
**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 13, 2023

SUTRO BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of Incorporation)

001-38662
(Commission
File Number)

47-0926186
(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
Common Stock, \$0.001 par value

Trading Symbol(s)
STRO

Name of each exchange on which registered
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 November 13, 2023, Sutro Biopharma, Inc. (the “*Company*”) issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 September 30, 2023, dated November 13, 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.

Date: November 13, 2023

Sutro Biopharma, Inc.

By:

/s/ Edward Albini
Edward Albini
Chief Financial Officer

Sutro Biopharma Reports Third Quarter 2023 Financial Results, Business Highlights and Select Anticipated Milestones

- Updated luvelta data from Compassionate Use Access demonstrating anti-leukemic activity in pediatric patients with relapsed/refractory CBF2AT3-GLIS2 AML to be presented in a poster at ASH 2023 -
- Luvelta demonstrated encouraging preliminary anti-tumor activity in initial data from the Phase 1 dose-expansion study for patients with endometrial cancer presented at ESMO 2023 -
- Dr. Hans-Peter Gerber joined Sutro as Chief Scientific Officer in September 2023 -
- As of September 30, 2023, Sutro had cash and investments of \$321.1 million and shares of Vaxcyte common stock valued at \$34.0 million, which together provide a projected cash runway into the first half of 2025 -

SOUTH SAN FRANCISCO, Calif., November 13, 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 third quarter of 2023, its recent business highlights, and a preview of select anticipated milestones.

“The last few months have been productive for Sutro, with the recent presentation of encouraging early data for luvelta in endometrial cancer, as well as the appointment of Dr. Hans-Peter Gerber as our CSO. Dr. Gerber’s extensive experience in discovering and developing novel ADCs further strengthens our position as a scientific leader in this important therapeutic modality,” said Bill Newell, Sutro’s Chief Executive Officer. “The recent encouraging update with luvelta in endometrial cancer gave us further confidence in the potential for luvelta to be a targeted treatment for a range of indications with significant unmet need. Additionally, we are pleased with the pace of enrollment of our Phase 2/3 trial for luvelta in patients with platinum resistant ovarian cancer, REFRA-ME-O1.”

“Sutro’s remarkable platform has the potential to yield best in class product candidates from all of our ADC design concepts – including ADCs, iADCs, and ADC². The diversity of product candidate attributes enabled by Sutro technology is what originally attracted me to the company,” said Hans-Peter Gerber, Sutro’s CSO. “After an in-depth review of the platform and programs developed at Sutro, I am excited to combine our industry leading technology with our established development capabilities to deliver fit-for-purpose molecules that could transform the lives of cancer patients with limited options.”

Recent Business Highlights and Select Anticipated Milestones

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

- Initial results from the Phase 1 dose-expansion study for luvelta in patients with endometrial cancer were presented in a mini oral presentation at the 2023 European Society for Medical Oncology (ESMO) Congress held in Madrid, Spain in October 2023. Luvelta demonstrated encouraging preliminary anti-tumor activity in FolR α -selected patients, defined by a Tumor Proportion Score (TPS) of >25% FolR α expression, and the safety profile was consistent with prior data in patients with platinum-resistant ovarian cancer.
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- Previous data from the Phase 1 dose-expansion study for luvelta in ovarian cancer demonstrated meaningful clinical benefit in FolR α -selected patients, defined by a TPS of >25%, irrespective of staining intensity, in which the data collected has shown to represent approximately 80% of the advanced ovarian cancer patient population.

- In June 2023, Sutro announced the initiation of Part I of REFRaME-O1, a Phase 2/3 registration-directed study for patients with platinum-resistant ovarian cancer. The trial is well underway, and sites have been activated globally. Sutro is also in discussions with both the FDA and EMA to refine the trial design for REFRaME-O1 to potentially support global registration of luvelta.

- Patients with CBFA2T3::GLIS2 (CBF/GLIS; RAM phenotype) AML, a highly refractory and uniformly fatal subtype of acute myeloid leukemia found exclusively in infants and young children, were treated with luvelta under compassionate use. Preliminary results from compassionate use of luvelta in this ultra rare indication suggested that luvelta was well tolerated as a monotherapy agent and in combination with standard cancer therapies. Soheil Meshinchi, M.D., Ph.D., expects to present updated data from this program in a poster at the 65th American Society of Hematology Annual Meeting and Exposition (ASH 2023) to be held December 9-12, 2023 in San Diego, CA.

Title: Anti-Leukemic Activity of Luveltamab Tazevibulin (LT, STRO-002), a Novel Folate Receptor- α (FR- α)-Targeting Antibody Drug Conjugate (ADC) in Relapsed/Refractory CBFA2T3::GLIS2 AML

Session: 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III

Date & Time: Monday, December 11, 2023, 6:00 PM - 8:00 PM PT

- Luvelta is also being studied in combination with bevacizumab for patients with advanced ovarian cancer.

- Translational work is ongoing to support an Investigational New Drug (IND) application for the initiation of a study of luvelta for patients with non-small cell lung cancer (NSCLC), for which the protocol is under development.

Additional Pipeline Development: STRO-003, a ROR1-targeting ADC, and STRO-004, a tissue factor-targeting ADC, have INDs planned for 2024 and 2025, respectively.

- STRO-003, a novel, next-generation ADC that has been designed to target ROR1, features eight precisely placed β -Glucuronidase-cleavable linkers attached to next-generation exatecan warheads, which, when released, 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 ROR1-expressing tumors. STRO-003 has also exhibited promising tolerability in preclinical studies involving rodents and non-human primates, with potentially reduced lung toxicity relative to other TOPO-1 inhibiting ADCs.

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 \$785 million in payments through September 30, 2023, including equity investments.

- In June 2023, Sutro announced a royalty monetization agreement with Blackstone Life Sciences, an affiliate of Blackstone, under which Sutro received \$140 million upfront and is eligible to receive up to an additional \$250 million in future milestone payments in exchange for the 4% royalty, or revenue interest, in potential future sales of Vaxcyte's products. This transaction with Blackstone provides non-dilutive capital to Sutro for continued pipeline advancement. Sutro retains the right

to discover and develop vaccines for the treatment or prophylaxis of any disease that is not caused by an infectious pathogen, including cancer.

- 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.

- 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 its partners including for Merck's MK-1484, currently in Phase 1 as monotherapy and in combination with pembrolizumab in advanced or metastatic solid tumors. 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), which recently received its first IND clearance by the National Medical Products Administration, or NMPA, for their initiation of clinical development activities in Greater China for STRO-002 and will provide initial drug supply for their Phase 1 study.

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

- Hans-Peter Gerber, Ph.D., joined Sutro as Chief Scientific Officer in September 2023, overseeing the research and early discovery functions, with a focus on the design and discovery of new molecules to rapidly progress into the clinic, in addition to being a member of Sutro's Senior Management Team.

Upcoming Events: Sutro plans to participate in two upcoming investor conferences. Webcasts of the presentations will be accessible through the News & Events page of the Investor Relations section of the company's website at www.sutro.bio.com. Archived replays will be available for at least 30 days after the events.

- Jefferies London Healthcare Conference in London, Wednesday, November 14-16, 2023

- Piper Sandler 35th Annual Healthcare Conference in New York, November 28-30, 2023

Third Quarter 2023 Financial Highlights

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2023, Sutro had cash, cash equivalents and marketable securities of \$321.1 million, as compared to \$358.3 million as of June 30, 2023, and approximately 0.7 million shares of Vaxcyte common stock with a fair value of \$34.0 million, which together provide a projected cash runway into the first half of 2025, based on current business plans and assumptions. Current market conditions provide a challenging financing environment. In this context, Sutro is evaluating its programs and spending as it fully develops its 2024 goals and financial plan.

Unrealized Gain from Increase in Value of Vaxcyte Common Stock

The non-operating, unrealized gain of \$0.7 million in the quarter ended September 30, 2023 was due to the increase since June 30, 2023 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.

Revenue

Revenue was \$16.9 million for the quarter ended September 30, 2023, as compared to \$25.1 million for the same period in 2022, with the 2023 amount related principally to the Astellas collaboration and the recognition of a contingent payment from Tasly. 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 quarter ended September 30, 2023 were \$60.9 million, as compared to \$46.4 million for the same period in 2022. The third quarter of 2023 includes non-cash expenses for stock-based compensation of \$6.0 million and depreciation and amortization of \$1.7 million, as compared to \$6.8 million and \$1.4 million, respectively, in the comparable 2022 period. Total operating expenses for the quarter ended September 30, 2023 were comprised of research and development expenses of \$45.7 million and general and administrative expenses of \$15.3 million.

Royalty Monetization Agreement

As related to the royalty monetization agreement between Sutro and an affiliate of Blackstone Life Sciences, Sutro received in June 2023 a \$140.0 million upfront payment and is eligible to receive up to an additional \$250.0 million in future milestone payments. Sutro recorded the \$140.0 million upfront payment from Blackstone as a deferred royalty obligation related to the sale of future royalties on the Company's condensed Balance Sheets as of June 30, 2023. Due to the Company's ongoing manufacturing obligations, the Company accounted for the proceeds as imputed debt and will recognize future non-cash royalty revenues. Non-cash interest expense will be recognized over the estimated life of the royalty term arrangement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Vaxcyte. As part of the sale, Sutro incurred approximately \$3.8 million in transaction costs, which are being amortized over the estimated life of the royalty term arrangement using the effective interest method. As future royalties are earned from Vaxcyte by Blackstone, the balance of the deferred royalty obligation will be amortized over the estimated life of the royalty term arrangement.

About Sutro Biopharma

Sutro Biopharma, Inc., is a clinical-stage company relentlessly focused on the discovery and development of precisely designed cancer therapeutics, transforming what science can do for patients. Sutro's fit-for-purpose technology, including cell-free XpressCF®, provides the opportunity for broader patient benefit and an improved patient experience. Sutro has multiple clinical stage candidates, including luveltamab tazevibulin, or luvelta, a registrational-stage folate receptor alpha (FolR α)-targeting ADC in clinical studies. A robust pipeline, coupled with high-value collaborations and industry partnerships, validates Sutro's continuous product innovation. Sutro is headquartered in South San Francisco. For more information, follow Sutro on social media @SutroBio, or visit www.sutroBio.com.

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, the Company’s expectations about its cash runway, 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, 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.

Contact

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

	Three Months Ended		September 30,		Nine Months Ended		September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Revenues	\$	16,924	\$	25,147	\$	40,010	\$	59,140
Operating expenses								
Research and development		45,669		31,714		126,660		94,036
General and administrative		15,269		14,643		45,780		44,825
Total operating expenses		60,938		46,357		172,440		138,861
Loss from operations		(44,014)		(21,210)		(132,430)		(79,721)
Interest income		4,550		1,014		9,952		1,327
Unrealized gain on equity securities		694		3,496		2,023		323
Non-cash interest expense related to the sale of future royalties		(5,936)		-		(6,378)		-
Interest and other income (expense), net		(2,739)		(2,788)		(8,640)		(4,039)
Loss before provision for income taxes		(47,445)		(19,488)		(135,473)		(82,110)
Provision for income taxes		1,839		-		2,385		2,500
Net loss	\$	(49,284)	\$	(19,488)	\$	(137,858)	\$	(84,610)
Net loss per share, basic and diluted	\$	(0.81)	\$	(0.37)	\$	(2.30)	\$	(1.74)
Weighted-average shares used in computing basic and diluted loss per share		60,599,025		52,345,732		59,894,181		48,622,258

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

	September 30, 2023 ⁽¹⁾	December 31, 2022 ⁽²⁾
Assets		
Cash, cash equivalents and marketable securities	\$ 321,108	\$ 302,344
Investment in equity securities	34,043	32,020
Accounts receivable	16,627	7,122
Property and equipment, net	22,344	24,621
Operating lease right-of-use assets	23,996	26,443
Other assets	13,616	14,394
Total Assets	<u>\$ 431,734</u>	<u>\$ 406,944</u>
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	\$ 36,312	\$ 32,822
Deferred revenue	102,137	106,644
Operating lease liability	31,038	34,159
Debt	7,137	16,271
Deferred royalty obligation related to the sale of future royalties	142,763	-
Total liabilities	319,387	189,896
Total stockholders' equity	112,347	217,048
Total Liabilities and Stockholders' Equity	<u>\$ 431,734</u>	<u>\$ 406,944</u>

⁽¹⁾ The condensed balance sheet as of September 30, 2023 was derived from the unaudited financial statements included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the Securities and Exchange Commission on November 13, 2023.

⁽²⁾ 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.

