

# Sutro Biopharma Reports Full Year 2023 Financial Results, Business Highlights and Select Anticipated Milestones

- Sutro highlighted luveltamab tazevibulin (luvelta) in a January 2024 investor webcast, describing the broad opportunity to address unmet needs in multiple FolRα-expressing cancers -
- Compelling anti-leukemic activity of luvelta in pediatric patients with relapsed/refractory CBF2AT3-GLIS2 AML treated under Compassionate Use shown in data presented at ASH 2023 -
- Jane Chung promoted to President and Chief Operating Officer in November 2023 -
- As of year-end 2023, Sutro had cash and investments of \$333.7 million and shares of Vaxcyte common stock valued at \$41.9 million, which together provide a projected cash runway into the second half of 2025 -

SOUTH SAN FRANCISCO, Calif., March 25, 2024 (GLOBE NEWSWIRE) -- 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 2023, its recent business highlights, and a preview of select anticipated milestones.

"The year 2023 was pivotal for Sutro, with the initiation of REFRαME-O1, our registration-directed study of luvelta for platinum-resistant ovarian cancer (PROC) patients, further validating our next-generation ADC capabilities. In addition, we advanced our earlier stage programs, strengthened our management team, and bolstered our already strong cash position with additional non-dilutive capital," said Bill Newell, Sutro's Chief Executive Officer. "We look forward to continuing the momentum in 2024, with the initiation of a second registration-directed trial with luvelta, REFRαME-P1, for pediatric patients with CBF/GLIS AML, and two additional planned INDs. I am delighted with the strides we are taking towards meaningfully impacting the lives of cancer patients in need."

# **Recent Business Highlights and Select Anticipated Milestones**

STRO-002, International Nonproprietary Name, "luveltamab tazevibulin," abbreviated as "luvelta," FolRα-Targeting ADC Franchise:

 In January 2024, Sutro hosted an investor webcast highlighting luvelta's broad opportunity to address unmet needs in several FolRα-expressing cancers, including platinum-resistant ovarian cancer (PROC), endometrial cancer, CBFA2T3::GLIS2 (CBF/GLIS; RAM phenotype) acute myeloid leukemia (AML), and non-small cell lung cancer (NSCLC).

- The registration-directed trial, REFRαME-O1, for treatment of PROC is enrolling, with an anticipated ~140 sites in ~20 countries to be opened by the end of 2024. Enrollment of Part 1 of the trial is expected to be completed in the first half of 2024.
- In December 2023, data demonstrating anti-leukemic activity with luvelta, either as a single agent or in combination, in pediatric patients with CBF/GLIS AML, were presented at the 65th American Society of Hematology Annual Meeting and Exposition (ASH 2023), including complete remission in 42% of patients with CBF/GLIS AML with ≥5% blasts and in 75% of pediatric patients with CBF/GLIS AML with <5% blasts.
- Enrollment of REFRαME-P1, a registration-enabling trial for pediatric patients with CBF/GLIS AML, is expected to be initiated in the second half of 2024.
- An Investigational New Drug (IND) application submission is planned for treatment of non-small cell lung cancer (NSCLC) in the first half of 2024.
- Continued clinical development is planned in combination with bevacizumab for the treatment of ovarian cancer and in endometrial cancer, as resources permit.

## **Additional Pipeline Development and Collaboration Updates:**

- Sutro plans to submit an IND for STRO-003, a ROR1-targeting ADC, in 2024.
- Sutro plans to submit an IND for STRO-004, a tissue factor-targeting ADC, in 2025.
- 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 \$854 million in payments through December 31, 2023, including equity investments.
- In November 2023, Vaxcyte exercised its option to enter into a manufacturing rights agreement with Sutro to obtain control over the development and manufacture of cell-free extract for use under its license agreement with Sutro, including for Vaxcyte's pneumococcal conjugate vaccine (PCV) franchise, which includes VAX-24 and VAX-31. Upon exercising the option, Vaxcyte paid Sutro \$50 million and is obligated to pay Sutro an additional \$25 million within six months. Upon the occurrence of certain regulatory milestones, Vaxcyte would be obligated to pay Sutro up to an additional \$60 million.

## **Corporate Updates:**

 Sutro continues to build a world-class leadership team through the promotion of Jane Chung to President and Chief Operating Officer, a newly created role in which she will be responsible for driving operational excellence, strategic growth, and overall business success at Sutro.

## **Full Year 2023 Financial Highlights**

Cash, Cash Equivalents and Marketable Securities

As of December 31, 2023, Sutro had cash, cash equivalents and marketable securities of \$333.7 million, as compared to \$321.1 million as of September 30, 2023, and approximately 0.7 million shares of Vaxcyte common stock with a fair value of \$41.9 million, which together

provide a projected cash runway into the second half of 2025, based on current business plans and assumptions. Current market conditions provide a challenging financing environment. In this context, Sutro is continuing its process of evaluating its programs and spending.

Unrealized Gain from Increase in Value of Vaxcyte Common Stock

The non-operating, unrealized gain of \$9.9 million for the year 2023 was due to the increase since December 31, 2022 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 \$153.7 million for the year ended December 31, 2023, as compared to \$67.8 million for the same period in 2022, with the 2023 amount related principally to the Vaxcyte manufacturing rights agreement option exercise, Astellas and Merck collaborations, 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 year ended December 31, 2023 were \$243.0 million, as compared to \$196.7 million for the same period in 2022. The year 2023 includes non-cash expenses for stock-based compensation of \$24.9 million and depreciation and amortization of \$6.8 million, as compared to \$26.3 million and \$5.7 million, respectively, in the comparable 2022 period. Total operating expenses for the year ended December 31, 2023 were comprised of research and development expenses of \$180.4 million and general and administrative expenses of \$62.6 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 $^{\mathbb{R}}$ , 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 $\alpha$ )-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 <a href="https://www.sutrobio.com">www.sutrobio.com</a>.

## **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 regulatory decisions; potential benefits of luvelta and the Company's other product candidates and platform; potential expansion into other indications and combinations, including the timing and development activities related to such expansion; 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, 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)

	For the year ended December 31						
		2023		2022		2021	
Revenues	\$	153,731	\$	67,772	\$	61,880	
Operating expenses							
Research and development		180,425		137,171		104,400	
General and administrative		62,584		59,544		56,004	
Total operating expenses		243,009		196,715		160,404	
Loss from operations		(89,278)		(128,943)		(98,524)	
Interest income		14,510		3,455		577	
Unrealized gain (loss) on equity securities		9,917		12,130		(4,454)	
Non-cash interest expense related to the sale of future royalties		(12,570)		-		_	
Interest and other income (expense), net		(11,180)		(3,346)		(3,137)	
Loss before provision for income taxes		(88,601)		(116,704)		(105,538)	
Provision for income taxes		18,192		2,500		-	
Net loss	\$	(106,793)	\$	(119,204)	\$	(105,538)	
Net loss per share, basic and diluted	\$	(1.78)	\$	(2.35)	\$	(2.29)	
Weighted-average shares used in computing basic and diluted loss per share		60,163,542		50,739,185		46,119,089	

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

	December 31,				
	2023 <sup>(1)</sup>			2022 <sup>(2)</sup>	
Assets					
Cash, cash equivalents and marketable securities	\$	333,681	\$	302,344	
Investment in equity securities		41,937		32,020	
Accounts receivable		36,078		7,122	
Property and equipment, net		21,940		24,621	
Operating lease right-of-use assets		22,815		26,443	
Other assets		14,285		14,394	
Total Assets	\$	470,736	\$	406,944	
Liabilities and Stockholders' Equity					
Accounts payable, accrued expenses and other liabilities	\$	64,293	\$	32,822	
Deferred revenue		74,045		106,644	
Operating lease liability		29,574		34,159	
Debt		4,061		16,271	
Deferred royalty obligation related to the sale of future royalties		149,114		-	
Total liabilities		321,087		189,896	
Total stockholders' equity		149,649		217,048	
Total Liabilities and Stockholders' Equity	\$	470,736	\$	406,944	

- (1) 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.
- (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.



Source: Sutro Biopharma, Inc.