August 10, 2023

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

- Enrollment is underway for REFRaME-O1, the Phase 2/3 pivotal study of luveltamab tazevibulin, or luvelta, for patients with platinum-resistant ovarian cancer -

- Sutro will present data from the Phase 1 dose expansion for luvelta for patients with endometrial cancers as a Mini Oral Session at ESMO 2023 -

- Sutro announced a royalty monetization agreement with Blackstone Life Sciences in June 2023, under which Sutro received an upfront payment of $140 million, and is eligible to receive up to an additional $250 million in milestone payments upon the achievement of certain return thresholds -

- As of June 30, 2023, Sutro had cash and investments of $358.3 million and shares of Vaxcyte common stock valued at $33.3 million, which together provide a projected cash runway into the first half of 2025 -

SOUTH SAN FRANCISCO, Calif., Aug. 10, 2023 (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 second quarter of 2023, its recent business highlights, and a preview of select anticipated milestones.

“We are delighted with the initiation of the REFRaME study, a pivotal Phase 2/3 trial for patients with platinum-resistant ovarian cancer. The oral presentation at ASCO has generated significant interest of luvelta within the medical community, providing momentum for patient enrollment into REFRaME across our global sites," said Bill Newell, Sutro’s Chief Executive Officer. “Our financial position has been bolstered by the Blackstone royalty agreement, which helps to extend our cash runway into the first half of 2025. We remain committed to our pipeline progress and eagerly anticipate sharing updated data from the Phase 1 STRO-002-GM1 study in the second half of this year for ovarian and endometrial cancers."

Recent Business Highlights and Select Anticipated Milestones

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

- Data from the Phase 1 dose-expansion study for luvelta in ovarian cancer were featured as an oral presentation at the 2023 American Society of Clinical Oncology (ASCO 2023) Annual Meeting in Chicago, IL in June 2023. Consistent with data reported in January 2023, luvelta demonstrated substantial clinical benefit in FolRα-selected patients, defined by a Tumor Proportion Score (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. Additionally, Sutro expects to release updated data from the Phase 1 STRO-002-GM1 study in patients with ovarian cancer in the second half of 2023.
- In June 2023, Sutro announced the initiation of REFRaME, a Phase 2/3 registration-directed study for patients with platinum-resistant ovarian cancer. Patient dosing has begun, and global sites have been activated, with additional sites expected this year. Once results are analyzed on ~110 patents with demonstrated high or unmet need, 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 may be pursued based on progression-free survival (PFS) as the primary endpoint, comparing results from the luvelta arm and the standard of care arm.
- 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. During the 64th American Society of Hematology Annual Meeting and Exposition (ASH 2022), an oral presentation was given by Soheil Meshinchi, M.D., Ph.D. summarizing preliminary results from compassionate use of luvelta in this rare indication, suggesting that luvelta was well tolerated as a monotherapy agent and in combination with standard cancer therapies. Sutro plans to initiate a pivotal, or registration-enabling protocol to pursue registration in this high unmet need, vastly underserved patient population.
- 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. Sutro will present data from the Phase 1 dose expansion of luveltamab tazevibulin for patients with endometrial cancers as a Mini Oral Session at the European Society for Medical Oncology (ESMO) Congress 2023 to be held October 20-24, 2023 in Madrid, Spain.

  Title: Luveltamab Tazevibulin (STRO-002), an anti-Folate Receptor Alpha (FolRα) Antibody Drug Conjugate (ADC), Demonstrates Clinical Activity in Recurrent/Progressive Epithelial Endometrial Cancer (EEC): STRO-002-GM1 Phase 1 Dose Expansion

  Session: Mini Oral Session 1 - Gynecological cancers

  Date & Time: Sunday, October 22, 2023, 10:15am-11:45am CEST

- Translational work is ongoing to support an Investigational New Drug (IND) application 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 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 future prioritization decisions regarding further clinical development.
- 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 for the treatment of advanced non-Hodgkin's lymphoma (NHL).

Additional Pipeline Development: STRO-003, a ROR1-targeting ADC and STRO-004, a tissue factor-targeting ADC have INDs planned for Q1 2024 and Q1 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.
- Expanded preclinical data for STRO-003 was presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2023, demonstrating potent anti-tumor activity and immune-modulating properties, suggesting that STRO-003 may have the potential to augment checkpoint blockade therapy.
- 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 $772 million in payments through June 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) for their IND filing and the initiation of clinical development activities in Greater China for STRO-002 and will provide initial clinical drug supply.

Corporate Updates: Sutro continues to strengthen its Research team.

- Gang Yin, Ph.D., has been promoted to Vice President, Platform and Process Sciences, and will continue to lead protein biochemistry efforts and serve as a key interface with other Sutro teams working on its cell-free technology and platform.
- Alice Yam, Ph.D., has been promoted to Vice President, Drug Discovery, and will lead pharmacology efforts and continue to provide leadership for pre-clinical efforts on Sutro's emerging product development candidates.

Second Quarter 2023 Financial Highlights

Cash, Cash Equivalents and Marketable Securities
As of June 30, 2023, Sutro had cash, cash equivalents and marketable securities of $358.3 million, as compared to $251.5 million as of March 31, 2023, and approximately 0.7 million shares of Vaxcyte common stock with a fair value of $33.3 million, which together provide a projected cash runway into the first half of 2025, based on current business plans and assumptions.

Unrealized Gain from Increase in Value of Vaxcyte Common Stock
The non-operating, unrealized gain of $8.3 million in the quarter ended June 30, 2023 was due to the increase since March 31, 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 $10.4 million for the quarter ended June 30, 2023, as compared to $28.1 million for the same period in 2022, with the 2023 amount related principally to the Astellas, Merck and BMS collaborations. 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 June 30, 2023 were $56.6 million, as compared to $47.5 million for the same period in 2022. The second quarter 2023 amount

includes non-cash expenses for stock-based compensation of $6.7 million and depreciation and amortization of $1.7 million, as compared to $6.7 million and $1.4 million, respectively, in the comparable 2022 period. Total operating expenses for the quarter ended June 30, 2023 were comprised of research and development expenses of $41.6 million and general and administrative expenses of $15.0 million, which are expected to increase in the remainder of 2023 as Sutro's internal product candidates advance in clinical development and additional general and administrative expenses are incurred as a public company.

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 developing next-generation cancer therapeutics, principally antibody-drug conjugates (ADCs), designed for greater potency, tolerability and improved safety. Sutro's cell-free technology, XpressCF®, enables the design and manufacture of homogeneous product candidates with precise and empirically-demonstrated positioning of linker-payloads and consistent drug antibody ratio (DAR). Sutro's platform has produced six clinical stage candidates to date, including two wholly-owned ADCs—luveltamab tazevibulin, or luvelta, a folate receptor alpha (FolRα)-targeting ADC in clinical studies for ovarian and endometrial cancers, as well as STRO-001, a CD74-targeting ADC in clinical studies for B-cell malignancies. In addition, the Company has a robust pipeline of preclinical and discovery stage candidates including STRO-003, a ROR1-targeting ADC, and STRO-004, a tissue factor-targeting ADC. Sutro has also entered into high-value collaborations with industry partners, including Astellas and Merck (MSD outside of the United States and Canada); and Sutro's platform technology enabled the formation of Vaxcyte. Sutro is headquartered in South San Francisco. For more information, follow Sutro on Twitter, @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, 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.

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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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues	$ 10,412	$ 28,096	$ 23,086	$ 33,993
Operating expenses				
Research and development	41,592	32,332	80,991	62,322
General and administrative	14,999	15,143	30,511	30,182
Total operating expenses	56,591	47,475	111,502	92,504
Loss from operations	(46,179)	(19,379)	(88,416)	(58,511)
Interest income	2,842	197	5,402	313
Unrealized gain (loss) on equity securities	8,321	(3,736)	1,329	(3,173)
Non-cash interest expense related to the sale of future royalties	(442)	-	(442)	-
Interest and other income (expense), net	(2,915)	(594)	(5,901)	(1,251)
Loss before provision for income taxes	(38,373)	(23,512)	(88,028)	(62,622)
Provision for income taxes	151	2,500	546	2,500
Net loss	$ (38,524)	$ (26,012)	$ (88,574)	$ (65,122)
Net loss per share, basic and diluted	$ (0.64)	$ (0.55)	$ (1.49)	$ (1.39)
Weighted-average shares used in computing basic and diluted loss per share	60,339,475	46,957,196	59,535,918	46,729,663

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

	June 30, 2023[1]	December 31, 2022[2]
Assets		
Cash, cash equivalents and marketable securities	$ 358,293	$ 302,344
Investment in equity securities	33,349	32,020
Accounts receivable	9,999	7,122
Property and equipment, net	23,636	24,621
Operating lease right-of-use assets	25,138	26,443
Other assets	14,484	14,394
Total Assets	$ 464,899	$ 406,944
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	$ 32,958	$ 32,822
Deferred revenue	97,916	106,644
Operating lease liability	32,460	34,159
Debt	10,197	16,271
Deferred royalty obligation related to the sale of future royalties	136,653	-
Total liabilities	310,184	189,896
Total stockholders' equity	154,715	217,048
Total Liabilities and Stockholders' Equity	$ 464,899	$ 406,944

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

SUTRO BIOPHARMA

Source: Sutro Biopharma, Inc.