

**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, 2024

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	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 November 13, 2024, Sutro Biopharma, Inc. (the “*Company*”) issued a press release announcing its financial results for the quarter ended September 30, 2024. 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, 2024, dated November 13, 2024.
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: November 13, 2024

By:

/s/ Edward Albini
Edward Albini
Chief Financial Officer

Sutro Biopharma Reports Third Quarter 2024 Financial Results and Business Highlights

- *Expects to deliver three Investigational New Drug (IND) applications in next three years based on next-generation ADC technology -*
- *Two new clinical trials, REFRaME-P1, a registration-enabling trial of luvelta for pediatric patients with rare leukemia, and REFRaME-L1, a Phase 2 trial of luvelta for patients with non-small cell lung cancer, are underway -*
- *Sutro presented data from the Phase 1b study of luvelta in combination with bevacizumab at ESMO 2024 demonstrating a 56% response rate at the recommended Phase 2 dose of luvelta (4.3 mg/kg) -*
- *As of September 30, 2024, Sutro had \$388.3 million in cash, cash equivalents and marketable securities -*

SOUTH SAN FRANCISCO, Calif., November 13, 2024 – 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 2024 and its recent business highlights.

With its lead program, luveltamab tazevibulin (luvelta), Sutro recently initiated a registrational trial for a rare form of pediatric leukemia, a clinical trial for non-small cell lung cancer (NSCLC), and presented expansion data in combination with bevacizumab. The randomized portion of Sutro's registrational trial for patients with advanced ovarian cancer is underway. Sutro expects to provide an update following alignment with the U.S. Food & Drug Administration (FDA) on the selected dose for the pivotal portion of this trial around the end of the year.

Recognizing the potential patient benefit and commercial opportunity for luvelta, Sutro engaged Lazard to assist in its efforts to identify a partner for luvelta who can provide financial resources and expertise for the multi-indication development and commercialization of luvelta.

Additionally, Sutro showcased at a recent Research Forum a portfolio of emerging next-generation ADCs, made possible by our unique cell-free platform, which are expected to drive value creation beyond luvelta. During the event, Sutro announced three planned IND filings over the next three years for wholly owned programs, including STRO-004, a tissue-factor targeting ADC, featuring a DAR8 exatecan payload and site-specific linker design, which is expected to enter the clinic next year.

Recent Business Highlights and Select Anticipated Milestones**Luveltamab Tazevibulin (luvelta), FR α -Targeting ADC Franchise:**

- Sutro presented updated data from the Phase 1b study of luvelta in combination with bevacizumab for patients with ovarian cancer in a poster presentation at the European Society for Medical Oncology (ESMO) Congress 2024, demonstrating a 56% response rate at the recommended Phase 2 dose of luvelta (4.3 mg/kg) for this study. An expansion study of this combination is ongoing, with data expected in the first half of 2025.
- Part 2 (randomized portion) of the Phase 3 trial, REFRaME-O1, for treatment of platinum-resistant ovarian cancer (PROC), is ongoing.
- REFRaME-P1, a registration-enabling trial for pediatric patients with CBFA2T3::GLIS2 (CBF/GLIS; RAM phenotype) AML, is underway.



- A Phase 2 trial for the treatment of NSCLC is underway, with initial data expected in 2025.

Additional Pipeline Development and Collaboration Updates:

- In October 2024, Sutro hosted a Research Forum highlighting next-generation ADC innovation and near-term pipeline milestones, including:
 - STRO-004, a tissue factor-targeting ADC, which features a drug-antibody-ratio (DAR) of eight exatecan payloads and site-specific linker design, demonstrated greater anti-tumor activity and lower toxicities than a tissue factor benchmark ADC in preclinical models. Sutro anticipates filing an IND for STRO-004 in the second half of 2025.
 - Dual-payload ADCs (ADC²) provide therapeutic benefits compared to standard ADCs, including potential to overcome tumor resistance mechanisms, and show increased anti-tumor activity and desirable properties in preclinical models.
 - iADCs provide a novel mechanism of action, bridging innate and adaptive immunity to enable broad protection in a single molecule, and show increased and durable anti-tumor activity in a preclinical model compared to standalone ADCs or immune-stimulating antibody conjugates.
 - Sutro's proprietary and partnered preclinical ADC portfolio has potential across a broad range of tumor types and the Company plans to deliver three INDs over the next three years.
- 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 \$975 million in payments through September 30, 2024, including equity investments.

Upcoming Events: Sutro plans to participate in three 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, November 19-21, 2024, in London
- The Citizens JMP Hematology and Oncology Summit, December 2, 2024, Virtual
- Piper Sandler 36th Annual Healthcare Conference, December 3-5, 2024, in New York

Third Quarter 2024 Financial Highlights

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2024, Sutro had \$388.3 million in cash, cash equivalents and marketable securities.

Realized Gain on Sale of Vaxcyte Common Stock

Included in non-operating interest and other income (expense), net, on the Statement of Operations for the nine months ended September 30, 2024 was a realized gain of \$32.1 million from the sale of approximately 0.7 million shares of Vaxcyte common stock, with net proceeds of approximately \$74.0 million. As of September 30, 2024, Sutro does not hold any shares of Vaxcyte common stock.

Revenue

Revenue was \$8.5 million for the quarter ended September 30, 2024, as compared to \$16.9 million for the same period in 2023, with the 2024 amount related principally to the Astellas collaboration and the Vaxcyte 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 quarter ended September 30, 2024 were \$76.4 million, as compared to \$60.9 million for the same period in 2023. The 2024 quarter includes non-cash expenses for stock-based



compensation of \$6.5 million and depreciation and amortization of \$1.8 million, as compared to \$6.0 million and \$1.7 million, respectively, in the comparable 2023 period. Total operating expenses for the quarter ended September 30, 2024 were comprised of research and development expenses of \$62.1 million and general and administrative expenses of \$14.3 million.

About Sutro Biopharma

Sutro Biopharma, Inc., is a clinical-stage company relentlessly focused on the discovery and development of precisely designed cancer therapeutics, to transform 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 (FolRα)-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, including enrollment and site activation; timing of announcements of clinical results, trial initiation, and regulatory filings; outcome of discussions with regulatory authorities; potential benefits of luvelta and the Company's other product candidates and platform; potential business development and partnering transactions; potential market opportunities for luvelta and the Company's other product candidates; and the Company's expected cash runway. 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, 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,	
	2024	2023	2024	2023
Revenues	\$ 8,520	\$ 16,924	\$ 47,234	\$ 40,010
Operating expenses				
Research and development	62,108	45,669	181,006	126,660
General and administrative	14,331	15,269	39,423	45,780
Total operating expenses	76,439	60,938	220,429	172,440
Loss from operations	(67,919)	(44,014)	(173,195)	(132,430)
Interest income	4,875	4,550	13,882	9,952
Unrealized gain on equity securities	-	694	-	2,023
Non-cash interest expense related to the sale of future royalties	(7,910)	(5,936)	(22,380)	(6,378)
Interest and other income (expense), net	22,167	(2,739)	26,683	(8,640)
Loss before provision for income taxes	(48,787)	(47,445)	(155,010)	(135,473)
Provision for income taxes	-	1,839	8	2,385
Net loss	<u>\$ (48,787)</u>	<u>\$ (49,284)</u>	<u>\$ (155,018)</u>	<u>\$ (137,858)</u>
Net loss per share, basic and diluted	<u>\$ (0.59)</u>	<u>\$ (0.81)</u>	<u>\$ (2.07)</u>	<u>\$ (2.30)</u>
Weighted-average shares used in computing basic and diluted loss per share	<u>82,043,671</u>	<u>60,599,025</u>	<u>74,934,737</u>	<u>59,894,181</u>

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

	September 30, 2024 ⁽¹⁾	December 31, 2023 ⁽²⁾
Assets		
Cash, cash equivalents and marketable securities	\$ 388,254	\$ 333,681
Investment in equity securities	-	41,937
Accounts receivable	6,655	36,078
Property and equipment, net	18,997	21,940
Operating lease right-of-use assets	19,027	22,815
Other assets	18,899	14,285
Total Assets	<u>\$ 451,832</u>	<u>\$ 470,736</u>
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	\$ 53,222	\$ 64,293
Deferred revenue	90,559	74,045
Operating lease liability	24,864	29,574
Debt	-	4,061
Deferred royalty obligation related to the sale of future royalties	171,967	149,114
Total liabilities	<u>340,612</u>	<u>321,087</u>
Total stockholders' equity	<u>111,220</u>	<u>149,649</u>
Total Liabilities and Stockholders' Equity	<u>\$ 451,832</u>	<u>\$ 470,736</u>

⁽¹⁾ The condensed balance sheet as of September 30, 2024 was derived from the unaudited financial statements included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission on November 13, 2024.

⁽²⁾ The condensed balance sheet as of December 31, 2023 was derived from the unaudited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on March 25, 2024.

