# 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**

**Date of Report (Date of earliest event reported): October 21, 2022**

# SILVERBACK THERAPEUTICS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39756** | **81-1489190** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **500 Fairview Ave N, Suite 600**<br>**Seattle, Washington** | **98109** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (206) 456-2900**

**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 obligation 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 | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, $0.0001 par value per share** | **SBTX** | **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. ☐

**Item 8.01 Other Events.**

**Press Release**

On October 21, 2022, Silverback Therapeutics, Inc. ("Silverback") issued a press release announcing the that the U.S. Food and Drug Administration has accepted for review ARS Pharmaceuticals, Inc.'s ("ARS Pharma") New Drug Application for *neffy*® for the emergency treatment of allergic reactions (type I) including anaphylaxis in adults and children ≥30 kg (66 lbs). The press release is attached hereto as Exhibit 99.1.

**Cautionary Statement Regarding Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements which include, but are not limited to, statements regarding the potential benefits of *neffy*, the expected Prescription Drug User Fee Act target action date, the expected timing, completion and effects of the proposed merger between Silverback and ARS Pharma (the "Merger") and the expected focus of the combined company following the Merger. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Silverback's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks, and changes in circumstances, including but not limited to risks and uncertainties related to: the ability of the parties to consummate the proposed Merger in a timely manner or at all; the satisfaction (or waiver) of closing conditions to the consummation of the proposed Merger, including with respect to the approval of Silverback's stockholders; potential delays in consummating the proposed Merger; the ability to obtain and maintain regulatory approval for *neffy*; the impact of health epidemics, including the COVID-19 pandemic, on the parties' respective businesses and the actions the parties may take in response thereto; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; the effect of the pendency of the proposed Merger on Silverback's business relationships, operating results and business generally; costs related to proposed Merger; and the outcome of any legal proceedings that may be instituted against Silverback, ARS Pharma or any of their respective directors or officers related to the merger agreement or the proposed Merger. 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 Silverback's most recent filings with the U.S. Securities and Exchange Commission ("SEC"), including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and any subsequent 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 Silverback's web page at https://ir.silverbacktx.com/ by clicking on the link "Financials & Filings."

The forward-looking statements included in this Current Report on Form 8-K are made only as of the date hereof. Silverback assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

**Additional Information and Where to Find It**

In connection with the proposed Merger, Silverback filed with the SEC the preliminary proxy statement on August 11, 2022 and a definitive proxy statement on October 6, 2022 relating to the proposed Merger and other relevant documents. The definitive proxy statement has been mailed to Silverback's stockholders as of September 19, 2022, the record date established for voting on the proposed Merger and any other matters to be voted on at the special meeting of Silverback's stockholders. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS, ANY AMENDMENTS OR SUPPLEMENTS THERETO AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENTS WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT SILVERBACK, ARS PHARMA, AND THE PROPOSED MERGER. Investors and security holders may obtain free copies of these documents (when they are available) on the SEC's web site at www.sec.gov, on Silverback's website at https://ir.silverbacktx.com/ or by contacting Silverback's Investor Relations via email at IR@silverbacktx.com or by telephone at (206) 736-7946.

**Participants in the Solicitation**

Silverback and its directors and certain of its executive officers may be deemed participants in the solicitation of proxies from the stockholders of Silverback in connection with the proposed Merger and any other matters to be voted on at the special meeting. Information regarding the names, affiliations and interests of such directors and executive officers have been included in the preliminary and definitive proxy statements related to the proposed Merger. Additional information regarding such directors and executive officers is included in Silverback's definitive proxy statement on Schedule 14A for the 2022 Annual Meeting of the Stockholders, which was filed with the SEC on April 28, 2022.

Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies of Silverback's stockholders in connection with the proposed Merger and any other matters to be voted upon at the special meeting are set forth in the preliminary and definitive proxy statements for the proposed Merger.

These documents are available free of charge as described in the preceding paragraph.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release of Silverback Therapeutics, Inc., dated October 21, 2022. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**SIGNATURES**

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

**SILVERBACK THERAPEUTICS, INC.**

Date: October 21, 2022

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

**Exhibit 99.1**

**Silverback Therapeutics, Inc. announces the FDA's acceptance of ARS Pharmaceuticals' NDA for *neffy*® (epinephrine nasal spray) for the Treatment of Allergic Reactions (type I) including Anaphylaxis**

- ***neffy*** *has potential to be the first non-injectable medicine indicated to treat allergic reactions (type I) including anaphylaxis in the U.S., if approved*

SEATTLE – October 21, 2022 – Silverback Therapeutics, Inc. (Nasdaq: SBTX) ("Silverback") today announced that the U.S. Food and Drug Administration (FDA) has accepted for review ARS Pharmaceuticals, Inc.'s (ARS Pharma) New Drug Application (NDA) for ***neffy*** for the emergency treatment of allergic reactions (type I) including anaphylaxis in adults and children ≥30 kg (66 lbs). If approved by the FDA, *neffy* would be the first non-injectable treatment available to patients with allergic reactions (type I) including anaphylaxis.

The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date that is anticipated in mid-2023.

"The FDA acceptance of our NDA for ***neffy*** is a major milestone in our efforts to bring to patients the ability to deliver epinephrine with comparable pharmacokinetics to an intramuscular injection, but in a needle-free and simple to administer nasal spray," said Richard Lowenthal, President and CEO of ARS Pharma. "We appreciate that the FDA recognizes the potential clinical benefit of this novel approach to treating patients with severe allergies and look forward to working with the FDA during this process, with the goal of potentially changing the treatment paradigm for the millions of patients with or at-risk for severe allergic reactions (type I)."

The NDA submission to the FDA was based on data from four primary registration studies supporting that a 2 mg intranasal dose of ***neffy*** met all clinical endpoints recommended by regulators and that its pharmacokinetics were within the range of approved epinephrine injection products. These data included studies in adults, with self-administration and caregiver administration, as well as in children with Type I allergies ≥30 kg (66 lbs). In addition, ***neffy*** has been well-tolerated to date with more than 500 individuals receiving at least one dose, and many with repeat administration. The majority of adverse events in clinical trials were mild in nature without any meaningful nasal irritation or pain.

**About Allergic Reactions (Type I) 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 Pharma 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***® (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.

**About Silverback Therapeutics, Inc.**

Silverback is a biopharmaceutical company focused on leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered and tissue targeted therapeutics for the treatment chronic viral infections, cancer, and other serious diseases. Silverback's platform enables the strategic pairing of proprietary payloads that modulate key disease modifying pathways with monoclonal antibodies directed at specific disease sites. Silverback Therapeutics is located in Seattle, Washington. To learn more, visit www.silverbacktx.com.

On July 21, 2022, Silverback and ARS Pharma announced that the companies entered into a definitive agreement under which ARS Pharma will merge with Silverback in an all stock transaction. Following the proposed merger (the "Merger") the combined company will focus on the potential regulatory approval and commercialization of ***neffy***, ARS Pharma's investigational epinephrine nasal spray for the treatment of Type I allergic reactions including anaphylaxis. The Merger is subject to customary closing conditions, including the approval by Silverback's stockholders. The Merger is currently expected to close in the fourth quarter of 2022.

**Cautionary Statement Regarding Forward-Looking Statements**

This communication contains forward-looking statements which include, but are not limited to, statements regarding the potential benefits of *neffy*, the expected PDUFA target action date, the expected timing, completion and effects of the Merger and the expected focus of the combined company following the Merger. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Silverback's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks, and changes in circumstances, including but not limited to risks and uncertainties related to: the ability of the parties to consummate the proposed Merger in a timely manner or at all; the satisfaction (or waiver) of closing conditions to the consummation of the proposed Merger, including with respect to the approval of Silverback's stockholders; potential delays in consummating the proposed Merger; the ability to obtain and maintain regulatory approval for *neffy*; the impact of health epidemics, including the COVID-19 pandemic, on the parties' respective businesses and the actions the parties may take in response thereto; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; the effect of the pendency of the proposed Merger on Silverback's business relationships, operating results and business generally; costs related to proposed Merger; and the outcome of any legal proceedings that may be instituted against Silverback, ARS Pharma or any of their respective directors or officers related to the merger agreement or the proposed Merger. 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 Silverback’s most recent filings with the U.S. Securities and Exchange Commission (“SEC”), including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and any subsequent 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 Silverback’s web page at https://ir.silverbacktx.com/ by clicking on the link “Financials & Filings.”

The forward-looking statements included in this communication are made only as of the date hereof. Silverback assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

**Additional Information and Where to Find It**

In connection with the proposed Merger, Silverback filed with the SEC the preliminary proxy statement on August 11, 2022 and a definitive proxy statement on October 6, 2022 relating to the proposed Merger and other relevant documents. The definitive proxy statement has been mailed to Silverback’s stockholders as of September 19, 2022, the record date established for voting on the proposed Merger and any other matters to be voted on at the special meeting of Silverback’s stockholders. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS, ANY AMENDMENTS OR SUPPLEMENTS THERETO AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENTS WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT SILVERBACK, ARS PHARMA, AND THE PROPOSED MERGER. Investors and security holders may obtain free copies of these documents (when they are available) on the SEC’s web site at www.sec.gov, on Silverback’s website at https://ir.silverbacktx.com/ or by contacting Silverback’s Investor Relations via email at IR@silverbacktx.com or by telephone at (206) 736-7946.

**Participants in the Solicitation**

Silverback and its directors and certain of its executive officers may be deemed participants in the solicitation of proxies from the stockholders of Silverback in connection with the proposed Merger and any other matters to be voted on at the special meeting. Information regarding the names, affiliations and interests of such directors and executive officers have been included in the preliminary and definitive proxy statements related to the proposed Merger. Additional information regarding such directors and executive officers is included in Silverback’s definitive proxy statement on Schedule 14A for the 2022 Annual Meeting of the Stockholders, which was filed with the SEC on April 28, 2022.

Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies of Silverback’s stockholders in connection with the proposed Merger and any other matters to be voted upon at the special meeting are set forth in the preliminary and definitive proxy statements for the proposed Merger.

These documents are available free of charge as described in the preceding paragraph.

**Silverback Media Contacts:**

Jason Spark

Canale Communications

jason.spark@canalecomm.com

**Silverback Investor Contacts:**

Miguel Arcinas

Silverback Therapeutics

ir@silverbacktx.com