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): November 10, 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 November 10, 2021, Silverback Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 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 November 10, 2021.
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: November 10, 2021

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

SEATTLE – November 10, 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 third quarter ended September 30, 2021 and provided a business update.

"In the third quarter, we provided our first interim clinical update for the dose escalation arms of the SBT6050-101 trial, establishing proof-of-mechanism for SBT6050 as evidenced by the activation of the innate and adaptive immune system in patients," said Laura Shawver, Ph.D., chief executive officer of Silverback. "In a short period of time, we have accumulated a robust clinical data set that has informed our development strategy. We are focused on advancing SBT6050 in patients with HER2-expressing cancers such as gastroesophageal and non-small cell lung, in combination with agents that we believe will maximize the therapeutic potential of our first-in-class TLR8 agonist conjugate. We also look forward to continuing to advance our pipeline, including SBT6290 for patients with bladder, triple negative breast, non-small cell lung, and head & neck cancers, and SBT8230 for patients with chronic hepatitis B virus."

Recent Business Updates:

SBT6050 (HER2-TL8 ImmunoTAC)

- ***Interim clinical data presented at the European Society for Medical Oncology (ESMO) 2021 Annual Meeting.*** In September 2021, Silverback presented interim clinical results from the ongoing Phase 1/1b study of SBT6050, including data that establish proof-of-mechanism through SBT6050's ability to activate myeloid, T and NK cells, as well as evidence of SBT6050 payload localization in the tumor microenvironment. Adverse events reported were consistent with on-mechanism immune activation, and early signals of anti-tumor activity were observed.
- ***Selected go forward dose of 0.3 mg/kg SBT6050 in combination with anti-PD-1 therapy in expansion cohorts.*** Silverback is prioritizing combination with Libtayo in gastroesophageal and non-small cell lung cancers and plans to initiate these expansion cohorts in the fourth quarter of 2021.
- ***SBT6050 expanded clinical development strategy announced, leveraging combination with trastuzumab-containing regimens.*** In the first quarter of 2022, Silverback plans to initiate SBT6050-201, a Phase 1/2 study of SBT6050 combined with Enhertu, or with Herceptin and Tukysa with or without capecitabine, in patients with HER2-expressing or HER2-amplified cancers.

SBT6290 (Nectin4-TL8 ImmunoTAC)

- ***SBT6290 Investigational New Drug application submitted to the U.S. Food and Drug Administration.*** Silverback remains on track to initiate the phase 1/1b trial in the first quarter of 2022, and plans to enroll patients with bladder, non-small cell lung, triple negative breast, and head and neck cancers in dose escalation.

SBT8230 (ASGR1-TLR8 ImmunoTAC for chronic HBV)

- ***SBT8230 preclinical development continues with GLP toxicology studies expected to commence in the first quarter of 2022.*** Silverback will be providing a preclinical update on the SBT8230 program at the American Association for the Study of Liver Diseases (AASLD) 2021 conference held from November 12-14, 2021.

Third Quarter Financial Results

For the third quarter ended September 30, 2021, Silverback reported a net loss of $22.7 million, compared to a net loss of $8.1 million for the comparable period in 2020. For the nine months ended September 30, 2021, Silverback reported a net loss of $66.0 million, compared to a net loss of $19.9 million for the comparable period in 2020. Included in the net losses for the three and nine months ended September 30, 2021 were $5.0 million and $14.0 million of non-cash stock-based compensation, respectively, compared to $0.2 million and $0.4 million for the same periods in 2020, respectively.

Research and development expenses for the third quarter ended September 30, 2021 were $15.6 million, compared to $6.2 million for the same period in 2020. Research and development expenses for the nine months ended September 30, 2021 were $45.6 million compared to $15.7 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 third quarter ended September 30, 2021 were $7.0 million, compared to $1.9 million for the same period in 2020. General and administrative expenses for the nine months ended September 30, 2021 were $20.4 million, compared to $4.1 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 September 30, 2021, Silverback reported cash, cash equivalents, and investments of $340.6 million compared to cash and cash equivalents of $386.6 million at December 31, 2020, which is expected to fund operating expenses and capital expenditure requirements into 2024.

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, among other things, Silverback's plans and ability to bring new treatments to patients in need, including potential combination efforts, the progress and expected timing of Silverback's drug development programs and clinical trials, and 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, 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

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

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 300,660	$ 386,569
Prepaid expenses and other current assets	4,695	4,087
Total current assets	305,355	390,656
Investments	39,938	—
Restricted cash	350	350
Right-of-use asset	5,011	2,180
Property and equipment, net	1,907	1,618
Total assets	$ 352,561	$ 394,804
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,720	$ 2,583
Accrued expenses	12,537	5,278
Term loan payable, net	—	844
Current portion of lease liability	1,090	896
Total current liabilities	15,347	9,601
Lease liability, net of current portion	5,080	2,326
Total liabilities	20,427	11,927
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.0001 par value per share; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020, 35,067,751 and 34,801,537 shares issued and 35,037,136 and 34,701,274 shares outstanding at September 30, 2021 and December 31, 2020, respectively	4	3
Additional paid-in capital	494,916	479,608
Accumulated other comprehensive loss	(34)	—
Accumulated deficit	(162,752)	(96,734)
Total stockholders' equity	332,134	382,877
Total liabilities, and stockholders' equity	$ 352,561	$ 394,804

Silverback Therapeutics, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 15,641	$ 6,200	45,630	$ 15,740
General and administrative	7,040	1,912	20,447	4,077
Total operating expenses	22,681	8,112	66,077	19,817
Loss from operations	(22,681)	(8,112)	(66,077)	(19,817)
Interest income (expense), net	26	(4)	59	(45)
Net loss	$ (22,655)	$ (8,116)	(66,018)	$ (19,862)
Unrealized gain (loss) on available-for-sale securities	(34)	—	(34)	—
Comprehensive loss attributable to common stockholders	$ (22,689)	$ (8,116)	(66,052)	$ (19,862)
Net loss per share applicable to common stockholders, basic and diluted	$ (0.65)	$ (11.97)	$ (1.89)	$ (29.53)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	35,001,466	678,048	34,884,656	672,531