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): August 12, 2021

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 **Seattle, Washington**	**98109**
(Address of principal executive offices)	**(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 August 12, 2021, Silverback Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the six months ended June 30, 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.

Exhibit No.	Description
99.1	Press Release of Silverback Therapeutics, Inc., dated August 12, 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: August 12, 2021

Silverback Therapeutics Reports Second Quarter 2021 Financial Results and Provides Business Update

SEATTLE – August 12, 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 second quarter ended June 30, 2021 and provided a business update.

"The second quarter was notable for the significant progress we made across our entire pipeline of tissue-targeted therapies, with SBT6050, our HER2-TLR8 ImmunoTAC leading the way with continued robust enrollment in our Phase 1/1b study," said Laura Shawver, Ph.D., chief executive officer of Silverback. "We are deeply appreciative of the patients, their families, and our clinical investigators who continue to contribute to the SBT6050-101 clinical trial, and we look forward to providing the first update of the clinical data at the ESMO conference in September."

Recent Highlights

- ***SBT6050 (HER2-TL8 ImmunoTAC) clinical abstract accepted for poster presentation at the European Society for Medical Oncology ("ESMO") 2021 Annual Meeting.*** The presentation will provide an update on the monotherapy dose-escalation arm (Part 1) and the pembrolizumab combination dose-escalation arm (Part 3) of the SBT6050-101 Phase 1/1b study. Details of the upcoming ESMO poster presentation are as follows:

  Title: "Interim results of a Phase 1/1b study of SBT6050 monotherapy and pembrolizumab combination in patients with advanced HER2-expressing or amplified solid tumors**"** Klempner, S., et al.

  Poster Number: 209P

  Session Date and Time: The ePoster will be released virtually on Thursday, September 16th at 8:30 AM Central European Summer Time / 2:30 AM Eastern Standard Time

- ***Announced a clinical supply agreement with Regeneron to evaluate SBT6050 in combination with Libtayo® (cemiplimab), a PD-1 inhibitor.*** Under the terms of the agreement, Silverback will expand the ongoing Phase 1/1b trial to evaluate the combination of SBT6050 and Libtayo® in tumor-specific dose expansion cohorts, initially in HER2-expressing non-small cell lung and gastric cancers.

- ***GLP toxicology study for SBT6290 (Nectin4-TLR8 ImmunoTAC) is nearing completion, with IND filing on track for the fourth quarter of 2021.*** Dosing was initiated in the GLP toxicology study in the second quarter and cGMP manufacturing of the drug product for Phase 1 clinical supply has been completed, with release testing in progress.

- ***SBT8230 (ASGR1-TLR8 ImmunoTAC for chronic HBV) continues to advance through preclinical development with early CMC activities initiated including selection of the clone and creation of a master cell bank.*** The GLP toxicology study is expected to commence in the first quarter of 2022.

Second Quarter Financial Results

For the second quarter ended June 30, 2021, Silverback reported a net loss of $24.5 million, compared to a net loss of $6.5 million for the comparable period in 2020. For the six months ended June 30, 2021, Silverback reported a net loss of $43.4 million, compared to a net loss of $11.7 million for the comparable period in 2020. Included in the net losses for the three and six months ended June 30, 2021 were $4.7 million and $9.0 million of non-cash stock-based compensation compared to $128,000 and $175,000 for the same periods in 2020.

Research and development expenses for the second quarter ended June 30, 2021 were $17.7 million, compared to $5.1 million for the same period in 2020. Research and development expenses for the six months ended June 30, 2021 were $30.0 million compared to $9.5 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, through preclinical development and the continued clinical development of SBT6050. Silverback also incurred additional personnel-related expenses as operations grew in support of program advancements.

General and administrative expenses for the second quarter ended June 30, 2021 were $6.8 million, compared to $1.3 million for the same period in 2020. General and administrative expenses for the six months ended June 30, 2021 were $13.4 million, compared to $2.2 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 2021, 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 June 30, 2021, Silverback reported cash and cash equivalents of $359.7 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)

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 359,689	$ 386,569
Prepaid expenses and other current assets	3,338	4,087
Total current assets	363,027	390,656
Property and equipment, net	1,984	1,618
Restricted cash	350	350
Right-of-use asset	1,615	2,180
Total assets	$ 366,976	$ 394,804
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,805	$ 2,583
Accrued expenses	12,785	5,278
Term loan payable, net	—	844
Current portion of lease liability	958	896
Total current liabilities	15,548	9,601
Lease liability, net of current portion	1,778	2,326
Total liabilities	17,326	11,927
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.0001 par value per share; 10,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at June 30, 2021 and December 31, 2020, 34,998,372 and 34,801,537 shares issued, and 34,963,085 and 34,701,274 shares outstanding at June 30, 2021 and December 31, 2020, respectively	4	3
Additional paid-in capital	489,743	479,608
Accumulated deficit	(140,097)	(96,734)
Total stockholders' equity	349,650	382,877
Total liabilities, and stockholders' equity	$ 366,976	$ 394,804

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 17,749	$ 5,126	29,988	$ 9,540
General and administrative	6,762	1,337	13,408	2,165
Total operating expenses	24,511	6,463	43,396	11,705
Loss from operations	(24,511)	(6,463)	(43,396)	(11,705)
Interest income (expense), net	15	(4)	33	(41)
Net loss and comprehensive loss	(24,496)	(6,467)	(43,363)	$ (11,746)
Net loss per share applicable to common stockholders, basic and diluted	$ (0.70)	$ (9.65)	$ (1.25)	$ (17.54)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	34,876,050	670,451	34,825,281	669,742