



DIVISION OF  
CORPORATION FINANCE

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

September 9, 2022

Laura Shawver, Ph.D.  
Chief Executive Officer  
Silverback Therapeutics, Inc.  
500 Fairview Ave. N, Suite 600  
Seattle, Washington 98109

**Re: Silverback Therapeutics, Inc.**  
**Preliminary Proxy Statement on Schedule 14A**  
**Filed August 11, 2022**  
**File No. 001-39756**

Dear Dr. Shawver:

We have reviewed your filing and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

Preliminary Proxy Statement on Schedule 14A filed August 11, 2022

Summary, page 11

1. We note various statements throughout the filing based on the assumption that "*neffy* is approved by the FDA within ARS Pharma's expected timeframe". However, we also note that ARS Pharma has not yet submitted a NDA to the FDA in relation to *neffy*. Please revise your disclosure in all places where such assumption appears to make clear that the timing of regulatory approvals is outside of the companies' control, may be delayed, and is uncertain.
2. We note your disclosure that "[d]ata from ARS Pharma's studies of *neffy* in more than 500 subjects demonstrated epinephrine was delivered at doses that are considered efficacious[.]" We also note your disclosure on page 171 that your product demonstrates a "[p]otentially improved safety profile compared to injection products[.]" Please revise these and similar statements indicating or implying that your product is, or will be determined to be, safe and effective. Safety and efficacy determinations are solely within

the authority of the FDA or similar regulators.

Risk Factors, page 25

3. We note your disclosure on page 175 that in 2020 ARS Pharma signed an exclusive licensing agreement with Recordati to commercialize *neffy* in Russia and the Commonwealth of Independent States. Please discuss here or elsewhere in your proxy statement the direct or indirect impact of Russia's invasion of Ukraine on this licensing agreement. In addition, please also consider any impact:
- resulting from sanctions, limitations on obtaining relevant government approvals, currency exchange limitations, or export or capital controls, including the impact of any risks that may impede your ability to sell assets located in Russia or Belarus, including due to sanctions affecting potential purchasers;
  - resulting from the reaction of your investors, employees, customers, and/or other stakeholders to any action or inaction arising from or relating to the invasion, including the payment of taxes to the Russian Federation; and
  - that may result if Russia or another government nationalizes your assets or operations in Russia or Belarus.

Additionally, to the extent material, please disclose the risk that you may suffer reputational damage from your potential operations in Russia during the ongoing conflict between Russia and Ukraine, which could negatively impact the overall demand for your products or services, including your operations or your results of operations.

Risks Related to the Combined Company

The market price of the combined company's common stock is expected to be volatile..., page 94

4. We note your disclosure that following a decline in Silverback's stock price, a federal securities class action complaint was filed against Silverback and certain of its officers and directors in the U.S. District for the Western District of Washington. Please revise this disclosure to explain when this litigation began and the current status of the litigation.

The combined company's amended and restated certificate of incorporation will designate...the exclusive forums..., page 98

5. Please revise your disclosure here to also note that such an exclusive forum provision may make it more expensive for stockholders to bring a claim against you.

The Merger

Background of the Merger, page 110

6. We note your disclosure that following scientific due diligence, "Silverback's senior management made the decision not to move forward with Company D in the process due to it meeting fewer Criteria than the other reverse merger targets Silverback continued to

advance[.]" Please explain which of the Criteria Company D did not meet.

7. We note your disclosure that Silverback's senior management "determined, based upon a[n] assessment of the Criteria, that ARS Pharma was the most promising reverse merger candidate[.]" Please provide further disclosure regarding Silverback's senior management's assessment of the Criteria when it determined that ARS Pharma was the most promising reverse merger candidate. For example, please explain which criterion weighed in favor of ARS Pharma as opposed to Company B or any of the other merger candidates.
8. We note your disclosure that "[t]he Transaction Committee recommended to the Silverback Board that Silverback pursue a reverse merger with ARS Pharma based on scientific evaluation, competitive differentiation, regulatory risk, potential valuation consideration relative to the opportunity, commercial potential and commercial launch plan feasibility, meaningful near-term catalysts to achieve value appreciation using Silverback's cash contribution, in addition to ARS Pharma's own cash, estimated to be approximately \$40 million as of May 17, 2022, including based on input from an experienced commercial advisor engaged to assess the market opportunity." Please clarify whether the experienced commercial advisor referenced here was a separate advisor from SVB Securities. If so, please disclose the identity of that commercial advisor and describe its role in this process.
9. We note your disclosure that on July 1, 2022 and on July 11, 2022, there were outstanding issues in the merger agreement. Please describe which terms remained at issue during these times.

#### Opinion of Silverback's Financial Advisor

#### Additional Factors Observed by SVB Securities - ARS Pharma Valuation Analysis - Selected Companies, page 128

10. In relation to the Selected Companies, please revise your disclosure to explain the "certain financial and operating characteristics that could be considered similar to those of ARS Pharma" that were considered in selecting the companies, as well as any other criteria used in selecting the companies for analysis. In this regard, we note that the statement that each of the companies either has a lead product being marketed or in regulatory development is quite broad and provides little insight into the reasons for selection. Please also disclose whether, and if so why, SVB Securities excluded any companies meeting the selection criteria from the analyses.

#### Certain Unaudited Financial Projections, page 129

11. We note your disclosure that the financial projections prepared by ARS Pharma and supplied to Silverback assumed, among other things, that *neffy* will launch in the third quarter of 2023. However, we note that ARS Pharma has not yet submitted a NDA to the FDA. Please explain how this timing was considered, as the launch of *neffy* is central to

the projection calculations, and why such assumption was deemed appropriate.

Description of ARS Pharma's Business

Our Pipeline: Suite of neffy Programs, page 173

12. Please remove the statements on page 173 that you "anticipate approval in 2023" for *neffy*, as the timing of regulatory approvals is outside of the company's control, may be delayed, and is uncertain.

Our Strategy, page 174

13. Please revise your disclosure to provide more information regarding the feedback received by ARS Pharma from the FDA in a pre-NDA meeting held in mid-2021 as well as prior FDA interactions, referenced on page 174.

Clinical Development of neffy, page 179

14. Please provide further details regarding the clinical trials conducted by ARS Pharma, including, but not limited to, how many trials were conducted, where they were conducted, how patients were selected, whether the trials were conducted by third parties, and if so, the identities of those third parties.

Legal Proceedings, page 195

15. Please provide further detail regarding the subject of the 414 patent (i.e., the intellectual property underlying the 414 patent).

Unaudited Condensed Combined Financial Statements , page 247

16. Please state that the information in the pro forma financial statements are presented in thousands, to be consistent with the financial statements of Silverback and ARS Pharmaceuticals Inc.
17. With respect to Note 3, you indicated on page 143 that the exchange ratio and the post-Merger equity ownership may change if Silverback Net Cash is between \$210 million and \$255 million. Please state how this will change the estimated shares of Silverback common stock to be issued to ARS Pharma stockholders upon closing and the transaction accounting adjustments.

General

18. Please supplementally provide us with copies of all materials prepared by SVB Securities LLC and shared with your board of directors and their representatives, including any board books, transcripts and summaries of oral presentations, that were material to the board's decision to approve the merger and the transactions contemplated thereby. We may have additional comments after we review those materials

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We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

You may contact Christie Wong at 202-551-3684 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Joshua Gorsky at 202-551-7836 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Kenneth J. Rollins, Esq.