

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): **August 10, 2023**

SELLAS Life Sciences Group, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

001-33958

(Commission File Number)

20-8099512

(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 August 10, 2023, SELLAS Life Sciences Group, Inc. ("SELLAS") issued a press release (the "Press Release") announcing its financial results for the quarter ended June 30, 2023 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 August 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SELLAS Life Sciences Provides Business Update and Reports Second Quarter 2023 Financial Results

First Patients Dosed in Phase 2a Clinical Trial of SLS009 (formerly GFH009) in Acute Myeloid Leukemia with Topline Data Expected in 4Q 2023

Phase 3 REGAL Study of Galinpepimut-S in Patients with Acute Myeloid Leukemia on Track for Interim Analysis by Late 2023/Early 2024

REGAL Independent Data Monitoring Committee to Meet in 3Q 2023

NEW YORK, August 10, 2023 (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 provided a business update and reported its financial results for the quarter ended June 30, 2023.

“We are pleased with the solid progress across our clinical programs in the first half of the year. We expect to complete enrollment in our Phase 3 REGAL study of galinpepimut-S (GPS) in the second half of this year. In addition to our REGAL study, following a strong safety and efficacy profile for SLS009, our CDK9 inhibitor, as a monotherapy in acute myeloid leukemia (AML) in our Phase 1 study, we are particularly excited about the commencement of the Phase 2a study of SLS009 in combination with azacitidine and venetoclax in relapsed and refractory AML, for which we expect topline data in the fourth quarter of 2023,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “The focus of our clinical programs is to potentially deliver treatments to impact the lives of patients with AML, from tackling active disease to prolonging patients’ lives in the maintenance setting, and we look forward to our upcoming milestones across the AML treatment landscape.”

Pipeline Update:

Galinepimut-S (GPS): Wilms Tumor-1 (WT1) targeting immunotherapeutic

Phase 3 REGAL study in AML:

The interim analysis of the ongoing REGAL global Phase 3 registrational clinical trial of GPS in patients with AML who have achieved complete remission following second-line salvage therapy (CR2 patients) is expected in late 2023 or early 2024.

In April, the Independent Data Monitoring Committee (IDMC) recommended that REGAL continue as planned, following a routine, prespecified risk-benefit assessment of unblinded data from the study. The next routine IDMC meeting is scheduled for the third quarter of 2023.

A trial in progress poster titled “A randomized, open-label study of the efficacy and safety of galinpepimut-S (GPS) maintenance monotherapy compared to investigator’s choice of best available therapy (BAT) in patients with acute myeloid leukemia (AML) who have achieved

complete remission (CR) after second-line salvage therapy” was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June.

Phase 1/2 Study in combination with pembrolizumab (Keytruda®) in ovarian cancer:

SELLAS plans to present final data at the International Gynecologic Cancer Society Annual Meeting in November 2023. The topline data showed clinical benefit of GPS and anti-PD-1 pembrolizumab combination therapy in WT1 positive relapsed or refractory platinum resistant advanced metastatic ovarian cancer patients.

Phase 1 Study in combination with nivolumab (Opdivo®) in MPM:

SELLAS reported topline data from the investigator sponsored open-label Phase 1 trial for GPS combination therapy with checkpoint inhibitor nivolumab (Opdivo®) for treatment of malignant pleural mesothelioma (MPM) in patients who were either refractory to or relapsed after at least one line of the standard of care therapy. Safety and efficacy endpoints were met with clinical activity and increased survival observed. Additional immune response data is expected in the fourth quarter of 2023.

SLS009: highly selective CDK9 inhibitor

Phase 1 clinical trial in relapsed/refractory (r/r) hematological malignancies:

The safety evaluation stage of the Phase 1 dose escalation clinical trial of SLS009 was completed for the highest dose cohort of AML patients who relapsed after or were refractory to available antileukemic therapies. No further dose escalations are planned in the AML group, while dose escalation continues in the lymphoma group with the addition of 75 mg and 100 mg once-a-week dose cohorts. The 100 mg cohort is planned to likely be the highest dose level for the lymphoma group. Observed clinical activity in the lymphoma group will be announced after the last dose level is complete and is expected during the third quarter of 2023.

SELLAS reported positive topline data in the second quarter of 2023 for the AML cohort as a monotherapy which supported advancement to a Phase 2a trial in AML with SLS009 in combination with azacitidine and venetoclax (aza/ven).

Phase 2a clinical trial in AML:

A Phase 2a trial was initiated studying SLS009 combination treatment with aza/ven in r/r AML patients who did not respond or stopped responding to venetoclax-based therapies. The Phase 2a clinical trial is an open label, single arm, multi-center study that is designed to evaluate safety, tolerability, and efficacy at two dose levels of SLS009. The first patients were dosed in June and topline data are expected in the fourth quarter of 2023.

Hosted a virtual expert panel discussion:

SELLAS hosted a virtual expert panel discussion on SLS009 in AML in May featuring hematology-oncology specialists Tapan Kadia, MD (The University of Texas MD Anderson Cancer Center), Joshua Zeidner, MD (University of North Carolina Lineberger Comprehensive Cancer Center), and Omer Jamy, MD (O’Neal Comprehensive Cancer Center at the University

of Alabama) who discussed the treatment landscape for AML and the potential for SLS009 to address unmet medical needs for patients with relapsed and/or refractory AML. A replay of the event is available on SELLAS' website.

Corporate Updates:

SELLAS expects to receive milestone payments totaling \$13.0 million from 3D Medicines by the end of the third quarter of 2023.

Financial Results for the Second Quarter 2023:

R&D Expenses: Research and development expenses for the second quarter of 2023 were \$5.9 million, compared to \$5.5 million for the same period in 2022. Research and development expenses for the first half of 2023 were \$13.1 million, compared to \$10.1 million for the same period in 2022. The increase was primarily due to an increase in clinical trial expenses related to the ongoing Phase 3 REGAL clinical trial of GPS in AML patients and the ongoing Phase 2a and Phase 1 clinical trials of SLS009 in hematological malignancies, increased clinical and regulatory consulting, and personnel-related expenses due to increased headcount.

G&A Expenses: General and administrative expenses for the second quarter of 2023 were \$3.1 million, as compared to \$3.1 million for the same period in 2022. General and administrative expenses for the first half of 2023 were \$7.2 million, as compared to \$6.1 million for the same period in 2022. The increase was primarily due to personnel-related expenses due to increased headcount.

Acquired In-Process Research and Development: There was no acquired in-process research and development for the first half of 2023 and second quarter of 2022. Acquired in-process research and development was \$10.0 million for the first half of 2022, resulting from the in-licensing of SLS009.

Net Loss: Net loss was \$8.8 million for the second quarter of 2023, or a basic and diluted loss per share of \$0.31, compared to a net loss of \$8.4 million for the same period in 2022, or a basic and diluted loss per share of \$0.41. Net loss was \$19.9 million for the first half of 2023, or a basic and diluted loss per share of \$0.77, compared to a net loss of \$25.2 million for the same period in 2022, or a basic and diluted loss per share of \$1.39.

Cash Position: As of June 30, 2023, cash and cash equivalents totaled approximately \$13.8 million.

Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA and is not a trademark of SELLAS. Opdivo® is a registered trademark of Bristol-Myers Squibb Company, New York, NY, USA and is not a trademark of SELLAS. The manufacturers of these brands are not affiliated with and do not endorse SELLAS or its products.

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 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, a small molecule, highly selective CDK9 inhibitor, which is licensed from GenFleet Therapeutics (Shanghai), Inc., for all therapeutic and diagnostic uses in the world outside of Greater China. 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 and SLS009 clinical development programs, clinical data for both GPS and SLS009, plans for further clinical development of SLS009 and the potential for GPS and SLS009 as drug development candidates. 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 16, 2023 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Licensing revenue	\$ —	\$ —	\$ —	\$ 1,000
Operating expenses:				
Cost of licensing revenue	—	—	—	100
Research and development	5,923	5,529	13,097	10,140
General and administrative	3,127	3,094	7,234	6,118
Acquired in-process research and development	—	—	—	10,000
Total operating expenses	9,050	8,623	20,331	26,358
Operating loss	(9,050)	(8,623)	(20,331)	(25,358)
Non-operating income:				
Change in fair value of warrant liability	2	48	4	37
Change in fair value of contingent consideration	—	115	—	115
Interest income	208	46	390	48
Total non-operating income	210	209	394	200
Net loss	\$ (8,840)	\$ (8,414)	\$ (19,937)	\$ (25,158)
Per share information:				
Net loss per common share, basic and diluted	\$ (0.31)	\$ (0.41)	\$ (0.77)	\$ (1.39)
Weighted-average common shares outstanding, basic and diluted	28,347,920	20,286,624	25,961,001	18,104,176

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

ASSETS	June 30, 2023	December 31, 2022
Current assets:		
Cash and cash equivalents	\$ 13,807	\$ 17,125
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	1,674	531
Total current assets	15,581	17,756
Operating lease right-of-use assets	690	874
Goodwill	1,914	1,914
Deposits and other assets	381	399
Total assets	\$ 18,566	\$ 20,943
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,734	\$ 3,357
Accrued expenses and other current liabilities	6,240	6,286
Operating lease liabilities	447	372
Acquired in-process research and development payable	3,000	5,500
Total current liabilities	13,421	15,515
Operating lease liabilities, non-current	302	573
Warrant liability	—	4
Total liabilities	13,723	16,092
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; Series A convertible preferred stock, 17,500 shares designated; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized, 28,347,920 and 21,005,405 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	204,681	184,753
Accumulated deficit	(199,841)	(179,904)
Total stockholders' equity	4,843	4,851
Total liabilities and stockholders' equity	\$ 18,566	\$ 20,943