May 15, 2023

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

- Data from the Phase 1 dose-expansion study for luveltamab tazevibulin, or luvelta, for patients with advanced ovarian cancer will be featured as an oral presentation at ASCO 2023 -

- As presented at AACR 2023, STRO-003 demonstrated potent anti-tumor activity and immune-modulating properties in preclinical models, suggesting its potential to augment checkpoint blockade therapy -

- As of March 31, 2023, Sutro had cash and investments of $251.5 million and shares of Vaxcyte common stock valued at $25.0 million, which together provide a projected cash runway into the second half of 2024 -

SOUTH SAN FRANCISCO, Calif., May 15, 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 first quarter of 2023, its recent business highlights, and a preview of select anticipated milestones.

“We’ve had a strong start to the year with the continued advancement of our pipeline,” said Bill Newell, Sutro’s Chief Executive Officer. “As we look toward the rest of the year, we are excited for the imminent initiation of REFRaME, our registration-directed trial for luveltamab tazevibulin, or luvelta, in the second quarter of 2023, in addition to the data readout from our ongoing dose expansion Cohort C in ovarian cancer anticipated in the second half of 2023. We will seek to build on the positive momentum from this quarter to deliver on our goal to provide transformational therapies to cancer patients.”

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, in the U.S. and Europe, for patients with ovarian and endometrial cancers.

- Data from the Phase 1 dose expansion study will be featured as an oral presentation at the 2023 American Society of Clinical Oncology (ASCO 2023) Annual Meeting in Chicago, IL in June 2023.

Presentation Title:	Luveltamab Tazevibulin (STRO-002), an anti-Folate Receptor alpha (FolRα) Antibody Drug Conjugate (ADC), Safety and Efficacy in a Broad Distribution of FOLRα Expression in Patients with Recurrent Epithelial Ovarian Cancer (OC): Update of STRO-002-GM1 Phase 1 Dose Expansion Cohort
Session Type/Title:	Oral Abstract Session - Gynecologic Cancer
Session Time:	Saturday, June 3, 2023, 3:00 p.m. – 6:00 p.m. CDT
Presentation Time:	5:24 p.m. CDT
Abstract Number:	#5508

- 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 results from 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 previously released data; asymptomatic, transient neutropenia was the primary adverse event and no new safety signals were observed. Interim data from an exploratory cohort (Cohort C), 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. Sutro plans to announce updated data from Cohort C in the second half of 2023.
- Patients with CBFA2T3::GLIS2 (CBF/GLIS) 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.
- 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 expects to announce data from both the combination study and endometrial study in the second half of 2023.
- 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).

STRO-003, ROR1-Targeting ADC: IND-enabling studies and manufacturing development are underway for STRO-003 with an IND planned for Q1 2024.

- 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 $626 million in payments through March 31, 2023, 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. 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.
- Sutro's collaboration with Astellas on the discovery of immunostimulatory antibody-drug conjugates (iADCs) for three targets is ongoing, for which Sutro receives additional 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 Phase 1; and clinical trial materials for Bristol Myers Squibb's (BMS) CC-99712, a BCMA-targeting ADC for treatment of multiple myeloma, also 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 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 strengthened and continues to build upon a world-class leadership team.

- Venkatesh Srinivasan, Ph.D., has been promoted to Chief Technical Operations Officer from SVP, Process and Analytical Development, and will be responsible for Chemistry, Manufacturing, and Controls (CMC) and Process and Analytical Development (P&AD) for Sutro's cell-free manufacturing technology and platform.
- Shabbir T. Anik, Ph.D., who has served as Sutro's Chief Technical Operations Officer since March 2016, will transition to the role of Strategic Advisor.
- As previously announced, Trevor Hallam, Ph.D., will be stepping down from his role as President of Research & Chief Scientific Officer, effective May 31, 2023. Dr. Hallam will become a member of Sutro's Scientific Advisory Board. Nicki Vasquez, Ph.D., Chief Portfolio Strategy & Alliance Officer, will assume interim responsibility for leading the research organization. An executive search is ongoing for a Chief Scientific Officer.

First Quarter 2023 Financial Highlights

Cash, Cash Equivalents and Marketable Securities
As of March 31, 2023, Sutro had cash, cash equivalents and marketable securities of $251.5 million, as compared to $302.3 million as of December 31, 2022, and approximately 0.7 million shares of Vaxcyte common stock with a fair value of $25.0 million, which together provide a projected cash runway into the second half of 2024, based on current business plans and assumptions.

Unrealized Loss from Decrease in Value of Vaxcyte Common Stock
The non-operating, unrealized loss of $7.0 million in the quarter ended March 31, 2023 was due to the decrease 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 $12.7 million for the quarter ended March 31, 2023, as compared to $5.9 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 March 31, 2023 were $54.9 million, as compared to $45.0 million for the same period in 2022. The first quarter 2023 amount includes non-cash expenses for stock-based compensation of $6.0 million and depreciation and amortization of $1.6 million, as compared to $7.0 million and $1.3 million, respectively, in the comparable 2022 period. Total operating expenses for the quarter ended March 31, 2023 were comprised of research and development expenses of $39.4 million and general and administrative expenses of $15.5 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.

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.

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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 March 31,	
	2023	**2022**
Revenues	$ 12,674	$ 5,897
Operating expenses		
Research and development	39,399	29,990
General and administrative	15,512	15,039
Total operating expenses	54,911	45,029
Loss from operations	(42,237)	(39,132)
Interest income	2,560	116
Unrealized (loss) gain on equity securities	(6,992)	563
Interest and other income (expense), net	(2,986)	(657)
Loss before provision for income taxes	(49,655)	(39,110)
Provision for income taxes	395	-
Net loss	$ (50,050)	$ (39,110)
Net loss per share, basic and diluted	$ (0.85)	$ (0.84)
Weighted-average shares used in computing basic and diluted loss per share	58,723,432	46,499,602

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

	March 31, 2023[1]	December 31, 2022[2]
Assets		
Cash, cash equivalents and marketable securities	$ 251,466	$ 302,344
Investment in equity securities	25,028	32,020
Accounts receivable	9,873	7,122
Property and equipment, net	24,029	24,621
Operating lease right-of-use assets	25,802	26,443
Other assets	21,818	14,394
Total Assets	$ 358,016	$ 406,944
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	$ 23,807	$ 32,822
Deferred revenue	102,232	106,644
Operating lease liability	33,322	34,159
Debt	13,242	16,271
Total liabilities	172,603	189,896
Total stockholders' equity	185,413	217,048
Total Liabilities and Stockholders' Equity	$ 358,016	$ 406,944

(1) The condensed balance sheet as of March 31, 2023 was derived from the unaudited financial statements included in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the Securities and Exchange Commission on May 15, 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.

Source: Sutro Biopharma, Inc.