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): December 10, 2024

SUTRO BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38662**	**47-0926186**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(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 Stock Market LLC

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 8.01 Other Events.

On December 10, 2024, Sutro Biopharma, Inc. (the "Company") announced the selected dose from the dose-optimization portion (Part 1) of REFRαME-O1, the registration-directed trial of luveltamab tazevibulin ("luvelta"), a novel folate receptor-α (FolRα) targeting antibody drug conjugate ("ADC"), in platinum-resistant ovarian cancer ("PROC").

REFRαME-O1 (Part 1):
REFRαME-O1 (Part 1) evaluated luvelta in patients with PROC with low, medium, and high FRα expression levels. This includes patients with ≥25% Tumor Proportion Score (TPS), defined as at least 25% of tumor cells expressing FRα, at any staining intensity. In the dose-optimization (Part 1), patients were randomized 1:1 to a 5.2 mg/kg with prophylactic pegfilgrastim (G-CSF) for 2 cycles followed by 4.3 mg/kg for subsequent cycles (5.2 mg/kg group), or a 4.3 mg/kg dose of luvelta for all cycles (4.3 mg/kg group).

Topline Results from evaluable patients (5.2 mg/kg group; N = 25):

- Achieved an objective response rate of 32%, which includes one partial response that confirmed post data extraction (as of August 16, 2024)
- Disease control rate of 96%
- Approximately half of the patients treated were ineligible for an approved FRα-targeting ADC
- 88% of patients received prior bevacizumab
- Grade 3 or higher neutropenia occurred in 32% of patients, no febrile neutropenia

REFRαME-O1 (Part 2) Registrational Trial:
REFRαME-O1 (Part 2) is an ongoing global registrational trial for patients with PROC, evaluating a 5.2 mg/kg dose with prophylactic pegfilgrastim (G-CSF) for the first two cycles followed by a 4.3 mg/kg dose for subsequent cycles. Part 2 will enroll approximately 500 patients, randomized 1:1 to luvelta or investigators' choice of chemotherapy.

This Current Report on Form 8-K 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; 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, 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Sutro Biopharma, Inc.

Date: December 10, 2024

By: /s/ Edward Albini
Edward Albini
Chief Financial Officer