, except that when the terms of this Agreement differ from or are in conflict with the Company’s general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. Executive shall receive a base salary at the annual rate of \$300,000, less standard payroll deductions and withholdings and payable in accordance with the Company’s regular payroll schedule.

2.2 Incentive Compensation. Subject to Board approval, the Company intends to establish an annual incentive compensation plan. Once established, the details of the annual incentive compensation plan, including the applicable terms and conditions of such plan and Executive’s eligibility to participate in such plan, will be provided to the Executive.

(i) Relocation. ARS will pay for the costs for relocation as a reimbursement of expenses based on actual costs incurred. These costs will be limited to \$40,000 for any direct costs related to relocation.

2.3 Equity Grant. Subject to approval of the Board, the Company will grant to Executive an option (the “**Time-Based Option**”) to purchase up to 400,000 shares of the Company’s Common Stock pursuant to the Company’s 2018 Equity Incentive Plan (the “**Plan**”). 25% of the Time-Based Option will vest on the one-year anniversary of the commencement of Executive’s employment with the Company, and the remaining portion of the Time-Based Option shall vest in equal monthly installments over the following three years.

2.4 Bonus Equity Grant. Subject to approval of the Board, the Company will grant to Executive an additional option (the “**Milestone-Based Option**”) to purchase up to 200,000 shares of the Company’s Common Stock pursuant to the Plan. The Milestone-Based Option shall vest and become exercisable as follows:

(i) 100,000 shares shall vest and become exercisable upon the first to occur of (i) immediately prior to the closing of the Company’s first firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 (an “**IPO**”) if the fully diluted equity value (measured on an as converted basis inclusive of shares sold in the IPO and issuable upon conversion of outstanding Preferred Stock and exercise of outstanding stock options, restricted stock and warrants) as of the closing of the IPO is equal to or greater than \$350M based on the per share price of the shares of Common Stock sold in the IPO or ii) immediately prior to the closing of a Liquidation Event (as defined in the Company’s Amended and Restated Certificate of Incorporation, as such may be amended from time to time) with cumulative upfront consideration paid to the Company and its stockholders (not counting milestones, escrows, or any amounts payable after the initial closing) equal to or greater than \$300M of value (as determined in the sole, good faith discretion of the Board of Directors of the Company);

OR

(ii) 200,000 shares shall vest and become exercisable upon the first to occur of (i) immediately prior to the closing of the IPO if the fully diluted equity value (measured on an as converted basis inclusive of shares sold in the IPO and issuable upon conversion of outstanding Preferred Stock and exercise of outstanding stock options, restricted stock and warrants) as of the closing of the IPO is equal to or greater than \$500M based on the per share price of the shares of Common Stock sold in the IPO or ii) immediately prior to the closing of a Liquidation Event with cumulative upfront consideration paid to the Company and its stockholders (not counting milestones, escrows, or any amounts payable after the initial closing) equal to or greater than \$500M of value (as determined in the sole, good faith discretion of the Board of Directors of the Company).

All unvested shares subject to the Milestone-Based Option shall be cancelled and no longer exercisable upon the first to occur of (i) the termination of Executive’s employment with the Company or (ii) the consummation of a Liquidation Event.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion.

4. Expenses. The Company shall pay or reimburse Executive, on a monthly basis, for reasonable travel, entertainment, promotional and other expenses incurred by Executive in the performance of his business-related obligations under this Agreement (collectively “**Expenses**”). To be eligible for reimbursement of any Expenses under this Agreement, Executive must submit timely detailed expense reports, receipts or other satisfactory evidence of payment for appropriate review within 30 days of incurring such expense, unless there is reasonable cause of delay. The Company shall reimburse Executive promptly, but in no event later than thirty (30) days after Executive submits an expense report in accordance with the preceding sentence.

5. Confidential Information Obligations.

5.1 Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement, Executive agrees to continue to abide by the Company’s Employee Confidential Information and Inventions Assignment Agreement (the “**Confidential Information Agreement**”) that she previously executed. In addition, Executive agrees to abide by the Company’s policies and procedures, as may be modified from time to time within the Company’s discretion.

5.2 Third-Party Agreements and Information. Executive represents and warrants that Executive’s employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive’s duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive’s employment by the Company, except as expressly authorized by that third party. During Executive’s employment by the Company, Executive will use in the performance of Executive’s duties only information that is generally known and used by persons with training and experience comparable to Executive’s own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive’s work for the Company.

6. Outside Activities and Non-Competition During Employment.

6.1 Outside Activities. Subject to the restrictions set forth herein and the Confidential Information Agreement, and only with prior written disclosure to and consent of the Board, Executive may engage in other types of business or public activities; provided that the Board may rescind such consent, if the Board determines, in its sole discretion, that such other activities compromise or threaten to compromise the Company’s or its affiliates’ business interests or conflict with Executive’s duties to the Company or its affiliates.

6.2 Non-Competition During Employment. Throughout Executive's employment with the Company, Executive will not, without the express written consent of the Board, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venturer, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

7. Termination of Employment

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause (as defined below) or advance notice.

7.2 Termination Without Cause or Resignation for Good Reason. In the event Executive's employment with the Company is terminated by the Company without Cause (and other than as a result of Executive's death or disability) or Executive resigns for Good Reason, such termination or resignation constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), and provided that Executive satisfies the Release Requirement in Section 8 below, and remains in compliance with the terms of this Agreement and the Confidential Information Agreement, the Company shall provide Executive with the following "**Severance Benefits**":

7.2.1 Severance Payments. Severance pay in the form of continuation of Executive's final base salary for a period of three (3) months following termination, if without cause, subject to required payroll deductions and tax withholdings (the "**Severance Payments**"). In addition, the Company shall pay to the Executive (i) any Salary, accrued vacation pay and expense reimbursement, accrued but unpaid as of the date of termination, and (ii) the awarded but unpaid portion of, if any, of the incentive compensation for any prior or current year. Subject to Section 9 below, the Severance Payments shall be made on the Company's regular payroll schedule in effect following Executive's termination date; provided, however that any such payments that are otherwise scheduled to be made prior to the Release Effective Date (as defined below) shall instead accrue and be made on the first administratively practicable payroll date following the Release Effective Date. For such purposes, Executive's final base salary will be calculated prior to giving effect to any reduction in base salary that would give rise to Executive's right to resign for Good Reason.

7.2.2 Health Care Continuation Coverage Payments.

(i) COBRA Premiums. If Executive timely elects continued coverage under COBRA, the Company will pay Executive's COBRA premiums to continue Executive's coverage (including coverage for Executive's eligible dependents, if applicable) ("**COBRA Premiums**") through the period starting on the termination date and ending six (6) months after the termination date (the "**COBRA Premium Period**"); provided, however, that the Company's provision of such COBRA Premium benefits will immediately cease if during the COBRA Premium Period Executive becomes eligible for group health insurance coverage through a new employer or Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event.

(ii) Special Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), regardless of whether Executive or Executive's dependents elect or are eligible for COBRA coverage, the Company instead shall pay to Executive, on the first day of each calendar month following the termination date, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including the amount of COBRA premiums for Executive's eligible dependents), subject to applicable tax withholdings (such amount, the "**Special Cash Payment**"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

7.3 Termination for Cause; Resignation Without Good Reason; Death or Disability. Executive will not be eligible for, or entitled to any severance benefits, including (without limitation) the Severance Benefits listed in Section 7.2 above, if (i) the Company terminates Executive's employment for Cause, (ii) Executive resigns Executive's employment without Good Reason, or (iii) Executive's employment terminates due to Executive's death or disability. Furthermore, Executive will not be eligible for, or entitled to, any severance benefits listed in Section 7.2.1 or Section 7.2.3 above if Executive's employment terminates for any reason prior to the first year anniversary of the Effective Date

8. Conditions to Receipt of Severance Benefits. To be eligible for the Severance Benefits pursuant to Section 7.2 above, Executive must satisfy the following release requirement (the "**Release Requirement**"): return to the Company a signed and dated general release of all known and unknown claims in a termination agreement acceptable to the Company (the "**Release**") within the applicable deadline set forth therein, but in no event later than forty-five (45) calendar days following Executive's termination date, and permit the Release to become effective and irrevocable in accordance with its terms (such effective date of the Release, the "**Release Effective Date**"). No Severance Benefits will be provided hereunder prior to the Release Effective Date. Accordingly, if Executive refuses to sign and deliver to the Company an executed Release or signs and delivers to the Company the Release but exercises Executive's right, if any, under applicable law to revoke the Release (or any portion thereof), then Executive will not be entitled to any severance, payment or benefit under this Agreement.

9. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be

treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month and one day period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 9 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the Company determines that any severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A, for purposes of determining the schedule for payment of the severance benefits, the effective date of the Release will not be deemed to have occurred any earlier than the sixtieth (60th) date following the Separation From Service, regardless of when the Release actually becomes effective. In addition to the above, to the extent required to comply with Section 409A and the applicable regulations and guidance issued thereunder, if the applicable deadline for Executive to execute (and not revoke) the applicable Release spans two calendar years, payment of the applicable severance benefits shall not commence until the beginning of the second calendar year. To the extent required to avoid accelerated taxation and/or tax penalties under Code Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not effect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Agreement will be exempt from or comply with Code Section 409A and makes no undertaking to preclude Code Section 409A from applying to any such payment.

10. Definitions.

10.1 Cause. For the purposes of this Agreement, "Cause" means the occurrence of any one or more of the following: (i) Executive's conviction of or plea of guilty or *nolo contendere* to any felony or any crime of moral turpitude; (ii) Executive's continued failure or refusal to follow lawful instructions of the Board or lawful policies and regulations of the Company; (iii) Executive's continued failure to faithfully and diligently perform the assigned duties of Executive's employment with the Company; (iv) Executive's violation of a fiduciary duty or duty or loyalty owed to the Company or its affiliates; (v) unprofessional, unethical, immoral or fraudulent conduct by Executive that materially discredits the Company or its affiliates, or is materially detrimental to the reputation, character and standing of the Company or its affiliates; or (vi) Executive's material breach of this Agreement, the Confidential Information Agreement, or any written Company policies. An event described in Section 10.1(ii) through

Section 10.1(vi) herein shall not be treated as “Cause” until after Executive has been given written notice of such event, failure, conduct or breach and Executive fails to cure such event, failure, conduct or breach within 30 calendar days from such written notice; provided, however, that such 30 calendar day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured.

10.2 Good Reason. For purposes of this Agreement, Executive shall have “**Good Reason**” for resignation from employment with the Company if any of the following actions are taken by the Company without Executive’s prior written consent: (i) a material reduction in Executive’s base salary, unless pursuant to a salary reduction program applicable generally to the Company’s senior executives; or (ii) a material reduction in Executive’s duties (including responsibilities and/or authorities), or (iii) the Company’s relocation of the principal place for performance of Executive’s duties to a location outside of San Diego County, California that requires a one-way increase in Executive’s commuting distance of more than fifty (50) miles. . In order for Executive to resign for Good Reason, each of the following requirements must be met: (iii) Executive must provide written notice to the Board within 30 calendar days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive’s resignation, (iv) Executive must allow the Board at least 30 calendar days from receipt of such written notice to cure such event, (v) such event is not reasonably cured within such 30 calendar day period (the “**Cure Period**”), and (vi) Executive must resign from all positions Executive then holds with the Company and its affiliates not later than 30 calendar days after the expiration of the Cure Period.

11. Dispute Resolution. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive’s employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive’s employment with the Company, or the termination of Executive’s employment with the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California by JAMS, Inc. (“**JAMS**”) or its successors by a single arbitrator. ***Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.*** Any such arbitration proceeding will be governed by JAMS’ then applicable rules and procedures for employment disputes, which will be provided to Executive upon request. Questions of whether a claim is subject to arbitration under this Agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. In any such arbitration, the arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written arbitration decision including the arbitrator’s essential findings and conclusions and a statement of the award. Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those which would be required if the dispute were decided in a court of law, and

shall pay the arbitrator's fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. In the event of any such arbitration, the arbitrator shall (as opposed to may) award the prevailing party his or its costs of arbitration including but not limited to reasonable attorney's fees; arbitration forum and arbitrator fees; travel expenses; expert fees and such other usual and customary costs incurred in an arbitration.

12. General Provisions.

12.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

12.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

12.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

12.4 Complete Agreement. This Agreement, together with the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company's and Executive's agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes and replaces any other agreements or promises made to Executive by anyone concerning Executive's employment terms, compensation or benefits, whether oral or written. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Board, with the exception of those changes expressly reserved to the Company's discretion in this Agreement.

12.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

12.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

12.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

12.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement shall be effective as of the Effective Date

ARS PHARMACEUTICALS, INC.

By: /s/ Richard Lowenthal
Richard Lowenthal
Chief Executive Officer

EXECUTIVE

/s/ Justin Chakma
Justin Chakma



CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (hereinafter “Agreement”) is made as of the 26 April 2021 (“Effective Date”), between ARS Pharmaceuticals, Inc. (“Company”) and Brent L. Saunders (“Consultant”). Company and Consultant also are each referred to herein individually as “Party” and collectively as the “Parties.”

BACKGROUND

The Company has products in development and is seeking consultation and assistance with regulatory and development work. The Company wishes to retain the Consultant to help support the current and future development of products in their pipeline. The Company and the Consultant are willing to accept such engagement on the terms and conditions of this Agreement.

In consideration of the mutual promises and covenants herein contained, the parties hereto agree as follows:

1. DUTIES

A. The Consultant shall provide general advice and assistance to the Company with respect to the development of current and future drug products (“Products”), including **support for (i) investor relations, (ii) financing activities and (iii) commercial launch preparation including building and/or recruiting a commercial team.** Upon request, the Consultant shall perform other activities as directed by the Company. In the event the Company decides to implement strategies or make business decisions based on any opinions, advice or assistance of Consultant, the Company does so at its own risk and without any recourse against the Consultant for any opinions, advice or assistance given.

B. Consultant also agrees to observe all reasonable policies and directives, including quality systems procedures, promulgated from time to time by Company’s officers and Board of Directors, including but not limited to, providing Company with monthly time sheets setting forth in reasonable detail the amount of hours worked and the services performed.

C. The Parties agree that this Agreement shall not interfere with Consultant’s ability to undertake other full time employment or pursue other full time business opportunities not involving the Company, nor to restrict Consultant’s ability to travel or relocate his personal residence.

Brent Saunders-ARS

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2. FEES AND EXPENSES

A. Company shall pay to Consultant compensation as outlined in Schedule A of this agreement.

B. Compensation shall be payable without deductions for federal income, social security, or state income taxes. Consultant acknowledges and agrees that this Agreement shall not give or extend to Consultant any rights with respect to additional contributions by Company to any deferred compensation plan, bonus plans, or fringe benefits, and further agrees to hold Company harmless from any taxes which may be assessed against Consultant in connection with payments to the Consultant under the terms of this Agreement.

C. During the term of this Agreement, the Company shall reimburse Consultant for all business expenses reasonably incurred by the Consultant in the performance of Services provided that such business expenses were approved by the Company. Consultant will submit to the Company a written accounting or other adequate documentary evidence of such expenses consistent with the reimbursement policies of Company. The Company agrees to reimburse Consultant for such expenses within fifteen (30th) business days of receipt of each such expense accounting.

3. INDEPENDENT CONTRACTOR

A. In the performance of this Agreement, it is mutually understood and agreed that Consultant is at all times acting and performing as an independent contractor with, and not as the employee of, Company, and no act, or failure to act, by any party hereto shall be construed to make or render the other party its partner, joint venturer, employee or associate.

B. The Consultant shall have no authority to bind the Company to, or assume, enter into, or act on behalf of the Company for, any obligation, agreement or act.

4. CONFIDENTIALITY

As stipulated in the 3 November 2020 Confidentiality Agreement, Company or Consultant shall not disclose any of the aforesaid trade secrets or other proprietary information directly or indirectly to any third party, or use them in any way either during the term of this Agreement or at any time thereafter, except as reasonably necessary to perform services pursuant to this Agreement.

5. OWNERSHIP RIGHTS

Except as specifically provided herein, Company shall retain all rights to all Investigational New Drug Applications (INDs), Abbreviated New Drug Applications (ANDAs), New Drug Applications (NDAs) or any other rights whatsoever to the Products whether or not such rights result from the Consultant's efforts or collaborative efforts on the Products. The Consultant further agrees that upon demand, Consultant will execute and deliver to Company such documents relating to the Products or the Project as may be deemed necessary or advisable by Company for filing in the appropriate regulatory office to protect the legitimate interests of Company. It is recognized and understood that the existing inventions and technologies of Company or the Consultant are their separate property, respectively, and are not affected by this Agreement (including, but not limited to the Confidential Information). Neither Party shall have any claims to, nor rights in, such existing inventions and technologies of the other Party. Any and all inventions and discoveries arising from this collaboration, including any inventions, modifications, or discoveries based, in whole or in part, on Confidential Information, are the sole and exclusive property of Company, unless otherwise agreed to by the Parties. Notwithstanding the foregoing, the Company grants an exclusive right to Consultant, at Consultant's expense, to execute any and all applications, assignments or other instruments and give testimony necessary to apply for and obtain letters of patent of the United States or of any foreign country or to otherwise protect Sponsor's interest therein. The obligations of the Parties under this Section 5 shall continue beyond the termination of this Agreement and shall be binding upon the Parties.

6. TERM AND TERMINATION

A. The term of this Agreement shall begin on the Effective Date and shall terminate after 12 months unless terminated earlier pursuant to this Section. The term of this Agreement may be extended by mutual written agreement of the Parties.

B. This Agreement can be terminated by either party upon sixty (60) days prior written notice to the other; provided, however, that Company shall pay Consultant for all services rendered prior to the termination.

Brent Saunders-ARS

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7. SEVERABILITY

If any provision of this Agreement is held to be unenforceable, invalid or illegal by any court of competent jurisdiction, such unenforceable, invalid or illegal provisions shall not affect the remainder of this Agreement.

8. ENTIRE AGREEMENT

This instrument contains the entire Agreement of the parties and it supersedes any other agreement between Company and the Consultant. This Agreement cannot be amended, modified or supplemented in any respect except by a subsequent written agreement entered into by both Parties.

9. LAWS

The validity of this Agreement and the interpretation and performance of all its terms shall be governed by the substantive laws of the State of California.

10. WAIVER

Failure of either party hereto to insist upon strict compliance with any of the terms, covenants and conditions hereof shall not be deemed a waiver or relinquishment of any similar right or power hereunder at any subsequent time or of any other provision hereof.

11. INDEMNIFICATION

Company agrees to indemnify and hold harmless Consultant, and each of its directors, officers, employees, agents, heirs and assigns from and against any and all losses, claims, damages, liabilities, costs, and expenses (including attorneys' fees and expenses related to the defense of any claims), joint or several, which may be asserted against Consultant or for which they may now or hereafter become subject arising in connection with any activity of the Company, including but not limited to alleged or actual failure by the Company to comply with any requirement applicable to the Company under any federal, state, or local law or regulation, provided that such claims have not been caused by the gross negligence or willful or wanton misconduct of Consultant.



12. NOTICES

All notices and any other acts required or permitted under this Agreement shall be in writing, and shall be sufficiently given if delivered to the addressees in person, by Federal Express or similar receipted delivery, or if mailed, postage prepaid, by certified mail, return receipt requested, as follows:

COMPANY: ARS Pharmaceuticals, Inc
3525 Del Mar Heights Rd., #855
San Diego, CA 92130

CONSULTANT: Brent L. Saunders

12. ASSIGNMENT

Neither Party shall assign or delegate any rights, duties or obligations under this Agreement, in whole or in part, without the prior written consent of the other Party.

13. COUNTERPARTS

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. The execution of this Agreement may be by actual or facsimile signature.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement effective as of the date first written above.

ARS Pharmaceuticals, Inc.

Vesper Healthcare Acquisition Corp.

By: /s/ Richard E. Lowenthal
Richard E. Lowenthal
President & CEO

/s/ Brent L. Saunders
Brent L. Saunders President, CEO & Chairman

Date: 5/3/2021

Date: 5/3/2021

Brent Saunders-ARS

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SCHEDULE A
COMPENSATION

1. Compensation.

- 1.1.** Subject to approval by the Company's Board of Directors (the "Board"), and pursuant to the Company's 2018 Equity Incentive Plan (the "Plan"), the Company shall grant you an option to purchase 500,000 shares of the Company's common stock at the fair market value as determined by the Board as of the date of grant (the "Option"). The Option will be subject to the terms and conditions of the Plan and your grant agreement. Your grant agreement will include a four years vesting schedule, under which 25 percent of your shares will vest after twelve months, with the remaining shares vesting monthly thereafter, until either the Option is fully vested or your service ends, whichever occurs first. Notwithstanding the foregoing, (i) only service pursuant to this Agreement shall qualify as Continuous Service under the Plan for purposes of the continued vesting of this Option and (ii) the vesting of the shares subject to your Option will accelerate in full immediately prior to the consummation of Liquidation Event (as defined in the Company's Amended and Restated Certificate of Incorporation, as currently in effect) provided that you provide Continuous Service to the Company pursuant to this Agreement through such date.

Brent Saunders-ARS

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AMENDMENT TO CONSULTING AGREEMENT

THIS AMENDMENT ("**Amendment**") to the Consulting Agreement dated as of April 26, 2021 ("**Agreement**"), by and between **Brent L. Saunders** (the "**Consultant**") and **ARS Pharmaceuticals, Inc.** (the "**Company**"), is effective as of April 25, 2022 (the "**Amendment Effective Date**"). All capitalized terms used herein shall have the same meaning as defined in the Agreement.

WHEREAS, Consultant and Company desire to amend the Agreement as set forth below;

NOW, THEREFORE, in consideration of the foregoing premises and the covenants and promises contained in the Agreement as amended hereby, Consultant and Company, intending to be bound, hereby agree that the Agreement shall be amended as follows:

1. The term of the Agreement shall continue to renew automatically on an annual basis unless the Company or Consultant terminate the Agreement as described in Section 6 of the Agreement.
2. All other terms of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their authorized representatives effective as of the date set forth above.

ARS Pharmaceuticals, Inc.

Vesper Healthcare Acquisition Corp.

By: /s/ Richard E. Lowenthal
Richard E. Lowenthal
President & CEO

By: /s/ Brent L. Saunders
Brent L. Saunders
President, CEO & Chairman

ARS Pharmaceuticals, Inc., 11682 El Camino Real, Suite 120, San Diego, CA 92130

ARS PHARMACEUTICALS, INC.
CONSULTING AGREEMENT
EFFECTIVE DATE: September 13, 2018

THIS CONSULTING AGREEMENT (the “*Agreement*”) is made as of the Effective Date set forth above by and between ARS Pharmaceuticals, Inc., a Delaware corporation (“*Client*”), and Marlinspike Group, LLC (“*Consultant*”).

1. Engagement of Services. Subject to the terms of this Agreement, Consultant agrees to render the services set forth on **Exhibit A** according to the schedule set forth therein, or as otherwise mutually agreed to by the parties (the “*Services*”).

2. Compensation. Client will pay Consultant the compensation set forth on **Exhibit A** for the Services. Consultant will be reimbursed only for expenses approved by the Client that Consultant has furnished such documentation as Client may reasonably request. Client will be invoiced for expenses on the last business day of each month of service and paid within 30 days thereafter. At the option of the Client, the Client may pay the Consultant semi-monthly. Upon termination of this Agreement for any reason, Consultant will be paid for work which has been completed. Payment to Consultant of undisputed expenses will be due 30 days following Client’s receipt of an invoice that contains accurate records of the work performed sufficient to document the invoiced expenses.

3. Ownership of Work Product. Consultant agrees that any and all Work Product (as defined below) shall be the sole and exclusive property of Client. Consultant hereby irrevocably assigns to Client all right, title and interest worldwide in and to any ideas, concepts, processes, discoveries, developments, formulae, information, materials, improvements, designs, artwork, content, software programs, other copyrightable works, and any other work product created, conceived or developed by Consultant (whether alone or jointly with others) for Client during the term of this Agreement, including all copyrights, patents, trademarks, trade secrets, and other intellectual property rights therein (the “*Work Product*”). For the avoidance of doubt, Consultant and Client acknowledge and agree that “*Work Product*”, as used in this Agreement, shall specifically exclude any ideas, concepts, processes, discoveries, developments, formulae, information, materials, improvements, designs, artwork, content, software programs, other copyrightable works, and any other work product created, conceived or developed by Consultant for any entity other than Client, including, without limitation, Design Therapeutics, Inc., Marlinspike Group, Inc. or Scribe Therapeutics Inc., provided, in each case, that Consultant does not breach its obligations under Section 5 below. Consultant retains no rights to use the Work Product following the term of this Agreement and agrees not to challenge the validity of Client’s ownership of the Work Product. Consultant agrees not to use or incorporate into Work Product any intellectual property developed by any third party or by Consultant other than in the course of performing the Services for Client. As requested by the Client, and only with respect to Work Product, Consultant shall take all steps reasonably necessary to assist the Client, at Client’s expense, in obtaining and enforcing in its own name rights to any such Work Product. Consultant’s obligation to assist the Client, at Client’s expense, shall continue beyond the termination of Consultant’s relationship with the Client.

4. Independent Contractor Relationship. Consultant’s relationship with Client is that of an independent contractor, and nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture or employment relationship between Client and any of Consultant’s employees or agents. Neither party is authorized to make any representation, contract or commitment on behalf of the other party. Consultant will not be entitled to any of the benefits that Client may make available to its employees, including, but not limited to, group health or life insurance, profit-sharing or

retirement benefits. Because Consultant is an independent contractor, Client will not withhold federal, state or any other employee payroll taxes or withhold or make payments for social security, make unemployment insurance or disability insurance contributions, or obtain workers' compensation insurance on behalf of Consultant.

5. Confidential Information. Consultant agrees that during the term of this Agreement and thereafter it will not use or permit the use of Client's Confidential Information in any manner or for any purpose not expressly set forth in this Agreement, will hold such Confidential Information in confidence and protect it from unauthorized use and disclosure, and will not disclose such Confidential Information to any third parties. "**Confidential Information**" as used in this Agreement shall mean all information disclosed by Client to Consultant, whether during or before the term of this Agreement, that is not generally known in the Client's trade or industry and shall include, without limitation: (a) concepts and ideas relating to the development and distribution of content in any medium or to the current, future and proposed products or services of Client or its subsidiaries or affiliates; (b) trade secrets, drawings, inventions, know-how, software programs, and software source documents; (c) information regarding plans for research, development, new service offerings or products, marketing and selling, business plans, business forecasts, budgets and unpublished financial statements, licenses and distribution arrangements, prices and costs, suppliers and customers; (d) existence of any business discussions, negotiations or agreements between the parties; and (e) any information regarding the skills and compensation of employees, contractors or other agents of Client or its subsidiaries or affiliates. Confidential Information also includes proprietary or confidential information of any third party who may disclose such information to Client or Consultant in the course of Client's business. Confidential Information does not include information that (x) is or becomes a part of the public domain through no act or omission of Consultant, (y) is disclosed to Consultant by a third party without restrictions on disclosure, or (z) was in Consultant's lawful possession prior to the disclosure and was not obtained by Consultant either directly or indirectly from Client. In addition, this section will not be construed to prohibit disclosure of Confidential Information to the extent that such disclosure is required by law or valid order of a court or other governmental authority; *provided, however*, that Consultant shall first have given notice to Client, if possible, and shall have made a reasonable effort to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued. All Confidential Information furnished to Consultant by Client is the sole and exclusive property of Client or its suppliers or customers. Upon request by Client, Consultant agrees to promptly deliver to Client the original and any copies of the Confidential Information.

6. No Conflict of Interest; Non-Solicitation

6.1 During the term of this Agreement, Consultant will not accept work, enter into a contract, or accept an obligation from any third party, inconsistent or incompatible with Consultant's obligations, or the scope of Services rendered for Client, under this Agreement. Consultant warrants that there is no other contract or duty on its part inconsistent with this Agreement. Consultant agrees to indemnify Client from any and all loss or liability incurred by reason of the actual breach by Consultant of any services agreement with any third party.

6.2 During the term of this Agreement, Consultant will not, without Client's express written consent, directly or indirectly, engage in any activities that are competitive with the Client.

6.3 During the term of this Agreement and for the one (1) year period thereafter, Consultant will not, either directly or through others, solicit, induce, encourage, or participate in soliciting, inducing or encouraging any employee, consultant, or independent contractor of Client to terminate his, her or its relationship with Client, even if Consultant does not initiate the discussion or seek out the contact.

7. Term and Termination. The initial term of this Agreement is for one year from the Effective Date set forth above. Thereafter, this Agreement will automatically renew monthly for 1 month terms, unless Client or Consultant provides 14 days' written notice prior that the Agreement shall not renew. Additionally, either party may terminate this Agreement with or without cause, at any time upon 14 days' prior written notice to the other party.

8. Successors and Assigns. Consultant may not subcontract or otherwise delegate or assign this Agreement or any of its obligations under this Agreement without Client's prior written consent. Any attempted assignment in violation of the foregoing shall be null and void. Subject to the foregoing, this Agreement will be for the benefit of Client's successors and assigns, and will be binding on Consultant's assignees.

9. Governing Law. This Agreement shall be governed in all respects by the laws of the United States of America and by the laws of the State of California, without giving effect to any conflicts of laws principles that require the application of the law of a different jurisdiction.

10. Severability. Should any provisions of this Agreement be held by a court of law to be illegal, invalid or unenforceable, the legality, validity and enforceability of the remaining provisions of this Agreement shall not be affected or impaired thereby.

11. Waiver. The waiver by Client of a breach of any provision of this Agreement by Consultant shall not operate or be construed as a waiver of any other or subsequent breach by Consultant.

12. Injunctive Relief for Breach. Consultant's obligations under this Agreement are of a unique character that gives them particular value; breach of any of such obligations will result in irreparable and continuing damage to Client for which there will be no adequate remedy at law; and, in the event of such breach, Client will be entitled to injunctive relief and/or a decree for specific performance, and such other and further relief as may be proper (including monetary damages if appropriate).

13. Entire Agreement. This Agreement constitutes the entire agreement between the parties relating to this subject matter and supersedes all prior or contemporaneous oral or written agreements concerning such subject matter. The terms of this Agreement will govern all the Services undertaken by Consultant for Client. This Agreement may only be changed or amended by mutual agreement of authorized representatives of the parties in writing. The Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall be taken together and deemed to be one instrument. This Agreement may be executed and delivered by facsimile signature, PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000 (e.g., www.docusign.com).

[Remainder of page intentionally left blank]

The parties have executed this Agreement as of the Effective Date.

CLIENT:

ARS Pharmaceuticals, Inc.

By: /s/ Richard Lowenthal
Name: Richard Lowenthal
Title: Chief Executive Officer

Email: _____

Address:

Marlinspike Group, LLC:

Pratik Shah, PhD
Marlinspike Group, LLC

/s/ Pratik Shah
Signature

President
Title (if applicable)

Email

Address: _____

EXHIBIT A

SERVICES:

Summary: Consultant will utilize the efforts of Pratik Shah, Ph.D. and Sean Jeffries to provide management and business consulting services, as well as business development support, to Client as reasonably requested by Client from time to time.

Consultant will also provide Client with use of its office space and conference room facilities in Carlsbad, CA on an as-available basis from time to time as reasonably requested by Client.

Compensation: \$20,000 per calendar month due on the first of each month.



MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (hereinafter “Agreement”) is made as of the 01 July 2022 (“Effective Date”), between ARS Pharmaceuticals, Inc. (“Company”) and Pacific-Link Regulatory Consulting, Inc. (“PLC”). Company and PLC also are each referred to herein individually as “Party” and collectively as the “Parties.”

BACKGROUND

The Company has products in development and is seeking clinical and regulatory support. The Company wishes to retain PLC to help support the current and future development of products in their pipeline. The Company and PLC are willing to accept such engagement on the terms and conditions of this Agreement. This agreement is intended to support both ad-hoc general support needs as well as complete projects through Work Orders signed by both parties that are included as addendums to this agreement.

In consideration of the mutual promises and covenants herein contained, the parties hereto agree as follows:

1. DUTIES

A. PLC shall provide general support and assistance to the Company with respect to the development of current and future drug products (“Products”), including clinical research support, regulatory support, medical writing, and general consulting. The scope of work may include countries outside the United States as needed. Upon request, PLC shall perform other activities as directed by the Company. After approval of this master agreement, work may be done on an ad-hoc basis per the fee schedule attached, or as a work order with variable and/or fixed costs approved for each discrete project as an amendment to this contract.

B. In the event the Company decides to implement strategies or make business decisions based on any opinions, advice or assistance of PLC, the Company does so at its own risk and without any recourse against the PLC for any opinions, advice or assistance given.

C. PLC also agrees to observe all reasonable policies and directives, including quality systems procedures, promulgated from time to time by Company’s officers and Board of Directors, including but not limited to, providing Company with monthly time sheets setting forth in reasonable detail the amount of hours worked and the services performed.

ARS – PLC

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D. The Parties agree that this Agreement shall not interfere with PLC's ability to undertake other full time employment or pursue other full time business opportunities not involving the Company, nor to restrict PLC's ability to travel or relocate the business residence.

2. FEES AND EXPENSES

A. Company shall pay to PLC fees as outlined in Schedule A of this agreement. Services rendered are payable by the 30th day of the month immediately following the month in which Services were rendered. Ad-hoc general support and consulting shall be considered as based on hourly fees. For significant projects, a work order may be issued based on a defined scope of work and budget. Any approved work order will become an Appendix to this contract. Company shall remit payment to PLC by Company check or wire transfer in a timely manner. If mailed payment is sent to PLC's address set forth in Section 12 hereof or such other address as PLC shall provide to the Company in a written change of address communication.

B. Compensation shall be payable without deductions for federal income, social security, or state income taxes. PLC acknowledges and agrees that this Agreement shall not give or extend to PLC any rights with respect to additional contributions by Company to any deferred compensation plan, bonus plans, or fringe benefits, and further agrees to hold Company harmless from any taxes which may be assessed against PLC in connection with payments to PLC under the terms of this Agreement.

C. During the term of this Agreement, the Company shall reimburse PLC for all business expenses reasonably incurred by PLC in the performance of Services provided that such business expenses were approved by the Company. PLC will submit to the Company a written accounting or other adequate documentary evidence of such expenses consistent with the reimbursement policies of Company. The Company agrees to reimburse PLC for such expenses within fifteen (30th) business days of receipt of each such expense accounting.

3. INDEPENDENT CONTRACTOR

A. In the performance of this Agreement, it is mutually understood and agreed that PLC is at all times acting and performing as an independent contractor with, and not as the employee of, Company, and no act, or failure to act, by any party hereto shall be construed to make or render the other party its partner, joint venturer, employee or associate.



B. PLC shall have no authority to bind the Company to, or assume, enter into, or act on behalf of the Company for, any obligation, agreement or act.

4. CONFIDENTIALITY

As stipulated in the 01 July 2022 Mutual Non-Disclosure Agreement, Company or PLC shall not disclose any of the aforesaid trade secrets or other proprietary information directly or indirectly to any third party, or use them in any way either during the term of this Agreement or at any time thereafter, except as reasonably necessary to perform services pursuant to this Agreement.

5. OWNERSHIP RIGHTS

Except as specifically provided herein, Company shall retain all rights to all Investigational New Drug Applications (INDs), Abbreviated New Drug Applications (ANDAs), New Drug Applications (NDAs) or any other rights whatsoever to the Products whether or not such rights result from PLC's efforts or collaborative efforts on the Products. PLC further agrees that upon demand, PLC will execute and deliver to Company such documents relating to the Products or the Project as may be deemed necessary or advisable by Company for filing in the appropriate regulatory office to protect the legitimate interests of Company. It is recognized and understood that the existing inventions and technologies of Company or the PLC are their separate property, respectively, and are not affected by this Agreement (including, but not limited to the Confidential Information). Neither Party shall have any claims to, nor rights in, such existing inventions and technologies of the other Party. Any and all inventions and discoveries arising from this collaboration, including any inventions, modifications, or discoveries based, in whole or in part, on Confidential Information, are the sole and exclusive property of Company, unless otherwise agreed to by the Parties. Notwithstanding the foregoing, the Company grants an exclusive to PLC, at PLC's expense, to execute any and all applications, assignments or other instruments and give testimony necessary to apply for and obtain letters of patent of the United States or of any foreign country or to otherwise protect Sponsor's interest therein. The obligations of the Parties under this Section 5 shall continue beyond the termination of this Agreement and shall be binding upon the Parties.



6. TERM AND TERMINATION

A. The term of this Agreement shall begin on the Effective Date and shall terminate after 12 months unless terminated earlier pursuant to this Section. The term of this Agreement will be considered extended automatically for an additional 12 months, unless notice is given by either party that the agreement will be discontinued.

B. This Agreement can be terminated by either party upon sixty (60) days prior written notice to the other; provided, however, that Company shall pay PLC for all services rendered prior to the termination.

7. SEVERABILITY

If any provision of this Agreement is held to be unenforceable, invalid or illegal by any court of competent jurisdiction, such unenforceable, invalid or illegal provisions shall not affect the remainder of this Agreement.

8. ENTIRE AGREEMENT

This instrument contains the entire Agreement of the parties and it supersedes any other agreement between Company and PLC. This Agreement cannot be amended, modified or supplemented in any respect except by a subsequent written agreement entered into by both Parties.

9. LAWS

The validity of this Agreement and the interpretation and performance of all its terms shall be governed by the substantive laws of the State of California.

10. WAIVER

Failure of either party hereto to insist upon strict compliance with any of the terms, covenants and conditions hereof shall not be deemed a waiver or relinquishment of any similar right or power hereunder at any subsequent time or of any other provision hereof.

11. INDEMNIFICATION

Company agrees to indemnify and hold harmless PLC, and each of its directors, officers, employees, agents, heirs and assigns from and against any and all losses, claims, damages, liabilities, costs, and expenses (including attorneys' fees and expenses related to the defense of any claims), joint or several, which may be asserted against PLC or for which they may now or hereafter become subject arising in connection with any activity



of the Company, including but not limited to alleged or actual failure by the Company to comply with any requirement applicable to the Company under any federal, state, or local law or regulation, provided that such claims have not been caused by the gross negligence or willful or wanton misconduct of PLC.

12. NOTICES

All notices and any other acts required or permitted under this Agreement shall be in writing, and shall be sufficiently given if delivered to the addressees in person, by Federal Express or similar receipted delivery, or if mailed, postage prepaid, by certified mail, return receipt requested, as follows:

COMPANY:

Kathleen D. Scott
ARS Pharmaceuticals, Inc.
11682 El Camino Real, Suite 120
San Diego, CA 92130

PLC:

Erica A. Kopensky
Pacific-Link Regulatory Consulting, Inc.

12. ASSIGNMENT

Neither Party shall assign or delegate any rights, duties or obligations under this Agreement, in whole or in part, without the prior written consent of the other Party.

13. COUNTERPARTS

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. The execution of this Agreement may be by actual or facsimile signature.

14. MERGER OR SALE OF THE COMPANY

In the event the Company merges into or is acquired by another company, the total outstanding balance of monies due PLC may, at PLC's option, be accelerated and immediately become payable to PLC.

ARS – PLC

Confidential



IN WITNESS WHEREOF, the Parties hereto have executed this Agreement effective as of the date first written above.

ARS Pharmaceuticals, Inc.

Pacific-Link Regulatory Consulting, Inc.

By: /s/ Kathleen D. Scott

/s/ Erica A. Kopensky

Kathleen D. Scott
CFO

Erica A. Kopensky
Controller

Date: July 12, 2022

Date: July 12, 2022

ARS – PLC

Confidential

ARS Pharmaceuticals Closes Merger with Silverback Therapeutics

Over \$280 Million in Combined Cash and Securities and at least Three Years Operating Runway to Support Launch and Commercialization of neffy® in the U.S., if Approved

*neffy® NDA Currently Under FDA Review; PDUFA Anticipated Mid-2023
MAA validated in the European Union Under Review*

SAN DIEGO – November 8, 2022 - ARS Pharmaceuticals, Inc. (Nasdaq: SPRY) (ARS or the Company), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis, today announced the closing of its merger with Silverback Therapeutics, Inc. (Silverback). This follows the satisfaction of all customary closing conditions, including approval of the merger by the stockholders of Silverback. The combined company will operate as ARS Pharmaceuticals, Inc., and shares of its common stock will commence trading under the trading symbol “SPRY” on November 9, 2022, on the Nasdaq Global Select Market. Effective as of the closing of the merger, ARS has over \$280 million in cash and marketable securities.

ARS has designed and developed **neffy®** to provide injection-like absorption of epinephrine, in a small, easy-to-carry, easy-to-use, rapidly administered, and reliable nasal spray device for the treatment of Type I severe allergic reactions, including anaphylaxis. With its needle-free administration, **neffy®** may help eliminate the anxiety and hesitation associated with using an epinephrine injection device.

The Company’s New Drug Application (NDA) submission for **neffy®** is currently under review by the U.S. Food and Drug Administration (FDA) with an anticipated Prescription Drug User Fee Act (PDUFA) date in mid-2023. ARS has also filed and cleared validation of a Marketing Authorization Application (MAA) in Europe, which is currently under review by the European Medicines Agency (EMA).

“This is a transformative time for ARS, enabling our move to a publicly traded organization and providing important resources to support the potential launch and commercialization of **neffy®**, upon approval,” said Richard Lowenthal, co-founder, president and CEO of ARS. “Millions of individuals suffer from severe allergic reactions, and unfortunately, too many do not treat their symptoms in time or at all with injection devices, leading to disease progression and potentially dangerous or life-threatening outcomes. With **neffy®**, our goal is to eliminate the fear of administering epinephrine with a small, needle-free and easy-to-use nasal spray. Our team at ARS believes that **neffy®** can add significant clinical value to the community by providing an alternative to the currently approved injection devices for patients and caregivers that either do not carry, avoid using or hesitate to use their epinephrine injection device. With the funding from our merger with Silverback, ARS is also dedicated to significant efforts on patient education and support of advocacy groups working to protect the community of allergy patients with this disease.”

Post-merger, ARS has approximately 94 million shares of common stock outstanding. Prior ARS equityholders collectively own approximately 62% of the combined company and prior Silverback equityholders collectively own approximately 38% of the combined company, in each case on a fully diluted basis using the treasury stock method and excluding out-of-the-money options of Silverback.

Effective as of the closing of the merger, the board of directors of ARS (Board) will be comprised of eleven directors, including three directors of Silverback:

- Pratik Shah, Ph.D., chairman of the Board;
- Rajeev Dadoo, Ph.D., managing partner, SR One Capital Management, L.P.;
- Saqib Islam, J.D. chief executive officer of Springworks Therapeutics, Inc.;
- Michael Kelly, former president of U.S. operations for Adapt Pharma, Inc.;
- Peter Kolchinsky, Ph.D., managing partner, RA Capital Management, L.P.;
- Jonathan Leff, partner, Deerfield Management and chairman of the Deerfield Institute;
- Richard Lowenthal, M.Sc., MSEL, co-founder, president and chief executive officer of ARS;
- Brent Saunders, executive chairman of The Beauty Health Company
- Phillip Schneider, board member of Longboard Pharmaceuticals Inc., former chief financial officer & senior vice president of IDEC Pharmaceuticals Corporation;
- Laura Shawver, Ph.D., chief executive officer of Capstan Therapeutics and former chief executive officer of Silverback;
- Peter Thompson, M.D., private equity partner at Orbimed Advisors LLC.

SVB Securities LLC acted as financial advisor to Silverback, and Cooley LLP served as legal counsel to Silverback for the merger. Inceptiv Law served as legal counsel to ARS for the merger.

About Type I Allergic Reactions including Anaphylaxis

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, the only FDA-approved medication for these reactions. While epinephrine autoinjectors 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. There are approximately 25 to 40 million people in the United States who experience Type I severe allergic reactions. Of those, 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.

About ARS Pharmaceuticals, Inc.

ARS is a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis. The Company is developing *neffy*[®] (previously referred to as ARS-1), an intranasal epinephrine product in clinical development for patients and their caregivers with Type I allergic reactions including food, medications and insect bites that could lead to life-threatening anaphylaxis. For more information, visit www.ars-pharma.com.

Forward Looking Statements

Statements in this press release that are not purely historical in nature are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, the design and potential benefits of *neffy*[®]; the anticipated PDUFA date; the potential regulatory approval and commercialization of *neffy*[®]; the potential market opportunity for *neffy*[®]; the planned use of funding from the merger; and other statements that are not historical fact. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “anticipate,” “plans,” “expects,” “will,” “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the ability to obtain and maintain regulatory approval for *neffy*[®]; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from *neffy*[®]; the labelling for *neffy*[®], if approved; the scope, progress and expansion of developing and commercializing *neffy*[®]; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS’s ability to protect its intellectual property position; and the impact of government laws and regulations. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption “Risk Factors” and elsewhere in ARS’s most recent filings with the U.S. Securities and Exchange Commission (SEC), including its preliminary proxy statement filed on August 11, 2022 and definitive proxy statement on October 6, 2022 and any reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from time to time and available at www.sec.gov. These documents can be accessed on ARS’s web page at ir.ars-pharma.com by clicking on the link “Financials & Filings.”

The forward-looking statements included in this presentation are made only as of the date hereof. ARS assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

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