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): December 7, 2020

SUTRO BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38662**	**47-0926186**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

310 Utah Avenue, Suite 150,
South San Francisco, California, 94080
(Address of principal executive offices) (Zip Code)

(650) 392-8412
(Registrant's telephone number, including area code)

Not Applicable
(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 (see General Instructions A.2. below):

☐ 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, $0.001 par value	STRO	Nasdaq Global Market

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 December 7, 2020, Sutro Biopharma, Inc. (the Company) issued a press release and presented a virtual poster at the 62nd American Society of Hematology (ASH) Annual Meeting announcing updated data from its ongoing Phase 1 clinical trial of STRO-001 for patients with late-line Non-Hodgkin Lymphoma (NHL).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The poster presentation is accessible through the Clinical/Scientific Presentation and Publication Highlights page of the News section of the Company's website at www.sutrobio.com.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for 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 it be deemed incorporated by reference into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On December 7, 2020, the Company announced data from its ongoing Phase 1 clinical trial of STRO-001for patients with late-line NHL.

STRO-001-BCM1 is an ongoing first-in-human, phase 1 dose-escalation study evaluating the safety, tolerability, and preliminary antitumor activity of STRO-001 in adults with B-cell malignancies. The study is ongoing, and data presented at ASH included results from the NHL cohort. There were 21 NHL patients treated and 18 evaluable patients for response. Patients had a median of 5 prior therapies. 6/21 patients (29%) had previous stem cell transplant or CAR-T therapy. Data as of October 30, 2020 are as follows:

- Most (90%) treatment-emergent adverse events were grade 1 or 2 and no ocular or neuropathy toxicity signals have been observed;
- Following a previously announced protocol amendment last year requiring pre-treatment screening imaging for patients at risk for thromboses, no additional thromboembolic events have been observed;
- In the 7 patients with diffuse large B-cell lymphoma, 1 complete response and 2 partial responses were observed; and
- Out of other NHL types, 2 patients with follicular lymphoma had stable disease (SD), of which one is still on treatment at 9 weeks. One patient with marginal zone lymphoma had SD and is still on treatment at 39 weeks.

STRO-001 has been well tolerated. Maximum tolerated dose (MTD) was not reached at 2.5 mg/kg. Active enrollment in the NHL cohort continues at the 3.5 mg/kg dose level and additional higher dose levels may be explored. The trial, registered with clinicaltrials.gov identifier NCT03424603, continues to enroll patients in dose escalation in both multiple myeloma and NHL cohorts.

This current report contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated preclinical and clinical development activities, timing of announcements of clinical results, potential benefits of the company's product candidates and platform and potential market opportunities for the company's product candidates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the company believes that the expectations reflected in such forward-looking statements are reasonable, the company cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, the impact of the COVID-19 pandemic on the Company's business, clinical trial sites, supply chain and manufacturing facilities, the Company's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property, and the Company's commercial collaborations with third parties and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Quarterly Report on Form 10-Q for the period ended September 30, 2020 filed with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release by Sutro Biopharma, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Sutro Biopharma, Inc.

Date: December 7, 2020

By: /s/ Edward Albini

Edward Albini
Chief Financial Officer

Exhibit 99.1

Sutro Biopharma Presents Data from Ongoing Phase 1 Dose-Escalation Study for STRO-001 for the Treatment of B-cell Non-Hodgkin Lymphoma at the 62nd American Society of Hematology Annual Meeting

- STRO-001 was generally well-tolerated in patients with late-line NHL with no ocular or neuropathy toxicity signals; MTD has not been reached -

- 1 CR & 2 PRs observed in heavily pretreated patients with DLBCL; 1 SD in marginal zone lymphoma; 2 SDs in follicular lymphoma

- Fred Hutchinson preclinical models with STRO-001 identifies CD74 as a potential target for the treatment of AML

SOUTH SAN FRANCISCO, Calif., Dec. 7, 2020 – Sutro Biopharma, Inc. (NASDAQ: STRO), a clinical-stagedrug discovery, development and manufacturing company focused on the application of precise protein engineering and rational design to create next-generation cancer and autoimmune therapeutics, today announced a poster presentation at the virtual 62nd American Society of Hematology (ASH) Annual Meeting for the ongoing Phase 1 dose-escalation clinical trial for its CD74-targeted antibody drug conjugate (ADC) STRO-001 for patients with late-line Non-Hodgkin Lymphoma (NHL). Additionally, data were presented from preclinical studies conducted in collaboration with researchers from the Fred Hutchinson Cancer Research Center.

“With three product candidates in the pipeline actively enrolling patients—STRO-001, STRO-002, our folate receptor alpha- (FolRα) targeting ADC, and CC-99712 in partnership with Bristol Myers Squibb, a BCMA-targeting ADC—Sutro is working on addressing unmet needs via targeted therapies that can tackle cancer evolution," said Bill Newell, Sutro’s Chief Executive Officer. “The encouraging safety and preliminary efficacy clinical data presented at ASH on STRO-001 for the treatment of late-line NHL further validates our platform and unique approach to ADC design, creating potential first-in-class and/or best-in-class therapeutic candidates.”

STRO-001 Phase 1 Dose Escalation Interim Data

STRO-001-BCM1 is an ongoing first-in-human, phase 1 dose-escalation study evaluating the safety, tolerability, and preliminary antitumor activity of STRO-001 in adults with B-cell malignancies. The study is ongoing, and data presented at ASH included results from the NHL cohort. There were 21 NHL patients treated and 18 evaluable patients for response. Patients had a median of 5 prior therapies. 6/21 patients (29%) had previous stem cell transplant or CAR-T therapy. Data as of October 30, 2020 are as follows:

- Most (90%) treatment-emergent adverse events (TEAEs) were grade 1 or 2 and no ocular or neuropathy toxicity signals have been observed

- Following a previously announced protocol amendment last year requiring pre-treatment screening imaging for patients at risk for thromboses, no additional thromboembolic events have been observed
- In the 7 patients with diffuse large B-cell lymphoma (DLBCL), 1 complete response (CR) and 2 partial responses (PRs) were observed
- Out of other NHL types, 2 patients with follicular lymphoma had stable disease (SDs), of which one is still on treatment at 9 weeks. One patient with marginal zone lymphoma had SD and is still on treatment at 39 weeks

“These results continue to demonstrate the potential clinical benefit of STRO-001 treatment in patients with NHL who are heavily pretreated, with a median of five prior lines of treatment,” said Dr. Arturo Molina, Sutro’s Chief Medical Officer. “We are especially pleased for the patients who responded to STRO-001 after previously progressing on CAR-T treatments and an additional post- CAR-T regimen to which they had no response, seeing comparable duration of disease control to the duration on a cell therapy. STRO-001 has been well tolerated. We look forward to continuing the dose-escalation study to learn more about the potential for STRO-001 for patients with NHL.”

Maximum tolerated dose (MTD) was not reached at 2.5 mg/kg. Active enrollment in the NHL cohort continues at the 3.5 mg/kg dose level and additional higher dose levels may be explored. The trial, registered with clinicaltrials.gov identifier NCT03424603, continues to enroll patients in dose escalation in both multiple myeloma (MM) and NHL cohorts.

The virtual poster titled “Preliminary Results of an Ongoing Phase 1 Dose Escalation Study of the Novel Anti-CD74 Antibody Drug Conjugate (ADC), STRO-001, in Patients with B-cell Non-Hodgkin Lymphoma,” presented by Nirav N. Shah, M.D., Associate Professor of Medicine at Medical College of Wisconsin, is accessible through the Clinical/Scientific Presentation and Publication Highlights page of the News section of the company’s website at www.sutrobio.com.

Preclinical Data from Fred Hutchinson Cancer Research Center in Collaboration with Sutro

Fred Hutchinson Cancer Research Center, in collaboration with Sutro, presented preclinical models showing the potential of CD74-targeted therapies, and in particular STRO-001, for the treatment of acute myelogenous leukemia (AML). The research is out of the lab of Soheil Meshinchi, M.D., Ph.D., Professor, Clinical Research Division at Fred Hutchinson Cancer Center and Professor of Pediatrics at University of Washington School of Medicine.

“My team at Fred Hutchinson Cancer Research Center has built a robust computational platform leveraging our large AML transcriptome dataset to identify highly expressed antigens on leukemic cells that are being targeted by agents in early phase trials or preclinical development with the goal of repurposing these therapeutics for use in AML,” said Soheil Meshinchi, M.D., Ph.D. “One of these therapies was the STRO-001 ADC which targets the cell surface protein CD74. We have demonstrated that CD74 is highly expressed in a significant proportion of patients with AML. Our initial studies of STRO-001 ADC in AML cell lines demonstrated robust in vitro cytotoxicity on AML cell lines expressing high- to moderate-levels of CD74, with no cytotoxicity in cells with no CD74 expression. This in vitro

data, which identifies CD74 as a viable target in AML, coupled with the 27% incidence of CD74 in nearly 1,000 pediatric AML patients from our clinical trial with bortezomib, strengthens the notion that targeting CD74 with STRO-001 represents a viable targeted therapy in this patient population. In addition to AML, CD74 is highly expressed in high risk acute lymphoblastic leukemia (ALL), including Ph-positive and Ph-like ALL, thus providing rationale for exploring the efficacy of STRO-001 in all leukemias.

- A virtual poster titled "Target-Informed Repurposing of Immunotherapies in AML – a Transcriptome Based Approach for Identifying Immediately Available Therapeutics," will be presented Amanda Leonti, MS, Computational Biology, Meshinchi lab, Fred Hutchinson Cancer Research Center, and include *in vitro* cytotoxicity data for STRO-001 in AML cell lines. See the abstracthere.

- A virtual oral session titled "Newly Diagnosed Childhood AML Patients Treated with Bortezomib Show Superior Survival If CD74 Is Expressed: A Report of 991 Patients from the Children's Oncology Group AAML1031 Protocol," will be presented by Lisa Eidenschink Brodersen PhD HCLD, Director, Flow Cytometry, Hematologics, Inc in Seattle Washington, and will highlight the potential of CD74 targeted therapies in pediatric AML. See the abstract here.

About Sutro Biopharma

Sutro Biopharma, Inc., located in South San Francisco, is a clinical-stage drug discovery, development and manufacturing company. Using precise protein engineering and rational design, Sutro is advancing next-generation oncology therapeutics.

Sutro's proprietary and integrated cell-free protein synthesis platform XpressCF® and site-specific conjugation platform XpressCF+™ led to the discovery of STRO-001 and STRO-002, Sutro's first two internally-developed ADCs. STRO-001 is a CD74-targeting ADC currently being investigated in a Phase 1 clinical trial of patients with advanced B-cell malignancies, including multiple myeloma and non-Hodgkin lymphoma. STRO-001 was granted Orphan Drug Designation by the FDA for multiple myeloma in October 2018. STRO-002 is a folate receptor alpha (FolRα)-targeting ADC, currently being investigated in a Phase 1 clinical trial of patients with ovarian and endometrial cancers. This is the second product candidate to be evaluated in clinical trials resulting from Sutro's XpressCF® and XpressCF+™ technology platforms. A third program, CC-99712 (BCMA-targeting ADC), which is part of Sutro's collaboration with Bristol Myers Squibb (formerly Celgene Corporation), is enrolling patients for its Phase 1 clinical trial of patients with multiple myeloma. Sutro's proprietary technology was responsible for the discovery and manufacturing of CC-99712, for which Bristol Myers Squibb has worldwide development and commercialization rights. Sutro is entitled to development and regulatory milestone payments and tiered royalties from Bristol Myers Squibb for this BCMA ADC. Sutro is dedicated to transforming the lives of cancer patients by creating medicines with improved therapeutic profiles for areas of unmet need.

To date, Sutro's platform has led to cytokine-based immuno-oncology therapies, ADCs, vaccines and bispecific antibodies directed at precedented targets in clinical indications where the current standard of care is suboptimal. The platform allows it to accelerate discovery and development of potential first-in-

class and best-in-class molecules through rapid and systematic evaluation of protein structure-activity relationships to create optimized homogeneous product candidates.

In addition to developing its own oncology pipeline, Sutro is collaborating with select pharmaceutical and biotech companies to discover and develop novel, next-generation therapeutics. As the pace of clinical development accelerates, Sutro and its partners are developing therapeutics designed to more efficiently kill tumors without harming healthy cells.

Additional multimedia content from Sutro regarding STRO-001 and STRO-002 can be foundhere and here.

Follow Sutro on Twitter, @Sutrobio, and at www.sutrobio.com to learn more about our passion for changing the future of oncology.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated preclinical and clinical development activities, timing of clinical trials and announcements of clinical results, potential benefits of the company's product candidates and platform and potential market opportunities for the company's product candidates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the company believes that the expectations reflected in such forward-looking statements are reasonable, the company cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, the impact of the COVID-19 pandemic on the Company's business, clinical trial sites, supply chain and manufacturing facilities, the Company's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical studies and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property, and the Company's commercial collaborations with third parties and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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