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): **May 13, 2025**

SELLAS Life Sciences Group, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-33958**	**20-8099512**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

7 Times Square, Suite 2503
New York, NY 10036

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(646) 200-5278**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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, $0.0001 par value per share	SLS	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 2.02. Results of Operations and Financial Condition.

On May 13, 2025, SELLAS Life Sciences Group, Inc. (“SELLAS”) issued a press release (the “Press Release”) announcing its financial results for the quarter ended March 31, 2025 and providing a corporate update.

A copy of the Press Release is furnished hereto as Exhibit 99.1 and is incorporated by reference herein. The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the SEC made by SELLAS whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated May 13, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

SELLAS Life Sciences Group, Inc.

Date: May 13, 2025

By: */s/ John T. Burns*

Name: John T. Burns

Title: Senior Vice President, Chief Financial Officer

Exhibit 99.1

SELLAS Life Sciences Reports First Quarter 2025 Financial Results and Provides Corporate Update

– Announced Positive Overall Survival in Cohort 3 from the Ongoing Phase 2 Trial of SLS009 (tambiciclib) in Relapsed/Refractory (r/r) Acute Myeloid Leukemia (AML) Demonstrating 8.9 mOS in AML-MRC and 8.8 mOS in All r/r to Venetoclax-Based Regimens Patients–

– SLS009 Shows Promising Efficacy in Pediatric Acute Lymphoblastic Leukemia (ALL) Xenograft Models -

– Final Analysis of Pivotal Phase 3 REGAL Trial of Galinpepimut-S (GPS) in AML Anticipated in 2025 –

– $28.4 million in Cash and Cash Equivalents as of March 31, 2025; Additional $4.0 million Proceeds received in April 2025 through Warrant Exercises -

NEW YORK, NY May 13, 2025 -- SELLAS Life Sciences Group, Inc. (NASDAQ: SLS) (“SELLAS” or the “Company”), a late-stage clinical biopharmaceutical company focused on the development of novel therapies for a broad range of cancer indications, today reported financial results for the first quarter ended March 31, 2025, and provided a corporate update.

“We are very encouraged by the strong momentum across our pipeline,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “The positive overall survival data in cohort 3 from the ongoing Phase 2 trial of SLS009 in r/r AML, showing a median OS that exceeds all historical benchmarks by over 3 times, further underscores the transformative potential of SLS009 for many underserved patients. In parallel, our new preclinical findings demonstrating the ability of SLS009 to overcome TP53-driven resistance, along with the promising clinical efficacy from the ongoing Phase 2, give us renewed optimism for patients across different genetic AML mutations. We look forward to presenting further data on SLS009 at ASCO, highlighting its preclinical efficacy in ASXL1-mutated colorectal cancer lines. With the full topline Phase 2 data of SLS009 anticipated soon, and the final analysis of our Phase 3 pivotal REGAL trial of GPS in AML expected later this year, we are well-positioned for an exciting and meaningful 2025.”

Recent Corporate Highlights:

Announced Positive Overall Survival in Cohort 3 from the Ongoing Phase 2 Trial of SLS009 in r/r AML: The data demonstrated that patients with AML-Myelodysplasia-Related Changes (AML-MRC) achieved a mOS of 8.9 months, while all relapsed or refractory to venetoclax-based regimens patients receiving 30 mg BIW achieved a mOS of 8.8 months, far surpassing the historical benchmark of 2.5 months. In addition, the therapy demonstrated a 67% ORR in patients with AML-MRC and 46% in all evaluable patients, significantly exceeding the targeted 20% ORR. The trial continues with full data and FDA regulatory path feedback expected in 1H 2025.

Presented Preclinical Data Highlighting Efficacy of SLS009 in TP53 Mutated AML at the 2025 AACR Conference: Preclinical data suggest that SLS009 can induce apoptosis downstream of p53 by targeting critical proteins such as MCL-1 and survivin, regardless of p53 status. Immunoblot analysis reveals near-complete removal of these proteins in treated cells within 8 hours of exposure to SLS009. Furthermore, the treatment reduced TP53-mutated leukemia cell populations by up to 97% in combination with azacitidine–venetoclax, and by up to 80% as monotherapy.

Preclinical Efficacy of SLS009 in ASXL1 Mutated Colorectal Cancer to be Showcased at ASCO 2025: The poster, entitled, *In vitro efficacy of CDK9 inhibitor tambiciclib (SLS009) in ASXL1 mutated colorectal cancer cell lines,* will be presented on Monday, June 2, 2025, 1:30 PM-4:30 PM CDT.

Announced Positive Outcome of Interim Analysis for Phase 3 REGAL Trial of GPS in AML: The interim futility, efficacy, and safety analysis was designed to assess whether the therapy is safe, demonstrates potential efficacy, and merits continuation. The IDMC's review supports the continuation of the study according to its original protocol. Based on this positive evaluation, GPS has shown preliminary signals of effectiveness, allowing the trial to advance toward completion. Fewer than 50% of enrolled patients were confirmed deceased after the median follow-up of 13.5 months, indicating a median survival of over 13.5 months in the trial vs. a historical median survival of 6 months for conventional therapy, as reported in a similar Phase 2 study. The next and final analysis will be conducted once 80 events (deaths) are reached, further determining the potential of GPS in addressing the needs of AML patients. SELLAS anticipates that 80 events will be reached this year.

Announced Promising Data from Phase 2a Trial of SLS009 in Combination with Zanubrutinib in DLBCL: The trial, conducted and funded by GenFleet Therapeutics (Shanghai), Inc. ("Genfleet"), was an open-label single-arm multicenter Phase 2a study in China evaluating SLS009 in combination with BTK inhibitor, Brukinsa® (zanubrutinib) in r/r DLBCL. The results showed an overall response rate (ORR) of 67%, more than double the expected ORR of zanubrutinib alone. Among responders, one achieved complete response (CR), while three had partial response (PR) with target lesion shrinkages of 89%, 78%, and 56%, respectively. As of the last follow-up, after the median of 4.6 (range: 1.4 - 7.4) months follow-up, median overall survival (OS) was not reached, and 6 out of 9 patients were alive. GenFleet will determine the next steps in development around lymphoma as SELLAS' focus remains on AML and spliceosome–chromatin mutations, including ASXL1 mutations.

PIVOT - Received Preliminary Data for Pediatric Acute Lymphoblastic Leukemia (ALL) Patients Derived Xenografts (PDX): The experiment conducted and funded by the National Institute of Health (NIH) through the PIVOT program included 27 patient-derived ALL tumors from pediatric patients. Tumors were xenografted in mice in two groups: vehicle control arm and SLS009 arm. Mice were treated with a fractionated dose once per week for 6 consecutive weeks. The treatment was well tolerated. For all models, median survival was approximately tripled in the SLS009 arm compared to the vehicle control arm. SLS009 demonstrated delayed progression in 25/27 (93%) models and more than 2 times longer time to progression in 15/27 (56%) of ALL models. In addition, there were complete responses (CR) in 2 models, and in one of the two models, CR was maintained after the treatment had been completed until the end of the study (4 months). Among 7 KMT2A rearranged models, time to progression was extended in all 7 models, and in 6/7 (86%) time to progression was more than doubled.

Raised $25.0 Million of Gross Proceeds from a Registered Direct Offering Priced At-the-Market under Nasdaq Rules: On January 28, 2025, SELLAS announced the closing of a $25 million registered direct offering with a single healthcare-focused institutional investor before deducting placement agent's fees and related offering expenses. The net proceeds from the offering strengthens the Company's financial position and will be used for working capital purposes and general corporate procedures, including the purchase of any pending or future acquisitions.

Financial Results for the First Quarter 2025:

R&D Expenses: Research and development expenses for the quarter ended March 31, 2025, were $3.2 million, compared to $5.1 million for the same period in 2024. The $1.9 million decrease was primarily due to decreases in clinical trial expenses, manufacturing costs, and

clinical drug supply purchases, and clinical and regulatory consulting costs primarily driven by the completion of enrollment in the REGAL study in the first quarter of 2024.

G&A Expenses: General and administrative expenses for the first quarter of 2025 were $2.9 million, as compared to $4.5 million for the same period in 2024. The $1.6 million decrease was primarily attributable to a decrease in personnel related expenses driven by the initial recognition of a one-time severance charge during the three months ended March 31, 2024, and a decrease in headcount, and decreases in professional fees and other general and administrative expenses.

Net Loss: The net loss was $5.8 million for the first quarter of 2025, or a basic and diluted loss per share of $0.07, as compared to a net loss of $9.6 million for the first quarter of 2024, or a basic and diluted loss per share of $0.21.

Cash Position: As of March 31, 2025, cash and cash equivalents totaled approximately $28.4 million. Subsequent to March 31, 2025, the Company received $4.0 million in proceeds from the exercise of warrants.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics for a broad range of cancer indications. SELLAS' lead product candidate, GPS, is licensed from Memorial Sloan Kettering Cancer Center and targets the WT1 protein, which is present in an array of tumor types. GPS has the potential as a monotherapy and combination with other therapies to address a broad spectrum of hematologic malignancies and solid tumor indications. The Company is also developing SLS009 (tambiciclib) - potentially the first and best-in-class differentiated small molecule CDK9 inhibitor with reduced toxicity and increased potency compared to other CDK9 inhibitors. Data suggests that SLS009 demonstrated a high response rate in AML patients with unfavorable prognostic factors including ASXL1 mutation, commonly associated with poor prognosis in various myeloid diseases. For more information on SELLAS, please visit www.sellaslifesciences.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are “forward-looking statements,” including those relating to future events. In some cases, forward-looking statements can be identified by terminology such as “plan,” “expect,” “anticipate,” “may,” “might,” “will,” “should,” “project,” “believe,” “estimate,” “predict,” “potential,” “intend,” or “continue” and other words or terms of similar meaning. These statements include, without limitation, statements related to the GPS clinical development program, including the REGAL study and the timing of future milestones related thereto. These forward-looking statements are based on current plans, objectives, estimates, expectations, and intentions, and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties with oncology product development and clinical success thereof, the uncertainty of regulatory approval, and other risks and uncertainties affecting SELLAS and its development programs as set forth under the caption “Risk Factors” in SELLAS’ Annual Report on Form 10-K filed on March 20, 2025 and in its other SEC filings. Other risks and uncertainties of which SELLAS is not currently aware may also affect SELLAS’ forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof. SELLAS undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations, or other circumstances that exist after the date as of which the forward-looking statements were made.

Investor Contact
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SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development	$ 3,205	$ 5,111
General and administrative	2,858	4,534
Total operating expenses	6,063	9,645
Loss from operations	(6,063)	(9,645)
Non-operating income:		
Interest income	250	79
Total non-operating income	250	79
Net loss	$ (5,813)	$ (9,566)
Per share information:		
Net loss per common share, basic and diluted	$ (0.07)	$ (0.21)
Weighted-average common shares outstanding, basic and diluted	87,760,320	44,812,996

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)
(Unaudited)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,397	$ 13,886
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	3,476	2,341
Total current assets	31,973	16,327
Operating lease right-of-use assets	806	925
Goodwill	1,914	1,914
Deposits and other assets	263	266
Total assets	$ 34,956	$ 19,432
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,756	$ 3,500
Accrued expenses and other current liabilities	2,571	5,466
Operating lease liabilities	561	544
Total current liabilities	6,888	9,510
Operating lease liabilities, non-current	309	457
Total liabilities	7,197	9,967
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 350,000,000 shares authorized, 90,896,125 and 73,977,459 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	9	7
Additional paid-in capital	281,688	257,583
Accumulated deficit	(253,938)	(248,125)
Total stockholders' equity	27,759	9,465
Total liabilities and stockholders' equity	$ 34,956	$ 19,432