

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024
OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-33958



SELLAS Life Sciences Group, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State of incorporation)

20-8099512

(I.R.S. Employer Identification No.)

7 Times Square, Suite 2503, New York, NY 10036
(646) 200-5278

(Address, including zip code, and telephone number, including
area code, of registrant's principal executive offices)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter time that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ Yes ☒ No

As of November 12, 2024, SELLAS Life Sciences Group, Inc. had outstanding 70,381,979 shares of common stock.

SELLAS LIFE SCIENCES GROUP, INC.
FORM 10-Q - Quarterly Report
For the Quarter Ended September 30, 2024

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The names "SELLAS Life Sciences Group, Inc.," "SELLAS," the SELLAS logo, and other trademarks or service marks of SELLAS Life Sciences Group, Inc. appearing in this Quarterly Report on Form 10-Q are the property of SELLAS Life Sciences Group, Inc. Other trademarks, service marks or trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We do not intend the use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of or by either of, these other companies.

Unless the context otherwise indicates, references in these notes to the "Company," "we," "us" or "our" refer to SELLAS Life Sciences Group, Inc. and its wholly owned subsidiaries.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes forward-looking statements that reflect our current views with respect to our development programs, business strategy, business plan, financial performance and other future events. These statements include forward-looking statements both with respect to us, specifically, and our industry, in general. Such forward-looking statements include the words "expect," "intend," "plan," "believe," "project," "estimate," "may," "should," "anticipate," "will" and similar statements of a future or forward-looking nature identify forward-looking statements and include, without limitation, statements regarding:

- our future financial and business performance;
- strategic plans for our business and product candidates;
- our ability to develop or commercialize products;
- the expected results and timing of clinical trials and nonclinical studies;
- our ability to comply with the terms of our license agreements;
- developments and projections relating to our competitors and industry;
- our expectations regarding our ability to obtain, develop and maintain intellectual property protection and not infringe on the rights of others;
- our ability to retain and attract highly-skilled executive officers and employees;
- our future capital requirements and the timing of those requirements and sources and uses of cash;
- our ability to obtain funding for our operations; and
- changes in applicable laws or regulations.

These statements are subject to known and unknown risks, uncertainties and assumptions that could cause actual results to differ materially from those projected or otherwise implied by the forward-looking statements, including the following:

- risks associated with preclinical or clinical development and trials;
- changes in the assumptions underlying our expectations regarding our future business or business model;
- our ability to develop, manufacture and commercialize product candidates;
- general economic, financial, legal, political and business conditions and changes in domestic and foreign markets;
- changes in applicable laws or regulations;
- the impact of natural disasters, including climate change, and the impact of health epidemics on our business;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- market acceptance of our planned products;
- our ability to raise capital;

- the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and
- other risks and uncertainties set forth in this report in the section entitled "Risk Factors."

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law. There are or will be important factors that could cause actual results to differ materially from those indicated in these statements. These factors include, but are not limited to, those factors set forth in the sections captioned "Business – Overview," "Risk Factors," "Legal Proceedings," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in this Quarterly Report on Form 10-Q, in our Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission ("SEC") on March 28, 2024 ("2023 Annual Report") and in our other public filings with the SEC, all of which you should review carefully. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,031	\$ 2,530
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	2,904	542
Total current assets	24,035	3,172
Operating lease right-of-use assets	513	858
Goodwill	1,914	1,914
Deposits and other assets	43	275
Total assets	<u>\$ 26,505</u>	<u>\$ 6,219</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 4,547	\$ 5,639
Accrued expenses and other current liabilities	5,490	7,650
Operating lease liabilities	576	446
Total current liabilities	10,613	13,735
Operating lease liabilities, non-current	—	460
Total liabilities	10,613	14,195
Commitments and contingencies (Note 6)		
Stockholders' equity (deficit):		
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 September 30, 2024 and December 31, 2023	—	—
Common stock, \$ 0.0001 par value; 350,000,000 shares authorized, 64,381,979 and 32,132,890 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	6	3
Additional paid-in capital	257,274	209,265
Accumulated deficit	(241,388)	(217,244)
Total stockholders' equity (deficit)	15,892	(7,976)
Total liabilities and stockholders' equity (deficit)	<u>\$ 26,505</u>	<u>\$ 6,219</u>

See accompanying notes to these unaudited consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 4,362	\$ 5,813	\$ 14,659	\$ 18,910
General and administrative	2,967	3,548	9,936	10,782
Total operating expenses	7,329	9,361	24,595	29,692
Loss from operations	(7,329)	(9,361)	(24,595)	(29,692)
Non-operating income:				
Change in fair value of warrant liability	—	—	—	4
Interest income	221	94	451	484
Total non-operating income	221	94	451	488
Net loss	<u>\$ (7,108)</u>	<u>\$ (9,267)</u>	<u>\$ (24,144)</u>	<u>\$ (29,204)</u>
Per share information:				
Net loss per common share, basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.33)</u>	<u>\$ (0.42)</u>	<u>\$ (1.09)</u>
Weighted-average common shares outstanding, basic and diluted	<u>68,254,021</u>	<u>28,355,427</u>	<u>56,940,617</u>	<u>26,767,914</u>

See accompanying notes to these unaudited consolidated financial statements.

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Amounts in thousands, except share amounts)
(Unaudited)

Three Months Ended September 30, 2024					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2024	57,754,928	\$ 5	\$ 237,188	\$ (234,280)	\$ 2,913
Issuance of common stock and common stock warrants, net of issuance costs	6,370,070	1	19,503	—	19,504
Issuance of common stock upon the exercise of warrants	207,500	—	155	—	155
Issuance of common stock under employee stock purchase plan	49,481	—	47	—	47
Stock-based compensation	—	—	381	—	381
Net loss	—	—	—	(7,108)	(7,108)
Balance at September 30, 2024	64,381,979	\$ 6	\$ 257,274	\$ (241,388)	\$ 15,892
Nine Months Ended September 30, 2024					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2023	32,132,890	\$ 3	\$ 209,265	\$ (217,244)	\$ (7,976)
Issuance of common stock and common stock warrants, net of issuance costs	27,500,070	3	46,161	—	46,164
Issuance of common stock upon the exercise of pre-funded warrants	3,899,316	—	—	—	—
Issuance of common stock upon the exercise of warrants	745,850	—	559	—	559
Issuance of common stock under employee stock purchase plan	103,853	—	98	—	98
Stock-based compensation	—	—	1,191	—	1,191
Net loss	—	—	—	(24,144)	(24,144)
Balance at September 30, 2024	64,381,979	\$ 6	\$ 257,274	\$ (241,388)	\$ 15,892
Three Months Ended September 30, 2023					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at June 30, 2023	28,347,920	\$ 3	\$ 204,681	\$ (199,841)	\$ 4,843
Issuance of common stock under employee stock purchase plan	46,038	—	54	—	54
Stock-based compensation	—	—	543	—	543
Net loss	—	—	—	(9,267)	(9,267)
Balance at September 30, 2023	28,393,958	\$ 3	\$ 205,278	\$ (209,108)	\$ (3,827)
Nine Months Ended September 30, 2023					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2022	21,005,405	\$ 2	\$ 184,753	\$ (179,904)	\$ 4,851
Issuance of common stock and common stock warrants, net of issuance costs	7,220,217	1	18,553	—	18,554
Issuance of common stock, net of issuance costs	76,882	—	268	—	268
Issuance of common stock under employee stock purchase plan	91,454	—	107	—	107
Stock-based compensation	—	—	1,597	—	1,597
Net loss	—	—	—	(29,204)	(29,204)
Balance at September 30, 2023	28,393,958	\$ 3	\$ 205,278	\$ (209,108)	\$ (3,827)

See accompanying notes to these unaudited consolidated financial statements.

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (24,144)	\$ (29,204)
Adjustment to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	1,191	1,597
Non-cash lease expense	413	367
Change in fair value of common stock warrants	—	(4)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,130)	(581)
Accounts payable	(1,021)	983
Accrued expenses and other current liabilities	(2,160)	643
Operating lease liabilities	(398)	(386)
Net cash used in operating activities	(28,249)	(26,585)
Cash flows from investing activities:		
Cash paid for acquisition of in-process research and development	—	(5,500)
Net cash used in investing activities	—	(5,500)
Cash flows from financing activities:		
Proceeds from issuance of common stock and common stock warrants, net of issuance costs	46,093	18,554
Proceeds from issuance of common stock, net of issuance costs	—	268
Proceeds from the exercise of common stock warrants	559	—
Proceeds from employee stock purchases	98	107
Net cash provided by financing activities	46,750	18,929
Net increase (decrease) in cash, cash equivalents, restricted cash, and restricted cash equivalents	18,501	(13,156)
Cash, cash equivalents, restricted cash, and restricted cash equivalents at the beginning of period	2,630	17,225
Cash, cash equivalents, restricted cash, and restricted cash equivalents at the end of period	\$ 21,131	\$ 4,069
Supplemental disclosure of cash flow information:		
Cash received during the period for interest	\$ 451	\$ 484
Supplemental disclosure of non-cash investing and financing activities:		
Offering expenses included in accounts payable and accrued expenses and other current liabilities	\$ 71	\$ —
Warrant modifications recorded in stockholders' equity (deficit)	\$ 725	\$ —

See accompanying notes to these unaudited consolidated financial statements.

SELLAS LIFE SCIENCES GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of Business

Overview

SELLAS Life Sciences Group, Inc. is a late-stage clinical biopharmaceutical company focused on novel therapeutics for a broad range of cancer indications. SELLAS' lead product candidate, galinpepimut-S ("GPS"), is a cancer immunotherapeutic agent licensed from Memorial Sloan Kettering Cancer Center ("MSK") and targets the Wilms Tumor 1 ("WT1") protein, which is present in an array of tumor types. GPS has potential as a monotherapy or in combination with other immunotherapeutic agents to address a broad spectrum of hematologic, or blood, cancers and solid tumor indications. SELLAS' second product candidate is SLS009 (formerly GFH009), a small molecule, highly selective cyclin-dependent kinase 9 ("CDK9") inhibitor, which the Company licensed from GenFleet Therapeutics (Shanghai), Inc. ("GenFleet"), for all therapeutic and diagnostic uses in the world outside of mainland China, Hong Kong, Macau and Taiwan ("SLS009 Territory").

2. Liquidity

Since inception, the Company has incurred recurring losses and negative cash flows from operations and, as of September 30, 2024, has an accumulated deficit of \$ 241.4 million. During the nine months ended September 30, 2024, the Company incurred a net loss of \$ 24.1 million, and used \$ 28.2 million of cash in operations. The Company expects to continue to generate operating losses and negative cash flows from operations for the next few years and will need additional funding to support its planned operating activities through profitability. The transition to profitability is dependent upon the successful development, approval, and commercialization of the Company's product candidates and the achievement of a level of revenues adequate to support its cost structure.

On August 1, 2024, the Company consummated a registered direct offering with an institutional investor priced at a premium to market (the "August 2024 Registered Direct Offering"), pursuant to which the Company agreed to issue and sell 6,370,070 shares of common stock and 9,478,986 pre-funded warrants exercisable for shares of common stock, together with accompanying warrants to purchase 15,849,056 shares of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$ 1.325 , and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$ 1.3249 . The common warrants have an exercise price of \$ 1.20 per share. The net proceeds to the Company from the August 2024 Registered Direct Offering were approximately \$ 19.5 million, after deducting the placement agent's fees and related offering expenses.

On March 19, 2024, the Company consummated a registered direct offering with two institutional investors priced at-the-market under Nasdaq rules (the "March 2024 Registered Direct Offering"), pursuant to which the Company agreed to issue and sell 11,000,000 shares of its common stock and 2,029,316 pre-funded warrants exercisable for shares of common stock. Each share of common stock was sold at a purchase price of \$ 1.535 and each pre-funded warrant was sold at a purchase price of \$ 1.5349 . The net proceeds to the Company from the March 2024 Registered Direct Offering were approximately \$ 18.5 million, after deducting the placement agent's fees and related offering expenses. In a concurrent private placement, the Company agreed to issue to the two institutional investors exercisable for up to an aggregate of 13,029,316 shares of common stock warrants at an exercise price of \$ 1.41 per share. Subsequent to the closing of the March 2024 Registered Direct Offering, all of the pre-funded warrants have been exercised for shares of common stock.

On January 8, 2024, the Company consummated a public offering on a "reasonable best efforts" basis (the "January 2024 Offering"), issuing 10,130,000 shares of common stock and an aggregate of 1,870,000 pre-funded warrants exercisable for shares of common stock, together with accompanying warrants to purchase an aggregate of 12,000,000 shares of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$ 0.75 , and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$ 0.7499 . The net proceeds to the Company from the January 2024 Offering were approximately \$ 8.2 million, after deducting the placement agent's fees and related offering expenses. Subsequent to the closing of the January 2024 Offering, all of the pre-funded warrants have been exercised for shares of common stock.

SELLAS LIFE SCIENCES GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
(Unaudited)

In December 2020, the Company, together with its wholly-owned subsidiary, SLSG Limited, LLC, entered into an Exclusive License Agreement (the "3D Medicines Agreement") with 3D Medicines Inc. ("3D Medicines"), pursuant to which the Company granted 3D Medicines a sublicensable, royalty-bearing license, under certain intellectual property owned or controlled by the Company, to develop, manufacture and have manufactured, and commercialize GPS and heptavalent GPS product candidates for all therapeutic and other diagnostic uses in mainland China, Hong Kong, Macau and Taiwan ("3D Med Territory"). As of September 30, 2024, the Company has received an aggregate of \$ 10.5 million in upfront payments and certain technology transfer and regulatory milestones. There is a total of \$ 191.5 million in potential future development, regulatory, and sales milestones, not including future royalties, that remains under the 3D Medicines Agreement, which milestones are all variable in nature and not under the Company's control. In December 2023, the Company commenced a binding arbitration proceeding against 3D Medicines, which involves, among other things, the trigger and payment of certain milestone payments due to the Company. See *Part II, Item 1. Legal Proceedings*.

As of September 30, 2024, the Company had cash and cash equivalents of approximately \$ 21.0 million and restricted cash and cash equivalents of \$ 0.1 million. In accordance with Accounting Standards Codification ("ASC") 205-40, *Presentation of Financial Statements - Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the consolidated financial statements are issued. The Company expects its cash and cash equivalents will not be sufficient to fund its current planned operations for at least the next twelve months from the date of issuance of these consolidated financial statements.

The Company will require substantial additional financing to commercially develop any current or future product candidates. If the Company is unable to obtain additional funding on a timely basis, it will be required to scale back its plans and place certain activities on hold. The Company currently does not have any commitments to obtain additional funds. The Company's management continues to evaluate different strategies to obtain the required funding for future operations. These strategies may include public and private placements of equity and/or debt securities, as well as payments from potential strategic research and development collaborations or licensing and/or marketing arrangements with pharmaceutical companies. Additionally, the Company continues to pursue discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to the Company's product candidates. There can be no assurance that these future funding efforts will be successful.

3. Basis of Presentation and Significant Accounting Policies

The Company's complete summary of significant accounting policies can be found in "Item 8. Financial Statements and Supplementary Data - Note 3. Basis of Presentation and Significant Accounting Policies" in the audited annual consolidated financial statements included in the 2023 Annual Report. The significant accounting policies summarized and included in the 2023 Annual Report have not materially changed, except as set forth below.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the ASC and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated upon consolidation. Unless the context otherwise indicates, reference in these notes to the "Company" refer to SELLAS Life Sciences Group, Inc., and its wholly owned subsidiaries, SELLAS Life Sciences Group, Ltd., a privately held Bermuda exempted company, SLSG Limited, LLC, Sellas Life Sciences Limited, and Aphera, Inc. The functional currency of the Company's non-U.S. operations is the U.S. dollar.

SELLAS LIFE SCIENCES GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
(Unaudited)

Unaudited Interim Results

These consolidated financial statements and accompanying notes should be read in conjunction with the Company's annual consolidated financial statements and the notes thereto included in the 2023 Annual Report. The accompanying consolidated financial statements as of September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023, are unaudited, but include all adjustments, consisting of normal recurring entries, that management believes to be necessary for a fair presentation of the periods presented. Interim results are not necessarily indicative of results for a full year. Balance sheet amounts as of December 31, 2023 have been derived from the audited financial statements as of that date.

Net Loss Per Share

Net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, stock options and unvested restricted stock that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share, the weighted average number of shares remains the same for both calculations due to the fact that, when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Common stock warrants	65,434	12,221
Stock options	1,953	1,643
Restricted stock units ("RSUs")	644	433
	<u>68,031</u>	<u>14,297</u>

Recent Accounting Standards Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. ASU No. 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. This ASU became effective for the Company on January 1, 2024 and did not have a material impact on the consolidated financial statements.

Recent Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures*, which amends the guidance in ASC 740, *Income Taxes*. The ASU is intended to improve the transparency of income tax disclosures by prescribing standard categories and greater disaggregation of information in the effective tax rate reconciliation, disclosure of income taxes paid disaggregated by jurisdiction, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption either prospectively or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of the ASU on the income tax disclosures within the consolidated financial statements but does not expect a material impact upon adoption.

SELLAS LIFE SCIENCES GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
(Unaudited)

4. Fair Value Measurements

The following tables present information about the Company's assets measured at fair value on a recurring basis in the consolidated balance sheets (in thousands):

<u>Description</u>	<u>September 30, 2024</u>	<u>Quoted Prices In Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Unobservable Inputs (Level 3)</u>
Assets:				
Cash equivalents	\$ 20,995	\$ 20,995	\$ —	\$ —
Restricted cash equivalents	100	100	—	—
Total assets measured and recorded at fair value	<u>\$ 21,095</u>	<u>\$ 21,095</u>	<u>\$ —</u>	<u>\$ —</u>

<u>Description</u>	<u>December 31, 2023</u>	<u>Quoted Prices In Active Markets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Unobservable Inputs (Level 3)</u>
Assets:				
Cash equivalents	\$ 2,314	\$ 2,314	\$ —	\$ —
Restricted cash equivalents	100	100	—	—
Total assets measured and recorded at fair value	<u>\$ 2,414</u>	<u>\$ 2,414</u>	<u>\$ —</u>	<u>\$ —</u>

The Company did not transfer any financial instruments into or out of Level 3 classification during the nine months ended September 30, 2024 or during the year ended December 31, 2023.

5. Balance Sheet Accounts

Prepaid expenses and other current assets consist of the following (in thousands):

	<u>September 30, 2024</u>	<u>December 31, 2023</u>
Clinical trial costs	\$ 2,167	\$ 399
Insurance	372	87
Professional fees	140	56
Other	225	—
Prepaid expenses and other current assets	<u>\$ 2,904</u>	<u>\$ 542</u>

Accrued expenses and other current liabilities consist of the following (in thousands):

	<u>September 30, 2024</u>	<u>December 31, 2023</u>
Clinical trial costs	\$ 3,211	\$ 5,672
Compensation and related benefits	1,789	1,493
Professional fees	316	443
Other	174	42
Accrued expenses and other current liabilities	<u>\$ 5,490</u>	<u>\$ 7,650</u>

SELLAS LIFE SCIENCES GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
(Unaudited)

6. Commitments and Contingencies

Leases

The Company has a non-cancelable operating lease for certain executive, administrative, and general business office space for its headquarters in New York, New York, which began on June 5, 2020, was amended in February 2022 to add additional space, and has a term through September 2025. The Company assessed the lease amendment for the additional space and determined it should be accounted for as a separate contract.

The weighted average discount rate of the Company's operating leases under *FASB Topic ASC 842, Leases ("ASC 842")* is approximately 13 %. As of September 30, 2024, the leases have a remaining term of 1.0 year.

Rent expense related to the Company's operating leases was approximately \$ 0.1 million for each of the three months ended September 30, 2024 and 2023, and \$ 0.4 million for each of the nine months ended September 30, 2024 and 2023.

The Company made cash payments related to its operating leases of approximately \$ 0.1 million for each of the three months ended September 30, 2024 and 2023, and \$ 0.4 million for each of the nine months ended September 30, 2024 and 2023.

Future minimum lease payments are as follows as of September 30, 2024 (in thousands):

Future minimum lease payments:		
2024 (remaining)	\$	135
2025		477
Total future minimum lease payments		612
Less: imputed interest		(36)
Current and non-current operating lease liabilities	\$	576

Subsequent to September 30, 2024, on October 3, 2024, the Company entered into an amendment to its operating leases which provides for the extension of the expiration date from September 30, 2025 to September 30, 2026, and approximately \$ 0.6 million in additional future minimum lease payments. The annual rent remains unchanged.

Exclusive License Agreement with GenFleet Therapeutics (Shanghai) Inc.

On March 31, 2022, the Company entered into an exclusive license agreement with GenFleet pursuant to which GenFleet granted to the Company a sublicensable royalty-bearing license under certain of its intellectual property, to develop, manufacture, and commercialize SLS009 for the treatment, diagnosis or prevention of disease in humans and animals in the SLS009 Territory.

In consideration for the exclusive license, the Company agreed to pay to GenFleet (i) an upfront and technology transfer fee of \$ 10.0 million, all of which has been paid, (ii) development and regulatory milestone payments for up to three indications totaling up to \$ 48.0 million in the aggregate upon the achievement of such milestones, and (iii) sales milestone payments totaling up to \$ 92.0 million in the aggregate upon the achievement of certain net sales thresholds in a given calendar year. The Company also agreed to pay GenFleet single-digit tiered royalties based upon a percentage of annual net sales, with the royalty rate escalating based on the level of annual net sales of SLS009 in the SLS009 Territory ranging from the low to high single digits.

SELLAS LIFE SCIENCES GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
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Legal Proceedings

From time to time, the Company may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business, which may include employment matters, breach of contract disputes and stockholder litigation. Such actions and proceedings are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. The Company records a liability in its consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, when the Company has assessed that a loss is probable and an amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, the Company records the most probable estimate of the loss or the minimum amount when no amount within the range is a better estimate than any other amount. The Company discloses a contingent liability even if the liability is not probable or the amount is not estimable, or both, if there is a reasonable possibility that a material loss may have been incurred.

On December 20, 2023, the Company commenced a binding arbitration proceeding against 3D Medicines, administered by the Hong Kong International Arbitration Centre and governed by New York State law in accordance with the dispute resolution provisions in the 3D Medicines Agreement. The arbitration proceeding involves, among other things, the trigger and payment of the relevant milestone payments due to the Company as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in the 3DMed Territory, and particularly in mainland China. See *Part II, Item 1. Legal Proceedings*. Except for this arbitration proceeding, as of September 30, 2024, there was no pending or threatened litigation.

7. Stockholders' Equity (Deficit)

Preferred Stock

The Company has authorized up to 5,000,000 shares of preferred stock, \$ 0.0001 par value per share, for issuance. There were no preferred shares outstanding as of September 30, 2024 and December 31, 2023.

Common Stock

The Company has authorized up to 350,000,000 shares of common stock, \$ 0.0001 par value per share, for issuance.

As of September 30, 2024, the Company has shares of common stock reserved for future issuance as follows (in thousands):

Warrants outstanding	65,434
Stock options outstanding	1,953
RSUs outstanding	644
Shares reserved for future issuance under the 2023 Amended and Restated Equity Incentive Plan	3,298
Shares reserved for future issuance under the 2021 Employee Stock Purchase Plan	80
Total common stock reserved for future issuance	71,409

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8. Warrants to Acquire Shares of Common Stock

Warrants Outstanding

The following is a summary of the activity of the Company's warrants to acquire shares of common stock for the nine months ended September 30, 2024 (in thousands except per share data):

Warrant Issuance	Outstanding, December 31, 2023	Granted	Exercised	Expired	Outstanding, September 30, 2024	Exercise Price per Share	Expiration
Warrants classified as equity:							
August 2024 Registered Direct Offering	—	15,849	—	—	15,849	\$ 1.20	August 2029
August 2024 Registered Direct Offering Pre-Funded Warrants	—	9,479	—	—	9,479	\$ 0.0001	n/a
March 2024 Registered Direct Offering	—	13,029	—	—	13,029	\$ 1.41	September 2029
March 2024 Registered Direct Offering Pre-Funded Warrants	—	2,029	(2,029)	—	—	\$ 0.0001	n/a
January 2024 Offering	—	12,000	(533)	—	11,467	\$ 0.75	January 2029
January 2024 Offering Pre-Funded Warrants	—	1,870	(1,870)	—	—	\$ 0.0001	n/a
November 2023 Registered Direct Offering	3,652	—	—	—	3,652	\$ 0.75	January 2029
February 2023 Offering	7,206	—	(212)	—	6,994	\$ 0.75	February 2028
April 2022 Offering	766	—	—	—	766	\$ 5.40	April 2027
April 2022 Offering - Modified Warrants	3,864	—	—	—	3,864	\$ 0.75	January 2029
January 2020 Offering	309	—	—	—	309	\$ 3.93	July 2025
July 2020 PIPE Offering	25	—	—	—	25	\$ 3.30	August 2025
Other	32	—	—	(32)	—	\$ 7.50	June 2024
	<u>15,854</u>	<u>54,256</u>	<u>(4,644)</u>	<u>(32)</u>	<u>65,434</u>		

Subsequent to September 30, 2024, 6,000,000 pre-funded warrants issued in the August 2024 Registered Direct Offering were exercised for shares of common stock.

Warrants Classified as Equity

The warrants to acquire shares of common stock issued during the August 2024 Registered Direct Offering, the March 2024 Registered Direct Offering, and the January 2024 Offering were recorded as equity upon issuance. During its evaluation of equity classification of these warrants, the Company considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity* ("ASC 815-40"). The conditions within ASC 815-40 are not subject to a probability assessment. The warrants to acquire shares of common stock do not fall under the liability criteria within ASC 480, *Distinguishing Liabilities from Equity*, as they are not puttable and do not represent an instrument that has a redeemable underlying security. The warrants do meet the definition of a derivative instrument under ASC 815 but are eligible for the scope exception as they are indexed to the Company's own stock and would be classified in permanent equity if freestanding.

In connection with the closing of the January 2024 Offering at a combined offering price of \$ 0.75 , the Company agreed to (i) reduce the exercise price of an aggregate of 3,863,851 warrants that were issued to certain purchasers in an underwritten public offering that closed on April 5, 2022 (the "April 2022 Offering") to \$ 0.75 , (ii) reduce the exercise price of an aggregate of 3,652,300 warrants that were issued in the November 2023 Registered

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Direct Offering to \$ 0.75 , and (iii) extend the termination date of the April 2022 Offering warrants and the November 2023 Registered Direct Offering warrants to January 8, 2029. Concurrent with the closing of the January 2024 Offering, the exercise price of an aggregate of 7,220,217 warrants issued in the February 2023 Offering were also reduced to an exercise price of \$ 0.75 per share. The Company accounted for these amendments as a cost to issue equity with the incremental fair value of approximately \$ 0.7 million recognized as an offset to the proceeds received. However, there was no net impact to the consolidated statements of stockholders' equity (deficit) because the warrants are equity classified.

9. Licensing Revenue

Exclusive License Agreement with 3D Medicines Inc.

In December 2020, the Company entered into the 3D Medicines Agreement pursuant to which the Company granted 3D Medicines a sublicensable royalty-bearing license under certain intellectual property owned or controlled by the Company, to develop, manufacture and have manufactured, and commercialize GPS and heptavalent GPS (referred to as GPS Plus) product candidates ("GPS Licensed Products") for all therapeutic and other diagnostic uses in the 3DMed Territory. In partial consideration for the rights granted by the Company, 3D Medicines agreed to pay the Company (i) a one-time upfront cash payment of \$ 7.5 million, and (ii) milestone payments totaling up to \$ 194.5 million in the aggregate upon the achievement of certain technology transfer, development and regulatory milestones, as well as sales milestones based on certain net sales thresholds of GPS Licensed Products in the 3DMed Territory in a given calendar year. 3D Medicines also agreed to pay tiered royalties based upon a percentage of annual net sales of GPS Licensed Products in the 3DMed Territory ranging from the high single digits to the low double digits.

Revenue Recognition

At inception, the Company evaluated the 3D Medicines Agreement under ASC 606 and recognized an initial transaction price of \$ 9.5 million, which included the \$ 7.5 million upfront fee as well as \$ 2.0 million in development milestones that were assessed to be probable of being achieved, while the remaining milestones were variable consideration subject to constraint at inception. In the first quarter of 2022, an additional \$ 1.0 million in licensing revenue was recognized upon approval by China's National Medical Products Administration ("NMPA") for a small Phase 1 clinical trial investigating safety of GPS in China.

There is \$ 191.5 million in potential future development, regulatory, and sales milestones, not including future royalties, remaining under the 3D Medicines Agreement as of September 30, 2024, which milestones are variable in nature and not under the Company's control. At the end of each reporting period, the Company reevaluates the probability of achievement of the future development, regulatory, and sales milestones subject to constraint and, if necessary, will adjust its estimate of the overall transaction price. Any such adjustments will be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For the sales-based royalties, the Company will recognize revenue when the related sales occur. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

There was no licensing revenue recognized during each of the three and nine months ended September 30, 2024 and 2023. There was no cost of licensing revenue recognized during each of the three and nine months ended September 30, 2024 and 2023.

10. Stock-Based Compensation

2017 Equity Incentive Plan

On December 29, 2017, the 2017 Equity Incentive Plan was approved by the stockholders of the Company, which currently allows for issuance of up to approximately 22,000 shares of common stock underlying stock options granted prior to September 10, 2019. The 2017 Equity Incentive Plan was terminated upon the approval of the 2019 Incentive Plan subject to outstanding stock options granted under the 2017 Equity Incentive Plan that remain exercisable through maturity for the Company's employees and directors.

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2023 Amended and Restated Equity Incentive Plan

On September 10, 2019, the 2019 Equity Incentive Plan ("2019 Equity Plan") was approved by the stockholders of the Company. On June 20, 2023, an amendment to the 2019 Equity Plan was approved by the stockholders of the Company, which amended and restated the 2019 Equity Plan (as amended and restated, the "2023 Amended and Restated Equity Incentive Plan") to increase the number of shares of common stock authorized for issuance under the 2019 Equity Plan by 3,000,000 shares.

The 2023 Amended and Restated Equity Incentive Plan currently allows for issuance of up to approximately 6,036,000 shares of common stock in connection with the grant of stock-based awards, including stock options, restricted stock, restricted stock units, stock appreciation rights and other types of awards as deemed appropriate.

As of September 30, 2024, approximately 3,298,000 shares of common stock were reserved for future grants under the 2023 Amended and Restated Equity Incentive Plan.

The following table summarizes the components of stock-based compensation expense in the consolidated statements of operations for the three and nine months ended September 30, 2024 and 2023, respectively (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 87	\$ 93	\$ 260	\$ 281
General and administrative	294	450	931	1,316
Total stock-based compensation	<u>\$ 381</u>	<u>\$ 543</u>	<u>\$ 1,191</u>	<u>\$ 1,597</u>

Options to Purchase Shares of Common Stock

The following table summarizes stock option activity of the Company for the nine months ended September 30, 2024:

	Total Number of Shares (In Thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2023	1,607	\$ 5.92		\$ —
Granted	671	0.53		
Canceled	(325)	3.53		
Outstanding at September 30, 2024	<u>1,953</u>	\$ 4.47	7.91	\$ 425
Options exercisable at September 30, 2024	<u>950</u>	\$ 7.17	7.00	\$ —

The aggregate intrinsic values of outstanding and exercisable stock options at September 30, 2024 were calculated based on the closing price of the Company's common stock as reported on the Nasdaq Capital Market on September 30, 2024 of \$ 1.25 per share. The aggregate intrinsic value equals the positive difference between the closing fair market value of the Company's common stock and the exercise price of the underlying stock options.

The Company uses the Black-Scholes option-pricing model to determine the fair value of all its stock options granted. The weighted average assumptions used during the three and nine months ended September 30, 2024 and 2023, respectively, were as follows:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk free interest rate	n/a	n/a	4.01 %	3.78 %
Volatility	n/a	n/a	130.41 %	127.77 %
Expected lives (years)	n/a	n/a	6.19	6.20
Expected dividend yield	n/a	n/a	— %	— %

There were no options granted during each of the three months ended September 30, 2024 and 2023. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2024 and 2023 was \$ 0.48 and \$ 2.88 , respectively.

The Company's expected common stock price volatility assumption is based upon the Company's own implied volatility in combination with the implied volatility of a basket of comparable companies. The expected life assumptions for employee grants were based upon the simplified method, which averages the contractual term of the Company's options of ten years with the average vesting term of four years for an average of approximately six years . The expected life assumptions for non-employees were based upon the contractual term of the option. The dividend yield assumption is zero because the Company has never paid cash dividends and presently has no intention to do so. The risk-free interest rate used for each grant was also based upon prevailing short-term interest rates. The Company accounts for forfeitures as they occur.

As of September 30, 2024, there was \$ 1.6 million of unrecognized compensation cost related to outstanding stock options that is expected to be recognized as a component of the Company's operating expenses over a weighted-average period of 2.0 years.

Time-vested RSUs and RSUs with Performance Conditions

The following table summarizes RSU activity of the Company for the nine months ended September 30, 2024:

	Shares (In Thousands)	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	338	\$ 2.99
Granted	429	\$ 0.52
Canceled	(123)	\$ 1.84
Unvested at September 30, 2024	644	\$ 1.57

As of September 30, 2024, there was \$ 0.7 million of unrecognized compensation cost related to outstanding RSUs that is expected to be recognized as a component of the Company's operating expenses over a weighted-average period of 2.0 years. No RSUs vested during the nine months ended September 30, 2024.

2021 Employee Stock Purchase Plan

On April 22, 2021, the Board of Directors adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP") which was approved by the Company's stockholders on June 8, 2021 and authorized the issuance of up to 300,000 shares of common stock pursuant to the 2021 ESPP. The 2021 ESPP allows employees to contribute up to 20 % of their cash earnings, subject to a maximum of \$25,000 per year under Internal Revenue Service rules, to be used to purchase shares of the Company's common stock on semi-annual purchase dates. The 2021 ESPP allows eligible employees to purchase shares of common stock at a price per share equal to 85 % of the lower of the fair market value of the common stock at the beginning or end of each six-month offering period during the term of the 2021 ESPP.

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During the nine months ended September 30, 2024, 103,853 shares of common stock were purchased by employees under the 2021 ESPP for proceeds of approximately \$ 0.1 million. There are currently 79,604 shares of common stock reserved for issuance under the 2021 ESPP as of September 30, 2024.

11. Subsequent Events

The Company evaluated all events or transactions that occurred after September 30, 2024 up through the date these consolidated financial statements were issued. Other than as disclosed elsewhere in the notes to the consolidated financial statements, the Company did not have any material subsequent events.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This management's discussion and analysis of financial condition as of September 30, 2024 and results of operations for the three and nine months ended September 30, 2024 and 2023, respectively, should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission, or SEC, on March 28, 2024, or our 2023 Annual Report, and our other public reports filed with the SEC.

Overview

We are a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics for a broad range of cancer indications. Our product candidates currently include galinpepimut-S, or GPS, a peptide immunotherapy directed against the Wilms tumor 1, or WT1, antigen, and SLS009 (formerly GFH009), a highly selective small molecule cyclin-dependent kinase 9, or CDK9, inhibitor.

Galnpepimut-S, or GPS: Highly Novel and Engineered Immunotherapy Targeting the WT1 Antigen

Our lead product candidate, GPS, is a cancer immunotherapeutic agent licensed from Memorial Sloan Kettering Cancer Center, or MSK, that targets the WT1 protein, which is present in 20 or more cancer types. Based on its mechanism of action as a directly immunizing agent, GPS has potential as a monotherapy or in combination with other immunotherapeutic agents to address a broad spectrum of hematologic, or blood, cancers and solid tumor indications.

In January 2020, we commenced in the United States an open label randomized Phase 3 clinical trial, the REGAL study, for GPS monotherapy in patients with acute myeloid leukemia, or AML, in the maintenance setting after achievement of second complete remission, or CR2, following successful completion of second-line antileukemic therapy. Patients are randomized to receive either GPS or best available treatment, or BAT. We expect this study will be used as the basis for submission of a Biologics License Application, or BLA, subject to a statistically significant and clinically meaningful data outcome and agreement with the U.S. Food and Drug Administration, or the FDA. The primary endpoint of the REGAL study is overall survival. We planned to enroll approximately 125 to 140 patients at approximately 95 clinical sites in North America, Europe and Asia with a planned interim safety, efficacy and futility analysis after 60 events (deaths) and final analysis after 80 events. In March 2024, we announced the completion of enrollment. In June 2024, we announced the Independent Data Monitoring Committee, or IDMC, conducted a prespecified risk-benefit assessment of unblinded data from the study and recommended that the trial continue without modifications. Based on a detailed analysis of all unblinded data, the IDMC projects with a high level of confidence that the interim analysis (60 events) will occur by the fourth quarter of 2024. Because these analyses are event driven, they are difficult to predict with any certainty and may occur at a different time than currently expected.

In December 2020, we entered into an exclusive license agreement, or 3D Medicines Agreement, with 3D Medicines Inc., or 3D Medicines, a China-based biopharmaceutical company developing next-generation immuno-oncology drugs, for the development and commercialization of GPS, as well as the Company's next generation heptavalent immunotherapeutic GPS+, which is at preclinical stage, across all therapeutic and diagnostic uses in mainland China, Hong Kong, Macau and Taiwan, which we collectively refer to as Greater China, or the 3DMed Territory. We have retained sole rights to GPS and GPS+ outside of Greater China. In November 2022, we announced that we had agreed with 3D Medicines for 3D Medicines to participate in the REGAL study through the inclusion of approximately 20 patients from mainland China. In December 2022, we entered into a Side Letter Agreement with 3D Medicines, or Side Letter, which, together with the 3D Medicines Agreement, details the terms and conditions of 3D Medicines' participation in the REGAL study. Although the REGAL study has completed enrollment as announced in March 2024, in accordance with the predetermined statistical analysis plan, 3D Medicines may still enroll patients in mainland China. The timing of such participation and patient enrollment by 3D Medicines, if at all, cannot be predicted with certainty. As of September 30, 2024, we have received an aggregate of \$10.5 million in upfront and milestone payments under the 3D Medicines Agreement and a total of \$191.5 million in potential future development, regulatory and sales milestones, not including future royalties, remains under the license agreement, which milestones are variable in nature and not under our control. In December 2023, we

commenced an arbitration proceeding against 3D Medicines regarding, among other things, the trigger and payment of \$13.0 million in milestone payments due to us. See *Part II, Item 1. Legal Proceedings*.

GPS was granted Orphan Drug Product Designations, or ODD, from the FDA, as well as orphan medicines designations from the European Medicines Agency, or EMA, for GPS in AML, MPM, and multiple myeloma, or MM, as well as Fast Track designation for AML, MPM, and MM from the FDA. In October 2024, the FDA granted Rare Pediatric Disease, or RPD, designation to GPS for the treatment of pediatric AML.

SLS009: Highly Selective Next Generation CDK9 Inhibitor

On March 31, 2022, we entered into an exclusive license agreement, or the GenFleet Agreement, with GenFleet Therapeutics (Shanghai), Inc., or GenFleet, a clinical-stage biotechnology company developing cutting-edge therapeutics in oncology and immunology, that grants rights to us for the development and commercialization of SLS009, a highly selective small molecule CDK9 inhibitor, across all therapeutic and diagnostic uses worldwide, except for Greater China.

CDK9 activity has been shown to correlate negatively with overall survival in a number of cancer types, including hematologic cancers, such as AML and lymphomas, as well as solid cancers, such as osteosarcoma, pediatric soft tissue sarcomas, melanoma, endometrial, lung, prostate, breast and ovarian. As demonstrated in preclinical and clinical data, to date, SLS009's high selectivity has the potential to reduce toxicity as compared to older CDK9 inhibitors and other next-generation CDK9 inhibitors currently in clinical development and to potentially be more efficacious.

We completed a Phase 1 dose-escalating clinical trial in the United States and China for SLS009 in mid-2023 and reported positive safety and efficacy data for both patient cohorts, that is relapsed and/or refractory AML and refractory lymphoma. We also established in the trial a recommended Phase 2 dose, or RP2D, of 60 mg once weekly for AML and 100 mg once weekly for lymphomas.

In the second quarter of 2023, we commenced an open label, single arm, multi-center Phase 2a clinical trial with SLS009 in combination with venetoclax and azacitidine, or aza/ven, in patients with AML who failed or did not respond to treatment with venetoclax-based therapies. The trial is evaluating safety, tolerability, and efficacy at two dose levels of SLS009, 45 mg once weekly, and 60 mg once weekly or 30 mg twice a week, in combination with aza/ven. In addition to safety and tolerability of SLS009 in combination with aza/ven, the efficacy endpoints are complete response composite rate and duration of response. Additional endpoints include event free survival, overall survival, and pharmacokinetic and pharmacodynamic assessments.

In the fourth quarter of 2023, we completed enrollment in the 45 mg (safety) dose cohort in the Phase 2a study and reported positive initial topline data. At that time, we also commenced enrollment in the 60 mg dose cohort with patients randomized to one of two groups, 60 mg fixed dose once weekly or 30 mg fixed twice weekly. Each group was planned to enroll five to 10 patients.

In March 2024, we announced positive topline data from the Phase 2a clinical trial of SLS009 in combination with aza/ven in *r/r* AML. A total of 21 patients were enrolled in the study as of March 15, 2024: 10 in the 45 mg safety cohort and 11 in the 60 mg cohort (30 mg twice a week or 60 mg once a week). Response rates observed in the three cohorts were 10% in the 45 mg once a week safety dose cohort (dose level below the RP2D), 20% in the 60 mg once a week dose cohort, and 50% in the 30 mg twice a week dose cohort. Additionally, we observed strong anti-leukemic activity, which is defined as 50% or more bone marrow blast reduction in 67% of patients across all dose levels. At the time of data cutoff, median OS had not been reached in any of the cohorts and the first patient enrolled in the study who achieved a CR continued on the study and remained leukemia-free 9 months after enrollment.

During the trial, we identified potential biomarkers currently undergoing testing as predictive markers in the most recent portion of the study. In May 2024, we announced additional preliminary data from the Phase 2a trial of SLS009 in *r/r* AML and successful filing of a provisional patent application around the ASXL1 mutation and SLS009, including all CDK9 inhibitor drugs. ASXL1 mutations are associated with poor prognosis in all myeloid diseases, owing to the reduced response to the current treatment options. We observed a high rate of responses in patients with myelodysplasia-related molecular mutations, as defined by the World Health Organization, and patients with the ASXL1 gene mutation accounted for the most responders across all dose cohorts. As of April 19, 2024, a 100% response rate had been achieved in *r/r* AML patients with ASXL1 truncating mutations at the optimal dose level (30 mg twice a week), and a 57% response rate in *r/r* AML patients with ASXL1 truncating mutations across all dose levels. Furthermore, we have clarified the proposed biological basis and mechanism of action for SLS009 activity in patients with these biomarkers. The relevant biomarkers are present in multiple hematologic and solid cancer indications, with a substantial proportion of patients exhibiting them in additional indications, ranging up to ~50% of patients in some indications. We also announced that we have expanded the ongoing study to include two additional cohorts, one with ASXL1 mutated AML patients and one with patients with myelodysplasia-related molecular abnormalities other than ASXL1.

In June 2024, we announced the completion of enrollment and additional positive data in the Phase 2a clinical trial of SLS009 in *r/r* AML. SLS009 was generally well-tolerated with no safety issues observed across all dose levels and there were no dose-limiting or high-grade-treatment-related non-hematological malignancies. The hematological malignancy profile was not different from that of venetoclax-based regimens alone. As of the May 25, 2024 data cutoff date, there were 27 patients with at least one efficacy assessment and were considered evaluable for efficacy. The overall response rate (ORR: response defined as leukemia-free status that includes complete response, complete response with incomplete hematologic recovery, and morphologic leukemia-free state) among evaluable patients:

- 50% (4 out of 8 patients) in the 30 mg BIW cohort
- 33% (3 out of 9 patients) in the 60 mg QW cohort
- 10% (1 out of 10 patients) in the 45 mg QW safety cohort
- 29.6% across all dose levels

The data in June 2024 was consistent with the data previously announced in May 2024, and the highest response rates were observed among patients harboring ASXL1 mutations. Notably, responses were highly correlated with mutational status, with 6 out of 8 responding patients having myelodysplasia-related somatic mutations and 5 having specifically ASXL1 mutations. A 100% overall response rate was achieved in evaluable patients with ASXL1 mutations in the 30 mg BIW cohort. Median overall survival was not reached in the 30 mg BIW and 60 mg QW cohorts. Median overall survival in the 45 mg QW safety cohort was 5.4 months. Observed efficacy outcomes exceeded the targeted ORR of 20% and targeted median overall survival of 3 months.

In November 2024, we announced that data from the Phase 2a trial of SLS009 in *r/r* AML will be presented at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition in December 2024.

Our partner, GenFleet, is focusing on lymphoma indications with SLS009 in its Greater China market. In March 2024, GenFleet announced that it entered into a collaboration and supply agreement with BeiGene Switzerland GmbH to initiate a study of SLS009 in combination with Zanubrutinib (Brukinsa®), a BTK inhibitor, in *r/r* diffuse large B-cell lymphoma, or DLBCL, and the first patient was dosed in the trial. The study is funded and sponsored by GenFleet and is being conducted in China only.

SLS009 is also currently being evaluated in pediatric solid tumors and leukemia models through the NCI Pediatric Preclinical in Vivo Testing, or PIVOT, program. Studies are supported through cooperative agreement grants from the NCI to the PIVOT research centers performing the testing in pediatric tumor models and a centralized coordinating center. We expect to report relevant data from the program in the fourth quarter of 2024.

For SLS009, the FDA granted Orphan Drug Product designations in AML and peripheral T-cell lymphoma, or PTCL, and Fast Track designations for *r/r* AML and *r/r* PTCL. The FDA granted RPD designation to SLS009 for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in June 2024 and the FDA granted RPD designation to SLS009 for the treatment of pediatric AML in July 2024. Also, the European Medicines Agency granted Orphan Drug Designation for SLS009 in AML and in PTCL in June 2024 and July 2024, respectively.

Components of Results of Operations

Research and Development

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- manufacturing and clinical drug supply expenses;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments made under our license agreements, under which we acquired certain intellectual property;
- expenses relating to certain regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses, utilities, and other facility-related costs.

The successful development of our current and future product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from, any current or future product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of our clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number and geographical location of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number and geographical location of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of clinical trials;
- the expenses associated with manufacturing and clinical drug supply;
- the receipt of marketing approvals; and
- the commercialization of current and future product candidates.

Research and development activities are central to our business model. Oncology product candidates in the later stages of clinical development generally have higher development costs than those in the earlier stages of clinical development, primarily due to the increased size and duration of the later-stage clinical trials. We expect our research and development expenses to increase for the foreseeable future as we conduct and complete our ongoing early and late-stage clinical trials and initiate additional clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our current or future product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or target indications or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses, fees for outside legal counsel, amortization of contract acquisition costs (commissions), and director and officer insurance premiums. Other general and administrative expenses include facility related costs, patent filing and prosecution costs, professional fees for business development, accounting, consulting, legal and tax-related services associated with maintaining compliance with our Nasdaq listing and SEC reporting requirements, investor relations costs, and other expenses associated with being a public company.

If and when we believe that regulatory approval of a product candidate appears likely, we anticipate that an increase in general and administrative expenses will occur as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of such product candidate. Oncology product commercialization may take several years and millions of dollars in development costs.

Non-Operating Income

Non-operating income consists of changes in fair value of our warrant liability, and interest income. Interest income primarily reflects interest earned from our cash and cash equivalents.

Critical Accounting Policies and Estimates

In the 2023 Annual Report, we disclosed our critical accounting policies and estimates upon which our consolidated financial statements are derived. There have been no material changes to these policies and estimates since December 31, 2023 that are not included in Note 3 of the accompanying consolidated financial statements for the three and nine months ended September 30, 2024. Readers are encouraged to read the 2023 Annual Report in conjunction with this Quarterly Report on Form 10-Q.

Results of Operations for the Three and Nine Months Ended September 30, 2024 and 2023

The following tables summarize our results of operations for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Change
	2024	2023	
Operating expenses:			
Research and development	\$ 4,362	\$ 5,813	\$ (1,451)
General and administrative	2,967	3,548	(581)
Total operating expenses	7,329	9,361	(2,032)
Operating loss	(7,329)	(9,361)	2,032
Non-operating income	221	94	127
Net loss	\$ (7,108)	\$ (9,267)	\$ 2,159

	Nine Months Ended September 30,		Change
	2024	2023	
Operating expenses:			
Research and development	\$ 14,659	\$ 18,910	(4,251)
General and administrative	9,936	10,782	(846)
Total operating expenses	24,595	29,692	(5,097)
Operating loss	(24,595)	(29,692)	5,097
Non-operating income	451	488	(37)
Net loss	\$ (24,144)	\$ (29,204)	\$ 5,060

Further analysis of the changes and trends in our operating results are discussed below.

Research and Development

Research and development expenses were \$4.4 million for the three months ended September 30, 2024 compared to \$5.8 million for the three months ended September 30, 2023. The \$1.4 million decrease was primarily attributable to a \$0.7 million decrease of clinical drug supply purchases and a \$0.4 million decrease in clinical trial related expenses primarily driven by the completion of enrollment in the REGAL study in the first quarter of 2024, as well as a \$0.2 million decrease in clinical and regulatory consultants and a \$0.1 million decrease in personnel related expenses due to a decrease in headcount. We anticipate that our research and development expenses will increase in the future as we continue to advance the development of GPS and SLS009.

Research and development expenses were \$14.7 million for the nine months ended September 30, 2024 compared to \$18.9 million for the nine months ended September 30, 2023. The \$4.2 million decrease was primarily attributable to a \$1.7 million decrease in clinical and regulatory consultants, a \$1.5 million decrease of clinical drug supply purchases driven by the completion of enrollment in the REGAL study in the first quarter of 2024, a \$0.6 million decrease in personnel related expenses due to a decrease in headcount, a \$0.3 million decrease in clinical trial related expenses driven by the completion of enrollment in REGAL, and a \$0.1 million decrease in licensing fees. We anticipate that our research and development expenses will increase in the future as we continue to advance the development of GPS and SLS009.

General and Administrative

General and administrative expenses were \$3.0 million for the three months ended September 30, 2024 compared to \$3.5 million for the three months ended September 30, 2023. The \$0.5 million decrease was primarily

attributable to a \$0.6 million decrease in personnel related expenses due to a decrease in headcount, including a \$0.2 million decrease in non-cash stock-based compensation, and a \$0.1 million decrease related to insurance premiums, which were partially offset by a \$0.2 million increase in legal fees.

General and administrative expenses were \$9.9 million for the nine months ended September 30, 2024 compared to \$10.8 million for the nine months ended September 30, 2023. The \$0.9 million decrease was primarily attributable to a \$1.3 million decrease in personnel related expenses due to a decrease in headcount, including a \$0.4 million decrease in non-cash stock-based compensation, a \$0.5 million decrease in outside services and public company costs, and a \$0.5 million decrease related to insurance premiums, which were partially offset by the initial recognition of a \$1.1 million one-time severance charge during the current period and a \$0.3 million increase in legal fees.

Non-Operating Income

Non-operating income for the three and nine months ended September 30, 2024 and 2023 was as follows (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Change in fair value of warrant liability	\$ —	\$ —	\$ —	\$ —	\$ 4	\$ (4)
Interest income	221	94	127	451	484	(33)
Total non-operating income	\$ 221	\$ 94	\$ 127	\$ 451	\$ 488	\$ (37)

Non-operating income of \$0.2 million and \$0.1 million during the three months ended September 30, 2024 and 2023, respectively, and \$0.5 million during each of the nine months ended September 30, 2024 and 2023, was primarily related to interest income earned from our cash and cash equivalents.

Liquidity and Capital Resources

We did not generate any revenue from product sales during the nine months ended September 30, 2024 and 2023. Through September 30, 2024, we have only generated licensing revenue from the 3DMed License Agreement. Since inception, we have incurred net losses, used net cash in our operations, and have funded substantially all of our operations through proceeds of the sale of equity securities and convertible notes.

Sources of Liquidity

On August 1, 2024, we consummated a registered direct offering with an institutional investor priced at a premium to market, or the August 2024 Registered Direct Offering, pursuant to which we agreed to issue and sell 6,370,070 shares of common stock and 9,478,986 pre-funded warrants exercisable for shares of common stock, together with accompanying warrants to purchase 15,849,056 shares of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$1.325, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$1.3249. The common warrants have an exercise price of \$1.20 per share. The net proceeds to us from the August 2024 Registered Direct Offering were approximately \$19.5 million, after deducting the placement agent's fees and related offering expenses.

On March 19, 2024, we consummated a registered direct offering with two institutional investors priced at-the-market under Nasdaq rules, or the March 2024 Registered Direct Offering, pursuant to which the Company agreed to issue and sell 11,000,000 shares of its common stock and 2,029,316 pre-funded warrants exercisable for shares of common stock. Each share of common stock was sold at a purchase price of \$1.535 and each pre-funded warrant was sold at a purchase price of \$1.5349. The net proceeds to us from the March 2024 Registered Direct Offering were approximately \$18.5 million, after deducting the placement agent's fees and related offering expenses. In a concurrent private placement, we agreed to issue to the two institutional investors exercisable for up to an aggregate of 13,029,316 shares of common stock warrants at an exercise price of \$1.41 per share. Subsequent to the closing of the March 2024 Registered Direct Offering, all of the pre-funded warrants have been exercised for shares of common stock.

On January 8, 2024, we consummated a public offering on a "reasonable best efforts" basis, or the January 2024 Offering, issuing 10,130,000 shares of common stock and an aggregate of 1,870,000 pre-funded warrants exercisable for shares of common stock, together with accompanying warrants to purchase an aggregate of 12,000,000 shares of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$0.75, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$0.7499. The net proceeds to us from the January 2024 Offering were approximately \$8.2 million, after deducting the placement agent's fees and related offering expenses. Subsequent to the closing of the January 2024 Offering, all of the pre-funded warrants have been exercised for shares of common stock.

In December 2020, together with our wholly-owned subsidiary, SLSC Limited, LLC, we entered into the 3D Medicines Agreement pursuant to which we granted 3D Medicines a sublicensable royalty-bearing license under certain intellectual property owned or controlled by us, to develop, manufacture and have manufactured, and commercialize GPS and heptavalent GPS product candidates for all therapeutic and other diagnostic uses in the 3D Med Territory. To date, we have received \$10.5 million in upfront payments and certain technology transfer and regulatory milestones. A total of \$191.5 million in potential future development, regulatory, and sales milestones, not including future royalties, remains under the 3D Medicines Agreement as of September 30, 2024, which milestones are all variable in nature and not under our control. In December 2023, we commenced a binding arbitration proceeding against 3D Medicines, which involves, among other things, the trigger and payment of certain milestone payments due to us. See *Part II, Item 1. Legal Proceedings*.

Funding Requirements

As of September 30, 2024, we had an accumulated deficit of \$241.4 million, cash and cash equivalents of \$21.0 million and restricted cash and cash equivalents of \$0.1 million. We expect that our cash and cash equivalents will not be sufficient to fund our current planned operations for at least the next twelve months from the date of issuance of these financial statements. These conditions give rise to a substantial doubt over our ability to continue as a going concern. This going concern assumption is based on management's assessment of the sufficiency of our current and future sources of liquidity and whether it is probable we will be able to meet our obligations as they become due for at least one year from the date our consolidated financial statements are available to be issued, and if not, whether our liquidation is imminent.

Our consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of any current or future product candidates in development.

We will require substantial additional financing to develop any current or future product candidates. If we are unable to obtain additional funding on a timely basis, we will be required to scale back our plans and place certain activities on hold. We currently do not have any commitments to obtain additional funds. Our management continues to evaluate different strategies to obtain the required funding for future operations. These strategies may include public and private placements of equity and/or debt securities, as well as payments from potential strategic research and development collaborations or licensing and/or marketing arrangements with pharmaceutical companies. Additionally, we continue to pursue discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our product candidates. There can be no assurance that these future funding efforts will be successful.

Our future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of any additional financings, (ii) our ability to complete revenue-generating partnerships with pharmaceutical and biotechnology companies, (iii) the success of our research and development activities, (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (v) regulatory approval and market acceptance of our product candidates.

Cash Flows

The following table summarizes our cash flows from operating, investing, and financing activities for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	\$ (28,249)	\$ (26,585)
Investing activities	—	(5,500)
Financing activities	46,750	18,929
Net increase (decrease) in cash, cash equivalents, restricted cash, and restricted cash equivalents	\$ 18,501	\$ (13,156)

Net Cash Used in Operating Activities

Net cash used in operating activities of \$28.2 million during the nine months ended September 30, 2024 was primarily attributable to our net loss of \$24.1 million and a net change in our operating assets and liabilities of approximately \$5.7 million, which were partially offset by net non-cash charges of approximately \$1.6 million. The net change in our operating assets and liabilities is primarily attributable to a decrease in accrued expenses and other current liabilities of approximately \$2.2 million, an increase in prepaid expenses and other assets of approximately \$2.1 million, a decrease in accounts payable of approximately \$1.0 million, and a \$0.4 million decrease in operating lease liabilities. Net non-cash charges were driven by \$1.2 million in non-cash stock-based compensation expense and \$0.4 million in non-cash lease expense.

Net cash used in operating activities of \$26.6 million during the nine months ended September 30, 2023 was primarily attributable to our net loss of \$29.2 million, which was partially offset by various net non-cash charges of \$2.0 million and a net change in our operating assets and liabilities of approximately \$0.6 million. Net non-cash charges were driven by \$1.6 million in non-cash stock-based compensation expense and \$0.4 million in non-cash lease expense. The net change in our operating assets and liabilities is primarily attributable to an increase in accounts payable and accrued expenses of approximately \$1.6 million, partially offset by an increase in prepaid expenses and other current assets of approximately \$0.6 million and a decrease in operating lease liabilities of approximately \$0.4 million.

Net Cash Used in Investing Activities

There was no cash used in investing activities during the nine months ended September 30, 2024.

Net cash used in investing activities of \$5.5 million during the nine months ended September 30, 2023 related to license payments made for the acquisition of in-process research and development under the GenFleet License Agreement.

Net Cash Provided by Financing Activities

We generated \$46.8 million in net cash from financing activities during the nine months ended September 30, 2024, which was due to approximately \$46.1 million in net proceeds from the January 2024 Offering, the March 2024 Registered Direct Offering, and the August 2024 Registered Direct Offering, \$0.6 million in proceeds from the exercise of warrants, and \$0.1 million from the purchase of shares of common stock by employees under the 2021 Employee Stock Purchase Plan.

We generated \$18.9 million in net cash from financing activities during the nine months ended September 30, 2023, which was due to approximately \$18.5 million in net proceeds from the February 2023 Offering, \$0.3 million in net proceeds under a Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., or the Sales Agreement, and \$0.1 million from the purchase of shares of common stock by employees under the 2021 Employee Stock Purchase Plan.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet financing arrangements as of September 30, 2024.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, our principal executive officer and our principal financial officer (the "Certifying Officers"), evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934 (the "Exchange Act"), such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Certifying Officers, as appropriate to allow timely decisions regarding required disclosure. Based on these evaluations, the Certifying Officers have concluded, that, as of the end of the period covered by this Quarterly Report on Form 10-Q:

- (a) our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and
- (b) our disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed by us in the reports we file or submit under the Exchange Act was accumulated and communicated to our management, including the Certifying Officers, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In December 2020, we entered into the 3D Medicines Agreement. In November 2022, we announced that we had agreed with 3D Medicines for 3D Medicines to participate in the REGAL study through the inclusion of approximately 20 patients from mainland China.

In accordance with the terms of the 3D Medicines Agreement and the Side Letter, we had expected that 3D Medicines would begin enrolling patients in mainland China in the REGAL study in the second half of 2023 and subsequently make two development milestone payments totaling \$13.0 million. Patients were enrolled in the REGAL study in Taiwan, which is part of the 3D Med Territory, prior to the second half of 2023.

On December 20, 2023, we commenced a binding arbitration proceeding against 3D Medicines, administered by the Hong Kong International Arbitration Centre and governed by New York State law as per the 3D Medicines Agreement. The arbitration proceeding involves, among other things, the trigger and payment of the relevant milestone payments due to us as well as 3D Medicines' failure to use commercially reasonable best efforts to develop GPS in the 3D Med Territory, and particularly in mainland China.

We have engaged an international law firm with expertise in mainland China to assist us with the arbitration proceeding. While we are unable at this time to predict with certainty the outcome of the arbitration proceeding, or the timing of the receipt of any milestone payments and other damages it is seeking in the arbitration proceeding, if at all, we believe that our claims are meritorious.

ITEM 1A. RISK FACTORS

Please refer to our note on forward-looking statements on page 2 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in our 2023 Annual Report. The risks described in such 2023 Annual Report are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition, operating results and stock price.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None of our directors or officers have adopted, modified, or terminated any trading plans under Rule 10b5-1 of the Exchange Act or any similar arrangements during the three months ended September 30, 2024.

ITEM 6. EXHIBITS

Exhibit #	Description	Form	Exhibit	Filing Date
3.1	Composite Amended and Restated Certificate of Incorporation of the Registrant (formerly, Galena Biopharma, Inc.) amended as of December 27, 2017	10-K	3.1	April 13, 2018
3.2	Amended and Restated By-Laws of the Registrant	8-K	3.3	January 5, 2018
10.1	Letter Agreement, effective October 3, 2024, by and between SELLAS Life Sciences Group, Inc. and Times Square Tower Associates LLC	8-K	10.1	October 3, 2024
31.1	Certification of Principal Executive Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.**			
31.2	Certification of Principal Financial Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.**			
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. ***			
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. ***			
101.INS	XBRL Instance Document.*			
101.SCH	XBRL Taxonomy Extension Schema.*			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.*			
101.DEF	XBRL Taxonomy Extension Definition Linkbase.*			
101.LAB	XBRL Taxonomy Extension Label Linkbase.*			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.*			

* Indicates management contract or compensatory plans or arrangements.

** Filed herewith

*** The certifications attached as Exhibit 32.1 and Exhibit 32.2 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 thereunto duly authorized.

SELLAS Life Sciences Group, Inc.

By: /s/ Angelos M. Stergiou

Angelos M. Stergiou, MD, ScD h.c.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2024

By: /s/ John T. Burns

John T. Burns, CPA
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

Date: November 13, 2024

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Angelos M. Stergiou, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SELLAS Life Sciences Group, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2024

/s/ Angelos M. Stergiou

Angelos M. Stergiou, MD, ScD h.c.
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John T. Burns, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SELLAS Life Sciences Group, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2024

/s/ John T. Burns

John T. Burns, CPA
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Quarterly Report of SELLAS Life Sciences Group, Inc., (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the Company's financial condition and results of operations.

By: /s/ Angelos M. Stergiou

Angelos M. Stergiou, MD, ScD h.c.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2024

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Quarterly Report of SELLAS Life Sciences Group, Inc., (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the Company's financial condition and results of operations.

By: /s/ John T. Burns

John T. Burns, CPA
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

Date: November 13, 2024

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.