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): **January 23, 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 7.01 REGULATION FD DISCLOSURE.

On January 23, 2025, SELLAS Life Sciences Group, Inc. (the "Company") issued a press release (the "Press Release") announcing the outcome of interim analysis conducted by the Independent Data Monitoring Committee ("IDMC") in its Phase 3 REGAL trial of galinpepimut-S ("GPS") in acute myeloid leukemia ("AML"). A copy of the Press Release is included as Exhibit 99.1 hereto and is incorporated by reference herein.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall they be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

The Press Release contains forward-looking statements. Such forward-looking statements can be identified by the use of the words "expect," "believe," "will," "anticipate," "estimate," "plan," "project" and other words of similar import. 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 the Company and its development programs as set forth under the caption "Risk Factors" in SELLAS' Annual Report on Form 10-K filed on March 28, 2024 and in its other filings with the U.S. Securities and Exchange Commission. Other risks and uncertainties of which the Company is not currently aware may also affect the Company 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. The Company 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.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated January 23, 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: January 23, 2025

By: /s/ John T. Burns
Name: John T. Burns
Title: Senior Vice President, Chief Financial Officer

Exhibit 99.1

SELLAS Life Sciences Announces Positive Outcome of Interim Analysis for its Pivotal Phase 3 REGAL Trial of GPS in Acute Myeloid Leukemia

2025-01-23

- REGAL Successfully Passes Event-Driven (60 Deaths) Interim Analysis for Efficacy, Futility, and Safety: The Independent Data Monitoring Committee (IDMC) Recommended Continuation of the Clinical Trial Without Modification -

- Based on a Review of Unblinded Data, the IDMC Confirmed that GPS Exceeded the Predetermined Futility Criteria, Noted no Safety Concerns and Commended SELLAS for its Operational Excellence and Study Data Integrity -

- Fewer than 50% of Enrolled Patients Confirmed Deceased After the Median Follow-Up of 13.5 Months, Indicating a Median Survival of Over 13.5 Months in the Trial vs. Historical Median Survival of 6 Months for Conventional Therapy, as Reported in Similar Phase 2 Study -

- 80% of Randomly Selected REGAL GPS Patients Showed a Specific T-Cell Immune Response, Surpassing the Results From the Previous Phase 2 Study -

- Next and Final Analysis Planned Upon Reaching 80 Events -

NEW YORK, January 23, 2025 (GLOBE NEWSWIRE) -- 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 announced that Independent Data Monitoring Committee (IDMC) has completed pre-specified interim analysis of the Phase 3 REGAL trial of galinpepimut-S (GPS) in acute myeloid leukemia (AML). Following this interim analysis triggered by 60 events (deaths) in the study population, the IDMC has recommended that the trial continue without modifications.

The interim futility, efficacy, and safety analysis is designed to assess whether the therapy is safe, demonstrates potential efficacy, and merits continuation. The IDMC's review of the interim data 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. 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.

"I am thrilled by the positive outcome of the interim analysis of our Phase 3 REGAL trial, marking the successful achievement of the most significant milestone for our GPS program to date. The IDMC's recommendation to support the continued advancement of GPS in our REGAL trial brings us one step closer towards potential approval for the treatment of AML," said Angelos Stergiou, MD, ScD hc, President and Chief Executive Officer of SELLAS. "Based on all available data, we believe that GPS could become a transformative treatment option for AML, offering hope to patients with limited choices, especially those with relapsed or refractory disease. We are optimistic about the IDMC's recommendation to continue the study without modifications, and diligently preparing for the Biologics License Application (BLA). Importantly, the REGAL trial provides a clear and straightforward path toward seeking regulatory approval for patients with AML in their second complete remission. We look forward to completing the trial with the final analysis to be conducted once 80 events are reached."

The Company is blinded to the trial outcomes, following regulations that safeguard study integrity. However, select blinded data has been presented, revealing that fewer than half of the enrolled patients have been confirmed deceased approximately 10 months after completion of enrollment, and an approximate median follow-up of 13.5 months (range 1 month to more than 3 years). This suggested a pooled median survival exceeding 12 months, compared to the expected survival of approximately 6 months in a similar patient population (patients in second complete remission who did not receive a transplant after the second remission). Separately, a blinded analysis of early immune response in a randomly selected sample of patients receiving GPS showed GPS-specific immune response in 80% of patients.

These data are consistent with previous GPS trials. In the Phase 2 study in AML patients in second complete remission, the median overall survival of GPS-treated patients was 21 months versus 5.4 months for patients on standard of care therapy and a GPS-specific immune response of 64%.

These promising data have encouraged the Company to continue preparations for the preclinical, clinical, manufacturing, and quality assurance components of the BLA regulatory submission in anticipation of final clinical data. No drug has yet been approved specifically for maintenance of remission in AML patients in CR2, further emphasizing the significance of this development.

“The interim results represent a major step forward in the treatment of AML, offering hope for patients in remission,” said Dr. Yair Levy, Director of Hematologic Malignancies Research at Texas Oncology Baylor University Medical Center. “I am very hopeful that we will see a new standard of care in treating AML patients based on the outcomes we have observed in previous GPS trials.”

In his comments during a recent webinar on January 8, Dr. Levy also stated, that he believes “that if approved, GPS would be highly accepted by the medical community and patients, and would become a standard-of-care in this high unmet need population. In addition to efficacy, this is also an extremely well-tolerated therapy. GPS efficacy does not come at the cost of quality of life. GPS has been shown to be very safe, with minimal side effects … This is particularly important, given that up to 60% of patients who receive standard therapies experience severe side effects, usually in the form of decreased white blood cell count, platelet count, and red blood cell count. These low counts, or cytopenias, often necessitate frequent hospitalizations or other interventions.”

REGAL is a Phase 3 open-label registrational clinical trial for GPS in AML patients who have achieved complete remission following second-line salvage therapy (CR2 patients). The primary endpoint is overall survival. The IDMC is an independent group of medical, scientific, and biostatistics experts who are responsible for reviewing and evaluating patient safety and efficacy data for REGAL, and for monitoring quality and overall conduct to ensure the validity, scientific and clinical merits of the study. The IDMC charter provides for periodic reviews of safety, efficacy, and futility in addition to the interim and final analyses.

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 (formerly GFH009) - 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 28, 2024 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.

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Source: SELLAS Life Sciences Group, Inc.