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): September 13, 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 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 7.01 Regulation FD Disclosure.

On September 12, 2021, an abstract providing interim results of Silverback Therapeutics, Inc.'s (the "Company") ongoing Phase 1/1b study of SBT6050 as monotherapy and combined with pembrolizumab in patients with advanced HER2-expressing or amplified solid tumors was published on the European Society for Medical Oncology's website. The abstract is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on 8-K (including Exhibit 99.1) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Abstract providing interim results of ongoing Phase 1/1b study of SBT6050 as monotherapy and combined with pembrolizumab in patients with advanced HER2-expressing or amplified solid tumors.
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: September 13, 2021

Title: Results of an ongoing Phase 1/1b study of SBT6050 as monotherapy and combined with pembrolizumab in patients with advanced HER2-expressing or amplified solid tumors

Samuel J. Klempner[1], Muralidhar Beeram[2], Dhanusha Sabanathan[3], Arlene Chan[4], Erika Hamilton[5], Sherene Loi[6], Do-Youn Oh[7], Leisha A. Emens[8], Amita Patnaik[2], Jeong Eun Kim[9], Yeon Hee Park[10], Valerie Odegard[11], Sue Hamke[11], Graham Jang[11], Celine Jacquemont[11], Naomi Hunder[11], Sarina Piha-Paul[12]

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Background

SBT6050 comprises a TLR8 agonist linker-payload conjugated to a HER2-directed antibody and is designed to activate myeloid cells in tumors expressing moderate to high levels of HER2. TLR8 is expressed in myeloid cell types prevalent in human tumors and TLR8 agonism can activate a broad spectrum of anti-tumor immune mechanisms.

Methods

This FIH, open-label, multicenter, dose-escalation and expansion study is evaluating SBT6050 alone and in combination with pembrolizumab (NCT04460456). Pts have HER2-expressing or -amplified solid tumors with progression following therapies known to confer clinical benefit. A single-agent dose-escalation (P1) is followed by tumor-specific expansion cohorts at the RP2D (P2). A pembrolizumab combination dose-escalation (P3) is followed by an expansion cohort at the RP2D (P4).

Results

As of 4 April 2021, 18 pts across multiple tumor types were treated at 4 dose levels (P1, n=14; P3, n=4). Dose levels of SBT6050 ranging from 0.15 mg/kg to 0.6 mg/kg, the predicted RP2D based on preclinical studies, were each pharmacologically active and demonstrated a greater than 70-fold difference in SBT6050 serum exposure. Induction of blood-based biomarkers associated with myeloid cell and NK or T lymphocyte activation, consistent with SBT6050 MOA, were observed at each dose level, generally increasing in a dose-dependent manner. The most frequent (>25%) related TEAEs were chills, diarrhea, fatigue, hypotension, injection site reaction, nausea, pyrexia, and vomiting. Dose levels >0.6 mg/kg were evaluated to assess the upper limits of the dose range; G3 DLTs were observed in P1 at 1.2 mg/kg Q2 wks. In response-evaluable pts (N=14), best overall response was PR (n=1), SD (n=3), and PD (n=9).

Conclusions

Based on preliminary safety data, SBT6050 given alone or in combination with pembrolizumab has a manageable safety profile. Related TEAEs are consistent with immune activation. Evidence of pharmacological activity was observed at each dose level evaluated. A single-agent dose of 0.6 mg/kg Q2 wks had a tolerable safety profile and had drug exposure and pharmacodynamic activity similar to preclinical doses associated with activity. P1 and P3 are ongoing.