

**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 13, 2021

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 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 13, 2021, Silverback Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended March 31, 2021. 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 13, 2021.

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 13, 2021

SILVERBACK

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Silverback Therapeutics Reports First Quarter 2021 Financial Results

SEATTLE – May 13, 2021 – Silverback Therapeutics, Inc. (Nasdaq: SBTX) (“Silverback”), a clinical-stage biopharmaceutical company leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered, tissue targeted therapeutics for the treatment of cancer, chronic viral infections, and other serious diseases, today reported financial results for the first quarter ended March 31, 2021 and provided a business update.

“In our first quarter as a public company, our team continues to execute on Silverback’s mission to bring tissue-targeted therapies to patients in need,” said Laura Shawver, Ph.D., chief executive officer of Silverback. “We are on track to report interim clinical data for SBT6050 in the second half of this year, and we are equally excited about the progress and preclinical data emerging from SBT6290 and SBT8230, highlighting the broad applicability of our ImmunoTAC platform.”

Recent Highlights

- ***SBT6050 (HER2-TLR8 ImmunoTAC) continues to advance through monotherapy and pembrolizumab combination dose escalation arms of the Phase 1/1b clinical study.*** Silverback is on track to deliver interim clinical data from the monotherapy dose escalation arm of the study in the second half of 2021.
- ***GLP toxicology studies have commenced for SBT6290 (Nectin4-TLR8 ImmunoTAC), with an IND submission anticipated in the fourth quarter of 2021.*** Dosing has been initiated in the GLP toxicology study and GMP manufacturing of the Phase 1 clinical supply is underway. In April 2021, Silverback presented data at the American Association of Cancer Research Annual Meeting 2021. These preclinical data showed that SBT6290 activates human myeloid cells in a Nectin4-dependent manner and that a SBT6290 mouse surrogate confers single agent anti-tumor activity in preclinical studies.
- ***SBT8230 (ASGR1-TLR8 ImmunoTAC for chronic HBV) continues to advance through preclinical development with CMC activities underway.*** GLP toxicology studies are expected to commence in the first quarter of 2022.
- ***Appointed Maria Koehler, M.D., Ph.D. to Board of Directors.*** In March 2021, Silverback appointed Dr. Koehler, M.D., Ph.D. to its board of directors, bringing more than 20 years of clinical development leadership experience.



First Quarter Financial Results

For the first quarter ended March 31, 2021, Silverback reported a net loss of \$18.9 million, compared to a net loss of \$5.3 million for the comparable period in 2020. Net loss for the first quarter of 2021 included non-cash stock-based compensation expense of \$4.3 million compared to \$47,000 for the same period in 2020.

Research and development expenses for the first quarter ended March 31, 2021 were \$12.2 million, compared to \$4.4 million for the same period in 2020. The increases in the Company's research and development expenses in 2021 were primarily attributable to the advancement of pipeline programs, including SBT6290 and SBT8230, into preclinical development and the continued development of SBT6050. Silverback also incurred additional personnel-related expenses as operations grew in support of program advances.

General and administrative expenses for the first quarter ended March 31, 2021 were \$6.6 million, compared to \$0.8 million for the same period in 2020. The increases in general and administrative expenses were primarily attributable to an increase in personnel-related expenses due to increased headcount in 2020, including new executives, as well as increases in salaries, bonuses, and stock-based compensation. The increases in general and administrative expenses were 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, 2021, Silverback reported cash and cash equivalents of \$374.2 million, compared to \$386.6 million at December 31, 2020, which is expected to fund operating expenses and capital expenditure requirements for at least the next 24 months.

About Silverback Therapeutics

Silverback Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on leveraging its proprietary ImmunoTAC technology platform to develop systemically delivered and tissue targeted therapeutics for the treatment of cancer, chronic viral infections, 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. Initially, Silverback is creating a new class of targeted immuno-oncology agents that direct a TLR8 agonist myeloid cell activator to the tumor microenvironment in solid tumors to promote cancer cell killing. Silverback Therapeutics is located in Seattle, Washington. To learn more, visit www.silverbacktx.com.

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 our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, Silverback's plans and ability to bring new treatments to patients in need, the progress and expected timing of Silverback's drug development programs and clinical trials, 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 clinical 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 performing clinical trials, regulatory filings and applications, risks associated with reliance on third parties to successfully conduct clinical trials, risks associated with the impact of the COVID-19 pandemic on our business and the global economy, the risks associated with reliance on outside financing to meet capital requirements, the risks associated with losing key members of management 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.

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

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 374,205	\$ 386,569
Prepaid expenses and other current assets	4,141	4,087
Total current assets	378,346	390,656
Property and equipment, net	1,603	1,618
Restricted cash	350	350
Right-of-use asset	1,900	2,180
Total assets	\$ 382,199	\$ 394,804
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,374	\$ 2,583
Accrued expenses	5,799	5,278
Term loan payable, net	495	844
Current portion of lease liability	927	896
Total current liabilities	11,595	9,601
Lease liability, net of current portion	2,055	2,326
Total liabilities	13,650	11,927
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$0.0001 par value per share; 10,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value per share; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020, 34,903,497 and 34,801,537 shares issued, and 34,827,204 and 34,701,274 shares outstanding at March 31, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	484,147	479,608
Accumulated deficit	(115,601)	(96,734)
Total stockholders' equity	368,549	382,877
Total liabilities, and stockholders' equity	\$ 382,199	\$ 394,804

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

	Three Months Ended	
	March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 12,239	\$ 4,414
General and administrative	6,646	828
Total operating expenses	18,885	5,242
Loss from operations	(18,885)	(5,242)
Interest income (expense), net	18	(37)
Net loss and comprehensive loss	\$ (18,867)	\$ (5,279)
Net loss per share applicable to common stockholders, basic and diluted	\$ (0.54)	\$ (7.89)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	34,773,950	669,033