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 30, 2023

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.)**

111 Oyster Point Blvd,
South San Francisco, California, 94080
(Address of principal executive offices) (Zip Code)

(650) 881-6500
(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:

☐ 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	The 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 2.02. Results of Operations and Financial Condition.

On March 30, 2023, Sutro Biopharma, Inc. issued a press release announcing its financial results for the year ended December 31, 2022. A copy of the press release is attached as Exhibit 99.1 to this report.

The information furnished with Item 2.02 of this report, including Exhibit 99.1, is being furnished and 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 under the Securities Act of 1933, as amended (the "***Securities Act***"), except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Sutro Biopharma, Inc. regarding its financial results for the period ended December 31, 2022, dated March 30, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 hereunto duly authorized.

Sutro Biopharma, Inc.

Date: March 30, 2023

By: /s/ Edward Albini
Edward Albini
Chief Financial Officer

Exhibit 99.1

Sutro Biopharma Reports Full Year 2022 Financial Results, Business Highlights and Select Anticipated Milestones

- Sutro plans to initiate a Phase 2/3 registration-directed study of luvelta for patients with platinum resistant ovarian cancer in the second quarter -

- Dr. Anne Borgman joined Sutro as Chief Medical Officer in February 2023 -

- Sutro expanded its relationship with Vaxcyte through an option agreement for the development and manufacturing rights for cell-free extract -

- As of year-end 2022, Sutro had cash and investments of $302.3 million and shares of Vaxcyte common stock valued at $32.0 million, which together provide a projected cash runway into the second half of 2024-

SOUTH SAN FRANCISCO, Calif., March 30, 2023 – Sutro Biopharma, Inc. (Sutro or the Company) (NASDAQ: STRO), a clinical-stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs), today reported its financial results for the full year 2022, its recent business highlights, and a preview of select anticipated milestones.

“In 2022, we achieved significant milestones in both our internal pipeline and strategic collaborations, while strengthening our management team with the appointment of Anne Borgman, M.D., as Chief Medical Officer,” said Bill Newell, Sutro’s Chief Executive Officer. “We are delighted with the recent data updates for our lead candidate, luvelta, in advanced ovarian cancer and rare pediatric AML, and are excited to progress it into a planned registration-directed study in ovarian cancer in the second quarter of this year. As we look to the future, we remain confident in our ability to drive value and deliver on our mission to develop next-generation therapies that have the potential to transform the lives of cancer patients.”

Recent Business Highlights and Select Anticipated Milestones

STRO-002, International Nonproprietary Name, “luveltamab tazevibulin” or abbreviated as “luvelta”, FolRα-Targeting ADC: Luvelta is being studied in the clinic, in the U.S. and Europe, for patients with ovarian and endometrial cancers.

- Sutro plans to initiate REFRaME, a Phase 2/3 registration-directed study for patients with platinum-resistant ovarian cancer, in the second quarter of 2023, as discussed with the U.S. Food and Drug Administration (FDA). Once results are collected on approximately 110 patients in the selected dose of the luvelta arm, Sutro plans to apply for accelerated approval based on overall response rate (ORR) as the primary endpoint. At the end of the trial, full approval can be sought based on progression free survival (PFS) as the primary endpoint, comparing the luvelta arm and the standard of care arm.

- In January 2023, the company announced results from the luvelta Phase 1 dose-expansion study demonstrating that FolRα-selected patients–-defined as patients with TPS >25%–-experienced meaningful clinical benefit, with 43.8% ORR, median duration of response (DOR) of 5.4 months, and median PFS of 6.6 months for those receiving the higher starting dose of 5.2 mg/kg. The safety profile is generally consistent with prior data; asymptomatic neutropenia was the primary adverse event and no new safety signals were observed. Interim data from an exploratory cohort, with 5.2 mg/kg doses of luvelta together with prophylactic pegfilgrastim, appear to demonstrate reduced dose delays and lower incidences of Grade 3+ neutropenia.

•Patients with CBFA2T3::GLIS2 (CBF/GLIS) AML, a highly refractory and uniformly fatal subtype of acute megakaryoblastic leukemia found exclusively in infants and young children, were treated with luvelta under compassionate use. During the 64th American Society of Hematology Annual Meeting and Exposition (ASH 2022), an oral presentation was given by the investigator who aggregated the experiences of patients who were treated.

•Additional ongoing clinical studies for luvelta include a combination study with bevacizumab for patients with advanced ovarian cancer and a dose-expansion study for patients with endometrial cancer. Translational work is ongoing to support an Investigational New Drug (IND) for the initiation of a non-small cell lung cancer (NSCLC) study, for which submission is planned in 2023.

STRO-001, CD74-Targeting ADC: The Phase 1 study for patients with B-cell malignancies has been completed in the global sites ex-Greater China and clinical studies in Greater China have been initiated.

•Sutro has completed the Phase 1 dose-escalation study in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM), after reaching a maximum tolerated dose (MTD). Sutro plans to leverage the clinical data produced by its partner BioNova Pharma (BioNova) in Greater China to make decisions regarding further clinical development, based on a prioritization assessment.

•BioNova is advancing clinical development of BN301 (STRO-001) for patients with hematological malignancies in Greater China. In February 2023, BioNova announced that the first patient had been dosed in the Phase 1 clinical study of BN301 (STRO-001) for the treatment of advanced B-cell Non-Hodgkin's Lymphoma (NHL).

Additional Pipeline Programs: A Sutro Research Forum, held in 2022, highlighted STRO-003 and Sutro's emerging research portfolio.

•STRO-003 is an advanced ADC that has been designed to target ROR1, takes advantage of innovative linker-warhead technology and features eight precisely placed β-Glucuronidase-cleavable linkers attached to next-generation exatecan warheads, known for their ability to inhibit topoisomerase-1 (TOPO-1) and cause DNA disruption.

•STRO-003 has demonstrated in NSCLC and breast cancer patient-derived xenograft models strong cell-killing activity in low and heterogeneous expressing tumors. STRO-003 has exhibited promising tolerability in preclinical studies involving rodents and non-human primates, potentially reducing lung toxicity, a concern that is commonly associated with TOPO-1 class payload ADCs. Preparations are underway for IND enabling studies for STRO-003, which we expect will be completed in the first quarter of 2024.

•Sutro provided details on its product and process design, which enables its emerging portfolio including novel therapeutic modalities—for example, a single antibody which can be conjugated site-specifically to deliver two different payloads with synergistic mechanisms.

Collaboration Updates: Sutro continues to seek to maximize the value of its proprietary cell-free platform by working with partners on programs in multiple disease spaces and geographies and has generated from collaborators an aggregate of approximately $621 million in payments through December 31, 2022, including equity investments.

•In December 2022, Sutro and Vaxcyte expanded upon a nearly decade-long relationship through a new agreement, under which Vaxcyte acquired an option to access expanded rights to develop and manufacture cell-free extract, among other rights, and includes a $22.5 million upfront payment and, upon exercise of the option, up to an additional $135 million in option exercise and contingent payments. In October 2022, Vaxcyte reported positive topline data from the Phase 1/2 proof-of-concept study of its 24-valent pneumococcal conjugate vaccine candidate (VAX-24) under investigation for the prevention of invasive pneumococcal disease in adults aged 18-64. Under an existing license agreement with Vaxcyte, Sutro is eligible to receive four percent (4%) royalties on worldwide net sales of any licensed vaccine candidates for human health use, including VAX-24.

•Sutro's collaboration with Astellas on the discovery of immunostimulatory antibody-drug conjugates (iADCs) for three targets is ongoing, for which Sutro receives financial support for its research efforts, potential milestone payments and royalties, and has an option to co-develop and co-commercialize product candidates in the U.S.

•Sutro is manufacturing initial drug supply for the clinical development of Merck's MK-1484, currently in a Phase 1; and clinical trial materials for Bristol Myers Squibb's (BMS) CC-99712, a BCMA-targeting ADC for treatment of multiple myeloma, currently in Phase 1.

•Sutro is providing clinical drug supply to BioNova for clinical studies for BN301 (STRO-001) in Greater China. Sutro is currently supporting Tasly Biopharmaceuticals (Tasly) for initiation of clinical development activities and an IND filing in Greater China for STRO-002 and will provide initial clinical drug supply.

Corporate Updates: Sutro strengthened and continues to build a world-class leadership team through the appointment of a new Chief Medical Officer and internal promotions.

•Anne Borgman, M.D., joined Sutro as Chief Medical Officer in February 2023 overseeing the Clinical Development & Regulatory teams, with focus on the development of luvelta and clinical strategy for Sutro's proprietary pipeline, in addition to being a member of Sutro's Senior Management Team.

•Sutro bolstered the Senior Management Team with the promotion of Brunilda Shtylla to Chief Business Officer, who leads Business Development. Devendra Luhar was promoted to SVP, Manufacturing & San Carlos Facility, and Carlos Lugo Ponce was promoted to SVP, Quality Control & Quality Assurance.

Full Year 2022 Financial Highlights

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2022, Sutro had cash, cash equivalents and marketable securities of $302.3 million, as compared to $287.3 million as of September 30, 2022, and approximately 0.7 million shares of Vaxcyte common stock with a fair value of $32.0 million, which together provide a projected cash runway into the second half of 2024, based on current business plans and assumptions.

Unrealized Gain from Increase in Value of Vaxcyte Common Stock

The non-operating, unrealized gain of $12.1 million for the year 2022 was due to the increase since December 31, 2021 in the estimated fair value of Sutro's holdings of Vaxcyte common stock. Vaxcyte common stock held by Sutro will be remeasured at fair value based on the closing price of Vaxcyte's common stock on the last trading day of each reporting period, with any non-operating, unrealized gains and losses recorded in Sutro's statements of operations. Sutro sold approximately 1.1 million shares of Vaxcyte common stock during 2022.

Revenue

Revenue was $67.8 million for the year ended December 31, 2022, as compared to $61.9 million for the same period in 2021, with the 2022 amount related principally to recognition of the upfront payment from Tasly, the milestone payment from Merck, and the Astellas, BMS, and EMD Serono collaborations and BioNova agreement. Future collaboration and license revenue under existing agreements and from any additional collaboration and license partners, will fluctuate as a result of the amount and timing of revenue recognition of upfront, milestones, and other agreement payments.

Operating Expenses

Total operating expenses for the year ended December 31, 2022 were $196.7 million, as compared to $160.4 million for the same period in 2021. The year 2022 includes non-cash expenses for stock-based compensation of $26.3 million and depreciation and amortization of $5.7 million, as compared to $23.2 million and $4.8 million, respectively, in the comparable 2021 period. Total operating expenses for the year ended December 31, 2022 were comprised of research and development expenses of $137.2 million and general and administrative expenses of $59.5 million, which are expected to increase in 2023 as Sutro's internal product candidates advance in clinical development and additional general and administrative expenses are incurred as a public company.

About Sutro Biopharma

Sutro Biopharma, Inc., headquartered in South San Francisco, is a clinical-stage oncology company pioneering site-specific and novel-format antibody drug conjugates (ADCs). Sutro has two wholly owned ADCs in the clinic—luveltamab tazevibulin (STRO-002 or luvelta), a folate receptor alpha (FolRα)-targeting ADC, in clinical studies for ovarian and endometrial cancers; and STRO-001, a CD74-targeting ADC, in clinical studies for B-cell malignancies. Additionally, Sutro is collaborating with Bristol Myers Squibb (BMS) on CC-99712, a BCMA-targeting ADC in the clinic for patients with multiple myeloma; with Merck, known as MSD outside of the United States and Canada, on MK-1484, a selective IL-2 agonist in clinical studies as a monotherapy and in combination with pembrolizumab for the treatment of solid tumors; and with Astellas Pharma (Astellas) on novel modality, immunostimulatory antibody-drug conjugates (iADCs). Sutro's platform technology also enabled the spin out of Vaxcyte and the creation of VAX-24, a 24-valent pneumococcal conjugate vaccine in clinical studies for the prevention of invasive pneumococcal disease. Sutro's rational design and precise protein engineering has enabled six product candidates in the clinic. 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 announcements of clinical results, trial initiation, and regulatory filings, potential benefits of luvelta and the Company's other product candidates and platform, potential future milestone and royalty payments, and potential market opportunities for luvelta and the Company's other 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 and the Company's ability to successfully leverage Fast Track designation, the market size for the Company's product candidates to be smaller than anticipated, 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, the value of the Company's holdings of Vaxcyte common stock, 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.

Investor Contact
Annie J. Chang
Sutro Biopharma
(650) 801-5728
ajchang@sutrobio.com

Media Contact
Amy Bonanno
Solebury Strategic Communications
(914) 450-0349
abonanno@soleburystrat.com

Sutro Biopharma, Inc.
Selected Statements of Operations Financial Data
(Unaudited)
(In thousands, except share and per share amounts)

	Year ended December 31,		
	2022	**2021**	**2020**
Revenue	$ 67,772	$ 61,880	$ 42,722
Operating expenses			
Research and development	137,171	104,400	76,961
General and administrative	59,544	56,004	36,818
Total operating expenses	196,715	160,404	113,779
Loss from operations	(128,943)	(98,524)	(71,057)
Interest income	3,455	577	1,508
Unrealized gain (loss) on equity securities	12,130	(4,454)	41,498
Interest and other income (expense), net	(3,346)	(3,137)	(3,974)
Loss before provision for income taxes	(116,704)	(105,538)	(32,025)
Provision for income taxes	2,500	-	103
Net loss	$ (119,204)	$ (105,538)	$ (32,128)
Net loss per share, basic and diluted	$ (2.35)	$ (2.29)	$ (0.99)
Weighted-average shares used in computing basic and diluted loss per share	50,739,185	46,119,089	32,573,469

Sutro Biopharma, Inc.
Selected Balance Sheets Financial Data
(Unaudited)
(In thousands)

	December 31,	
	2022 [1]	**2021** [2]
Assets		
Cash, cash equivalents and marketable securities	$ 302,344	$ 229,532
Investment in equity securities	32,020	37,181
Accounts receivable	7,122	12,454
Property and equipment, net	24,621	22,550
Operating lease right-of-use assets	26,443	29,041
Other assets	14,394	10,650
Total Assets	$ 406,944	$ 341,408
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	$ 32,822	$ 25,974
Deferred revenue	106,644	5,496
Operating lease liability	34,159	32,261
Debt	16,271	25,113
Total liabilities	189,896	88,844
Total stockholders' equity	217,048	252,564
Total Liabilities and Stockholders' Equity	$ 406,944	$ 341,408

[1] The condensed balance sheet as of December 31, 2022 was derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 30, 2023.

[2] The condensed balance sheet as of December 31, 2021 was derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on February 28, 2022.