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): March 31, 2022

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 March 31, 2022, Silverback Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2021 and providing a corporate update. 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 March 31, 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: March 31, 2022

Exhibit 99.1

Silverback Therapeutics Updates Strategic Priorities and Reports Fourth Quarter and Full Year 2021 Financial Results

- Strategic realignment to focus resources on SBT8230 for chronic hepatitis B virus (cHBV) and discovery pipeline by discontinuing SBT6050 and SBT6290 clinical oncology programs

- On track to complete a Phase 1 regulatory submission for SBT8230 in the fourth quarter of 2022

- Silverback to restructure workforce to support prioritized development, reduce operating expense, and extend cash runway

- Estimated cash runway extended into the second half of 2026

SEATTLE – March 31, 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 provided an update on strategic priorities and reported financial results for the fourth quarter and full year ended December 31, 2021.

"Upon comprehensive review of our clinical and preclinical data for our TLR8 oncology programs, we have made the decision to discontinue the development of SBT6050 and SBT6290, and focus our resources on SBT8230 for chronic HBV as well as our ImmunoTAC discovery programs," said Laura Shawver, Ph.D., chief executive officer of Silverback. "We would like to thank the investigators and the staff at each of our sites, and most importantly, the patients who participated in our trial and their families."

Business Update and Strategy

SBT6050 and SBT6290 (HER2-TLR8 and Nectin4-TLR8 ImmunoTAC conjugates for oncology)

Silverback has discontinued the SBT6050 development program. In the Phase 1/1b trial, a total of 58 patients were enrolled and received SBT6050 as monotherapy and in combination with a checkpoint inhibitor at dose levels ranging from 0.15 mg/kg through 1.2 mg/kg with the length of patient experience ranging from 2 weeks through 41 weeks. A dose response was observed in serum and intratumoral exposure, and in pharmacodynamic markers, inclusive of data that demonstrates immune activation in biopsies collected from patients after treatment. Further development was discontinued based on limited monotherapy anti-tumor activity and cytokine-related adverse events that limited the dose in combination with pembrolizumab.

SBT6290, comprised of the same linker payload conjugated to a Nectin4 antibody, was expected to show a similar clinical profile and, therefore, this development program was also discontinued.

SBT8230 (ASGR1-TLR8 ImmunoTAC conjugate for chronic HBV)

“Our understanding of TLR8 conjugates in preclinical species and in the clinic provides a lens for interpretation of the preclinical characteristics of SBT8230,” said Valerie Odegard, Ph.D., president and chief scientific officer. “The comparative preclinical data between SBT6050 and SBT8230 suggest that the clinical safety, pharmacokinetic and pharmacodynamic profiles for SBT8230 will likely be different than those for SBT6050, given the significant differences in preclinical serum exposures and expected overall conjugate disposition for SBT8230 in patients due to its efficient liver targeting. We continue to advance SBT8230 and are on track to complete a Phase 1 regulatory submission in the fourth quarter of 2022.”

SBT8230 is comprised of an ASGR1 monoclonal antibody conjugated to a TLR8 linker-payload and is designed to elicit an anti-viral immune response by targeting TLR8 activation to the liver. ASGR1 is highly expressed in liver and is restricted in its expression to this organ. An anti-viral immune response is achieved through activation of myeloid cells and subsequent indirect activation of B cells and T cells. In non-human-primate studies, SBT8230 demonstrated lower serum exposures compared to SBT6050 due to its efficient localization to liver. Liver-localized TLR8 agonism has the potential to lead to durable responses and possibly seroconversion, an important determinant of functional cure. At the AASLD Liver Meeting 2021, Silverback presented preclinical studies demonstrating that SBT8230 was efficiently delivered to the liver, resulting in myeloid cell activation in the liver but not in the blood. Silverback initiated Phase 1-enabling toxicology studies for SBT8230 in the first quarter of 2022.

ImmunoTAC Discovery Program

Silverback will continue advancement of early-stage discovery research that is focused on exploring different antigen targets, novel linker technologies, and small molecule payloads that expand the reach of the ImmunoTAC platform.

Key Strategic Priorities and Cash Runway Extension

- Complete the Phase 1 regulatory submission for SBT8230 in the fourth quarter of 2022
- Open enrollment for a Phase 1 single ascending dose study of SBT8230 in healthy volunteers in the first half of 2023
- Provide an update on Silverback’s discovery pipeline in the fourth quarter of 2022
- Restructure workforce to focus resources on SBT8230 program and discovery pipeline, reducing headcount by 27%
- Estimated cash runway extended into the second half of 2026 following strategic prioritization

Dr. Shawver added, “Over the course of the next few days and weeks, we are restructuring our workforce and allocating resources around our new strategic priorities. It will be difficult to part with valued team members who have been so committed to the organization, and I’d like to thank each one of them for their valuable contributions towards our mission to develop the next generation of tissue targeted therapeutics.”

Financial Results

For the fourth quarter ended December 31, 2021, Silverback reported a net loss of $23.5 million, compared to a net loss of $13.1 million for the comparable period in 2020. For the year ended December 31, 2021, Silverback reported a net loss of $89.5 million, compared to a net loss of $32.9 million for 2020. Net loss for the fourth quarter and full year of 2021 included non-cash stock-based compensation expense of $5.2 million and $19.2 million, respectively, compared to $2.3 million and $2.6 million for the same periods in 2020, respectively.

Research and development expenses for the fourth quarter ended December 31, 2021 were $15.9 million, compared to $8.8 million for the same period in 2020. For the year ended December 31, 2021, research and development expenses were $61.5 million, compared to $24.6 million for 2020. The increases in Silverback's research and development expenses for the 2021 periods, as compared to the same periods in 2020, were primarily attributable to an increase in direct costs related to the development of SBT6050 and SBT6290 and direct costs related to SBT8230 and other preclinical research efforts. Silverback also incurred additional personnel-related expenses in 2021 as compared to 2020 as operations grew in support of program advances.

General and administrative expenses for the fourth quarter ended December 31, 2021 were $7.6 million, compared to $4.3 million for the same period in 2020. For the year ended December 31, 2021, general and administrative expenses were $28.1 million, compared to $8.3 million for 2020. The increases in general and administrative expenses for the 2021 periods, as compared to the same periods in 2020, were primarily attributable to an increase in personnel-related expenses due to increased headcount in 2021, including new executives that were new in 2020 being present for a full year in 2021, as well as increases in salaries, bonuses, and stock-based compensation. To a lesser extent, the increase in general and administrative expenses was due to an increase in professional fees primarily attributable to legal, insurance, and outside consultant costs.

As of December 31, 2021, Silverback reported cash, cash equivalents, restricted cash, and investments of $319.1 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 the second half of 2026 following strategic prioritization. As of December 31, 2021, Silverback had 35,133,934 shares of common stock outstanding.

Conference Call and Webcast on Thursday, March 31, 2022 at 5:00 PM ET

Silverback's management team will host a conference call on Thursday, March 31, 2022 at 5:00 PM ET to discuss the strategic prioritization and corporate update. A live webcast, including slides, can be accessed through the Events section of the Company's website at https://ir.silverbacktx.com/news-events/events. An archived replay will be available shortly after the conclusion of the event.

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.

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 potential benefits of SBT8230 as compared to SBT6050, the success and impact of Silverback's corporate restructuring plan, 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, uncertainties related to Silverback's corporate restructuring plan, 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.
Balance Sheets
(in thousands, except share and par value data)

	December 31, 2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 254,045	$386,569
Prepaid expenses and other current assets	7,447	4,087
Total current assets	261,492	390,656
Investments	64,780	—
Restricted cash	250	350
Right-of-use assets	4,733	2,180
Property and equipment, net	2,212	1,618
Total assets	$ 333,467	$394,804
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,078	$ 2,583
Accrued expenses	11,727	5,278
Term loan payable, net	—	844
Current portion of lease liability	1,087	896
Total current liabilities	14,892	9,601
Lease liability, net of current portion	4,760	2,326
Total liabilities	19,652	11,927
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.0001 par value per share; 10,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at December 31, 2021 and 2020, 35,133,934 and 34,801,537 shares issued and 35,107,651 and 34,701,274 shares outstanding at December 31, 2021 and 2020, respectively	4	3
Additional paid-in capital	500,349	479,608
Accumulated other comprehensive loss	(326)	—
Accumulated deficit	(186,212)	(96,734)
Total stockholders' equity	313,815	382,877
Total liabilities and stockholders' equity	$ 333,467	$394,804

Silverback Therapeutics, Inc.

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

	Years Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 61,501	$ 24,577
General and administrative	28,083	8,341
Total operating expenses	89,584	32,918
Loss from operations	(89,584)	(32,918)
Interest income (expense), net	106	(29)
Net loss	$ (89,478)	$ (32,947)
Unrealized loss on available-for-sale securities	(326)	—
Comprehensive loss attributable to common stockholders	$ (89,804)	$ (32,947)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.56)	$ (11.33)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	34,926,403	2,907,542