

**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): May 12, 2022

Silverback Therapeutics, 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.)

500 Fairview Ave N, Suite 600
Seattle, Washington
(Address of principal executive offices)

98109
(Zip Code)

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

N/A
(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(s)	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 2.02 Results of Operations and Financial Condition.

On May 12, 2022, Silverback Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item and the exhibit attached hereto are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether filed before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Silverback Therapeutics, Inc., dated May 12, 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.

By: /s/ Laura Shawver, Ph.D.

Laura Shawver, Ph.D.
Chief Executive Officer

Dated: May 12, 2022

SILVERBACK

THERAPEUTICS

Silverback Therapeutics Reports First Quarter 2022 Financial Results and Provides Business Update

SEATTLE – May 12, 2022 – Silverback Therapeutics, Inc. (Nasdaq: SBTX) (“Silverback”), a biopharmaceutical company leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of chronic viral infections, cancer, and other serious diseases, today reported financial results for the first quarter ended March 31, 2022 and provided a business update.

“In the first quarter of 2022, we have made significant progress in advancing the preclinical development of SBT8230, a first-in-class antibody-drug conjugate that we believe has the potential to drive functional cure in patients with chronic hepatitis B (CHBV) by eliciting a liver-localized anti-viral response,” said Laura Shawver, Ph.D., chief executive officer of Silverback. “We believe that activating the immune response is an important component of a functional cure and may be combined with treatments that target the HBV life cycle to improve durability. Our team is on track to complete a regulatory submission in the fourth quarter of 2022, enabling the planned initiation of the single ascending dose healthy volunteer cohort of the Phase 1 study in the first quarter of 2023. We plan to report data from this cohort in the second half of 2023.”

SBT8230 (ASGR1-TLR8 ImmunoTAC conjugate for chronic HBV)

- **Initiated Phase 1-enabling toxicology study for SBT8230 in the first quarter of 2022 and on track to complete Phase 1 regulatory submission in the fourth quarter of 2022.** Silverback expects to open enrollment for the single ascending dose healthy volunteer cohort of the Phase 1 study in the first quarter of 2023 and anticipates reporting data from this portion of the study in the second half of 2023. SBT8230 is comprised of an ASGR1 monoclonal antibody conjugated to a TLR8 linker-payload. ASGR1 is highly expressed in liver and is restricted in its expression to this organ. SBT8230 is designed to elicit a liver-localized anti-viral immune response and has the potential to improve the therapeutic window observed with untargeted, orally administered TLR8 agonists in CHBV, which have shown promise preclinically, but have been limited by toxicities in the clinic associated with immune activation in the gastrointestinal tract.

ImmunoTAC Discovery Programs

- **Silverback continues to advance discovery programs, with an update anticipated in the fourth quarter of 2022.** Discovery efforts are focused on evaluating and developing new antigen binding domains specific for targets of interest (including antibodies), next-generation linker technologies, and both agonist and antagonist small molecule payloads, that may be combined to create novel tissue-targeted antibody conjugates.



First Quarter Financial Results

For the first quarter ended March 31, 2022, Silverback reported a net loss of \$24.6 million, compared to a net loss of \$18.9 million for the comparable period in 2021.

Research and development expenses for the first quarter ended March 31, 2022 were \$16.9 million, compared to \$12.2 million for the same period in 2021. The increase in the Company's research and development expenses in 2022 were primarily attributable to an increase in direct costs related to preclinical research efforts, including the Company's SBT8230 program, and increases in personnel-related expenses as operations grew in support of program advances.

General and administrative expenses for the first quarter ended March 31, 2022 were \$7.8 million, compared to \$6.6 million for the same period in 2021. The increase in general and administrative expenses in 2022 were primarily attributable to an increase in personnel-related expenses, including increases in salaries, bonuses, and stock-based compensation. The increase in general and administrative expenses in 2022 was also due to an increase in legal fees, professional fees, and other various general and administrative expenses as we now operate as a public company.

As of March 31, 2022, Silverback reported cash, cash equivalents, and investments of \$298.1 million compared to \$319.1 million at December 31, 2021, which is expected to fund operating expenses and capital expenditure requirements into the second half of 2026. As of March 31, 2022, Silverback had 35,145,281 shares of common stock outstanding.

About Silverback Therapeutics

Silverback Therapeutics, Inc. 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.

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Forward-Looking Statements

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, Silverback's plans and ability to bring new treatments to patients in need, including the progress and expected timing of Silverback's drug development programs and planned clinical trials, the timing for data and program updates, the potential benefits of SBT8230, the strength of Silverback's balance sheet and the adequacy of cash on hand. Factors that may cause actual results to differ materially include the risk that compounds that appeared promising in early research or preclinical trials do not demonstrate safety and/or efficacy in later preclinical studies or clinical trials, the risk that Silverback may not obtain approval to market its product candidates, uncertainties associated with regulatory filings and applications, risks associated with reliance on third parties to successfully conduct research, preclinical studies or clinical trials, the risks associated with reliance on outside financing to meet capital requirements, and other risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "promise," "potential," "expects," "plans," "anticipates," "intends," "continues," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties that Silverback faces, please refer to Silverback's periodic and other filings with the Securities and Exchange Commission, which are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and Silverback assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact:

Miguel Arcinas
Silverback Therapeutics
(206) 736-7946
ir@silverbacktx.com

Media Contact:

Jason Spark
Canale Communications
(619) 849-6005
jason.spark@canalecomm.com

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Silverback Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and par value data)
(unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 233,989	\$ 254,045
Short-term investments	19,858	—
Prepaid expenses and other current assets	7,485	7,447
Total current assets	261,332	261,492
Long-term investments	43,973	64,780
Restricted cash	250	250
Right-of-use asset	4,484	4,733
Property and equipment, net	2,430	2,212
Total assets	\$ 312,469	\$ 333,467
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,631	\$ 2,078
Accrued expenses	11,054	11,727
Current portion of lease liability	1,123	1,087
Total current liabilities	14,808	14,892
Lease liability, net of current portion	4,431	4,760
Total liabilities	19,239	19,652
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$0.0001 par value per share; 10,000,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value per share; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021, 35,145,281 and 35,133,934 shares issued and 35,123,330 and 35,107,651 shares outstanding at March 31, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	505,317	500,349
Accumulated other comprehensive loss	(1,248)	(326)
Accumulated deficit	(210,843)	(186,212)
Total stockholders' equity	293,230	313,815
Total liabilities and stockholders' equity	\$ 312,469	\$ 333,467

SILVERBACK THERAPEUTICS

Silverback Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 16,897	\$ 12,239
General and administrative	7,801	6,646
Total operating expenses	24,698	18,885
Loss from operations	(24,698)	(18,885)
Interest income, net	67	18
Net loss	\$ (24,631)	\$ (18,867)
Unrealized loss on available-for-sale securities	(922)	—
Comprehensive loss	\$ (25,553)	\$ (18,867)
Net loss per share, basic and diluted	\$ (0.70)	\$ (0.54)
Weighted-average shares used in computing net loss per share, basic and diluted	35,114,131	34,773,950