

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

OR

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

For the transition period from _____ to _____

Commission File Number 001-32157



Savara Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

84-1318182

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

1717 Langhorne Newtown Road, Suite 300
Langhorne, Pennsylvania

(Address of principal executive offices)

19047

(Zip Code)

(512) 614-1848

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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, par value \$0.001 per share	SVRA	The Nasdaq Global Select Market

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 period 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 August 12, 2024, the registrant had 164,600,603 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

	<u>Page</u>
PART I. FINANCIAL INFORMATION	1
Item 1. Financial Statements (Unaudited)	1
Condensed Consolidated Balance Sheets	1
Condensed Consolidated Statements of Operations and Comprehensive Loss	2
Consolidated Statements of Changes in Stockholders' Equity	3
Condensed Consolidated Statements of Cash Flows	5
Notes to Condensed Consolidated Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3. Quantitative and Qualitative Disclosures About Market Risk	22
Item 4. Controls and Procedures	22
PART II. OTHER INFORMATION	23
Item 1. Legal Proceedings	23
Item 1A. Risk Factors	23
Item 2. Unregistered Shares of Equity Securities and Use of Proceeds	23
Item 3. Defaults Upon Senior Securities	23
Item 4. Mine Safety Disclosures	23
Item 5. Other Information	23
Item 6. Exhibits	23
Exhibit Index	24
Signatures	25

PART I – FINANCIAL INFORMATION

Item I. Financial Information

Savara Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	June 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,864	\$ 26,585
Short-term investments	97,652	135,734
Prepaid expenses and other current assets	6,178	3,628
Total current assets	127,694	165,947
Property and equipment, net	236	270
In-process R&D	10,634	10,960
Other non-current assets	1,106	387
Total assets	\$ 139,670	\$ 177,564
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,386	\$ 3,504
Accrued expenses and other current liabilities	7,900	7,093
Total current liabilities	11,286	10,597
Long-term liabilities:		
Long-term debt	26,484	26,348
Other long-term liabilities	169	247
Total liabilities	37,939	37,192
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, \$0.001 par value, 300,000,000 authorized as of June 30, 2024 and December 31, 2023; 138,199,047 and 138,143,545 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	140	140
Additional paid-in capital	538,429	533,872
Accumulated other comprehensive loss	(880)	(271)
Accumulated deficit	(435,958)	(393,369)
Total stockholders' equity	101,731	140,372
Total liabilities and stockholders' equity	\$ 139,670	\$ 177,564

The accompanying notes are an integral part of these condensed consolidated financial statements.

Savara Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 17,617	\$ 8,911	\$ 34,424	\$ 17,649
General and administrative	5,540	3,302	11,176	6,668
Depreciation and amortization	33	8	65	16
Total operating expenses	<u>23,190</u>	<u>12,221</u>	<u>45,665</u>	<u>24,333</u>
Loss from operations	<u>(23,190)</u>	<u>(12,221)</u>	<u>(45,665)</u>	<u>(24,333)</u>
Other income (expense)				
Interest income	1,072	709	2,425	1,474
Foreign currency exchange gain (loss)	(125)	33	(146)	62
Tax credit income	—	36	797	797
Total other income, net	<u>947</u>	<u>778</u>	<u>3,076</u>	<u>2,333</u>
Net loss	<u>\$ (22,243)</u>	<u>\$ (11,443)</u>	<u>\$ (42,589)</u>	<u>\$ (22,000)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.07)</u>	<u>\$ (0.23)</u>	<u>\$ (0.14)</u>
Weighted-average common shares outstanding:				
Basic and diluted	<u>182,584,078</u>	<u>152,796,617</u>	<u>182,567,091</u>	<u>152,778,031</u>
Other comprehensive income (loss):				
Gain (loss) on foreign currency translation	(113)	(98)	(333)	32
Unrealized loss on short-term investments	(25)	(60)	(276)	(46)
Total comprehensive loss	<u>\$ (22,381)</u>	<u>\$ (11,601)</u>	<u>\$ (43,198)</u>	<u>\$ (22,014)</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

Savara Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity
Periods Ended June 30, 2024 and 2023
(In thousands, except share amounts)
(Unaudited)

	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Number of Shares	Amount				
Balance on December 31, 2023	138,143,545	\$ 140	\$ 533,872	\$ (393,369)	\$ (271)	\$ 140,372
Issuance of common stock upon exercise of stock options	31,914	—	51	—	—	51
Issuance of common stock for settlement of RSUs	1,563	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(381)	—	(2)	—	—	(2)
Stock-based compensation	—	—	2,257	—	—	2,257
Foreign exchange translation adjustment	—	—	—	—	(220)	(220)
Unrealized loss on short-term investments	—	—	—	—	(251)	(251)
Net loss	—	—	—	(20,346)	—	(20,346)
Balance on March 31, 2024	138,176,641	\$ 140	\$ 536,178	\$ (413,715)	\$ (742)	\$ 121,861
Issuance of common stock upon exercise of stock options	21,225	—	11	—	—	11
Issuance of common stock for settlement of RSUs	1,562	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(381)	—	(2)	—	—	(2)
Reimbursement of commissions from the prior issuance of common stock upon at the market sales, net	—	—	46	—	—	46
Stock-based compensation	—	—	2,196	—	—	2,196
Foreign exchange translation adjustment	—	—	—	—	(113)	(113)
Unrealized loss on short-term investments	—	—	—	—	(25)	(25)
Net loss	—	—	—	(22,243)	—	(22,243)
Balance on June 30, 2024	138,199,047	\$ 140	\$ 538,429	\$ (435,958)	\$ (880)	\$ 101,731

The accompanying notes are an integral part of these condensed consolidated financial statements.

Savara Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (continued)
Periods Ended June 30, 2024 and 2023
(In thousands, except share amounts)
(Unaudited)

	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Number of Shares	Amount				
Balance on December 31, 2022	114,046,345	\$ 116	\$ 446,938	\$ (338,671)	\$ (605)	\$ 107,778
Issuance of common stock upon exercise of options	17,129	—	27	—	—	27
Issuance of common stock for settlement of RSUs	1,813	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(551)	—	(1)	—	—	(1)
Stock-based compensation	—	—	864	—	—	864
Foreign exchange translation adjustment	—	—	—	—	130	130
Unrealized gain on short-term investments	—	—	—	—	14	14
Net loss	—	—	—	(10,557)	—	(10,557)
Balance on March 31, 2023	114,064,736	\$ 116	\$ 447,828	\$ (349,228)	\$ (461)	\$ 98,255
Issuance of common stock upon exercise of options	84,375	—	103	—	—	103
Issuance of common stock for settlement of RSUs	1,812	—	—	—	—	—
Repurchase of shares for minimum tax withholdings	(468)	—	—	—	—	—
Stock-based compensation	—	—	958	—	—	958
Foreign exchange translation adjustment	—	—	—	—	(98)	(98)
Unrealized loss on short-term investments	—	—	—	—	(60)	(60)
Net loss	—	—	—	(11,443)	—	(11,443)
Balance on June 30, 2023	114,150,455	\$ 116	\$ 448,889	\$ (360,671)	\$ (619)	\$ 87,715

The accompanying notes are an integral part of these condensed consolidated financial statements.

Savara Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	For the six months ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (42,589)	\$ (22,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65	16
Amortization of right-of-use assets	71	31
Foreign currency gain (loss)	146	(62)
Amortization of debt issuance costs	135	135
Accretion on premium to short-term investments	(2,495)	(1,837)
Stock-based compensation	4,453	1,822
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,677)	377
Non-current assets	(814)	(792)
Accounts payable and accrued expenses and other current liabilities	566	12
Net cash used in operating activities	(43,139)	(22,298)
Cash flows from investing activities:		
Purchase of property and equipment	(31)	(229)
Purchase of available-for-sale securities, net	(34,138)	(60,872)
Maturity of available-for-sale securities	74,500	54,000
Net cash provided by (used in) investing activities	40,331	(7,101)
Cash flows from financing activities:		
Proceeds from exercise of stock options, net	62	131
Reimbursement of commissions from the prior issuance of common stock upon at the market sales, net	46	—
Repurchase of shares for minimum tax withholdings	(4)	(1)
Net cash provided by financing activities	104	130
Effect of exchange rate changes on cash and cash equivalents	(17)	(86)
Decrease in cash and cash equivalents	(2,721)	(29,355)
Cash and cash equivalents beginning of period	26,585	52,100
Cash and cash equivalents end of period	\$ 23,864	\$ 22,745
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,078	\$ 973

The accompanying notes are an integral part of these condensed consolidated financial statements.

Savara Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Organization and Nature of Operations

Description of Business

Savara Inc. (together with its subsidiaries "Savara," the "Company," "we" or "us") is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. The Company's sole program, molgramostim nebulizer solution ("molgramostim"), a novel inhaled biologic, is a granulocyte-macrophage colony-stimulating factor in Phase 3 development for autoimmune pulmonary alveolar proteinosis ("aPAP"). The Company and its wholly-owned domestic and foreign subsidiaries operate in one segment with its principal office in Langhorne, Pennsylvania, though a significant portion of employees work remotely.

Since inception, Savara has devoted its efforts and resources to identifying and developing its product candidates, recruiting personnel, and raising capital. Savara has incurred operating losses and negative cash flow from operations and has no product revenue from inception to date. The Company has not yet commenced commercial operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") as defined by the Financial Accounting Standards Board ("FASB"). The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments that are necessary to fairly present the statements of financial position, operations and cash flows for the periods presented. The results of operations for interim periods shown in this report are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other future annual or interim period.

Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted from these condensed consolidated financial statements, as permitted by rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"). The Company believes the disclosures made in these condensed consolidated financial statements are adequate to make the information herein not misleading. The Company recommends that these condensed consolidated financial statements be read in conjunction with its audited consolidated financial statements and related notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2023. The Company's significant accounting policies are described in Note 2 to the audited consolidated financial statements. There have been no changes to the Company's significant accounting policies since the date of those financial statements.

Principles of Consolidation

The interim condensed consolidated financial statements of the Company are stated in U.S. dollars and are prepared under U.S. GAAP. These condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The financial statements of the Company's wholly-owned subsidiaries are recorded in their functional currency and translated into the reporting currency. The cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency is reported in *Accumulated other comprehensive loss* in the condensed consolidated balance sheet. All intercompany transactions and accounts have been eliminated in consolidation. The condensed consolidated balance sheet at December 31, 2023 has been derived from the Company's audited consolidated financial statements at that date but does not include all of the information and notes required by U.S. GAAP for complete financial statements.

Liquidity

As of June 30, 2024, the Company had an accumulated deficit of approximately \$436.0 million. The Company used cash in operating activities of approximately \$43.1 million during the six months ended June 30, 2024. The cost to further develop and obtain regulatory approval for any drug is substantial and, as noted below, the Company may have to take certain steps to maintain a positive cash position. Although the Company has sufficient capital to fund many of its planned activities, it may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, its product candidate and begin to commercialize any approved product.

The Company is currently focused on the development of molgramostim for the treatment of aPAP and believes such activities will result in the continued incurrence of significant research and development and other expenses related to this program. If the Company's product candidate does not gain regulatory approval or, if approved, fails to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash and cash equivalents on hand, short-term investments, and through a combination of equity offerings, debt financings, government or other third-party funding, and other collaborations and strategic alliances with partner companies. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders.

The Company's cash and cash equivalents of \$23.9 million and short-term investments of \$97.7 million as of June 30, 2024 are sufficient to fund the Company's operations for at least the next twelve months subsequent to the issuance date of these condensed consolidated financial statements and excludes a registered direct offering completed on July 1, 2024 (the "July 2024 Offering") that resulted in gross proceeds of approximately \$100.0 million, refer to [Note 12. Subsequent Events](#). The Company may continue to raise additional capital as needed through the issuance of additional equity securities and potentially through borrowings and strategic alliances with partner companies. However, if such additional financing is not available timely and at adequate levels, the Company will need to reevaluate its long-term operating plans. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

In order to mitigate risks associated with our banking deposits, the Company maintains a significant portion of its liquidity in U.S. Treasury money market funds and other short-term investments with custodial services provided by U.S. Bank, N.A., refer to [Note 5. Short-term Investments](#) and [Note 7. Fair Value Measurements](#).

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Management's estimates include, but are not limited to, those related to the accrual and prepayment of research and development expenses and general and administrative costs, certain financial instruments recorded at fair value, stock-based compensation, and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience, changes in circumstance and facts, and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Accordingly, actual results could be materially different from those estimates.

Risks and Uncertainties

The product candidate being developed by the Company requires approval from the U.S. Food and Drug Administration ("FDA") or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's product candidate will receive the necessary approvals. If the Company is denied regulatory approval of its product candidate, or if approval is delayed, it will have a material adverse impact on the Company's business, results of operations, and its financial position.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of drug candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology, and market acceptance of the Company's product. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

Concentration of Credit Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. These investments were made in accordance with our investment policy which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. We maintain our cash and cash equivalents and marketable securities with a limited number of financial institutions. Deposits held with the financial institutions exceed the amount of insurance provided on such deposits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and marketable securities to the extent recorded on the consolidated balance sheets.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the Chief Executive Officer. We have one operating segment, specialty pharmaceuticals within the respiratory system.

Recent Accounting Pronouncements

There are no recent accounting pronouncements issued by the FASB, the American Institute of Certified Public Accountants, or the SEC that are believed by the Company's management to have a material effect, if any, on the Company's condensed consolidated financial statements.

3. Prepaid Expenses and Other Current Assets

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

	June 30, 2024	December 31, 2023
Prepaid contracted research and development costs	\$ 4,268	\$ 2,167
R&D tax credit receivable	790	814
Prepaid insurance	162	176
VAT receivable	226	191
Deferred financing costs	325	—
Deposits and other	407	280
Total prepaid expenses and other current assets	\$ 6,178	\$ 3,628

Prepaid Contracted Research and Development Costs

As of June 30, 2024, *Prepaid contracted research and development costs* are primarily comprised of contractual prepayments associated with the Company's clinical trial for molgramostim for the treatment of aPAP. This includes prepaid amounts paid under agreements with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and other outside service providers that provide services in connection with the Company's research and development activities.

R&D Tax Credit Receivable

The Company has recorded a Danish tax credit earned by its subsidiary, Savara ApS, as of June 30, 2024. Under Danish tax law, Denmark remits a research and development tax credit equal to 22% of qualified research and development expenditures, not to exceed established thresholds. During the year ended December 31, 2023, the Company generated a Danish tax credit of \$0.8 million, which is included in *Prepaid expenses and other current assets* and is expected to be received in the fourth quarter of 2024. During the six months ended June 30, 2024, the Company generated a Danish tax credit of \$0.8 million, which is recorded in *Other non-current assets* in the condensed consolidated balance sheet and is expected to be received in the fourth quarter of 2025.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of (in thousands):

	June 30, 2024	December 31, 2023
Accrued compensation	\$ 1,826	\$ 4,046
Accrued contracted research and development costs	4,543	2,166
Accrued general and administrative costs	1,379	738
Lease liability	152	143
Total accrued expenses and other current liabilities	\$ 7,900	\$ 7,093

Accrued Compensation

As of June 30, 2024, *Accrued compensation* includes amounts to be paid to employees for salary, bonuses, vacation and non-equity performance-based compensation. At the end of any period, the amounts accrued for such compensation may vary due to many factors including, but not limited to, timing of payments to employees and vacation usage.

Accrued Contracted Research and Development Costs

As of June 30, 2024, *Accrued contracted research and development costs* are primarily comprised of costs associated with molgramostim for the treatment of aPAP, including expenses resulting from obligations under agreements with CROs, CMOs, and other outside service providers that provide services in connection with the Company's research and development activities.

5. Short-term Investments

The Company's investment policy seeks to preserve capital and maintain sufficient liquidity to meet operational and other needs of the business. The following table summarizes, by major security type, the Company's investments (in thousands):

As of June 30, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	\$ 97,738	\$ 1	\$ (87)	\$ 97,652
Total short-term investments	\$ 97,738	\$ 1	\$ (87)	\$ 97,652

As of December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	\$ 135,541	\$ 194	\$ (1)	\$ 135,734
Total short-term investments	\$ 135,541	\$ 194	\$ (1)	\$ 135,734

The Company has classified its investments as available-for-sale securities. These securities are carried at estimated fair value with the aggregate unrealized gains and losses related to these investments reflected as a part of *Accumulated other comprehensive loss* in the condensed consolidated balance sheet. Classification as short-term or long-term is based upon whether the initial maturity of the debt securities is less than or greater than twelve months.

There were no significant realized gains or losses related to investments for the six months ended June 30, 2024 and 2023.

6. Long-term Debt

On April 21, 2022, the Company and its subsidiary, Aravas Inc. ("Aravas") entered into an Amended and Restated Loan and Security Agreement (the "Amended Loan Agreement"), as co-borrowers, and Silicon Valley Bank, a division of First Citizens BancShares, as lender (the "Lender") which provides for a \$26.5 million term loan facility.

Pursuant to the Amended Loan Agreement, the loan has an interest-only monthly payment through April 21, 2026 (the "Interest-Only Period") and thereafter equal monthly installments of principal plus interest over 12 months until April 21, 2027 (the "Maturity Date"). However, the Company may elect to extend the Interest-Only Period until the Maturity Date if it maintains cash and cash equivalents equal to at least 1.75 times the outstanding principal amount of the loan during the fifth year. If the Interest-Only Period is extended, all principal and unpaid interest is due and payable on the Maturity Date.

The loan bears interest at a floating rate equal to the greater of (i) 3% and (ii) the prime rate reported in The Wall Street Journal, minus a spread of 0.5%. The Company is obligated to pay customary closing fees and a final payment of 2.75% of the principal amount advanced under the facility. The Company may currently prepay the loan in whole or in part at any time without penalty or prepayment fee.

The Lender was granted a perfected first priority lien in all of the Company's assets with a negative pledge on intellectual property. The Amended Loan Agreement contains customary affirmative and negative covenants, including among others, covenants that limit the Company's and its subsidiaries' ability to dispose of assets, permit a change in control, merge or consolidate, make acquisitions, incur indebtedness, grant liens, make investments, make certain restricted payments, and enter into transactions with affiliates, in each case subject to certain exceptions.

Additionally, the Amended Loan Agreement contains an affirmative covenant providing that if the Company's balance of cash and cash equivalents falls below \$40.0 million, the Company is required to maintain cash and cash equivalents equal to at least (i) six months of operating expenses and (ii) 1.2 times the outstanding principal amount of the loan (or 1.75 in the final year of the loan if the Interest-Only Period is extended).

Approximately \$0.1 million of fees paid to the Lender were capitalized and will be amortized over the term of the Amended Loan Agreement. Expenses paid to third parties associated with the Amended Loan Agreement were immediately expensed and recorded in the *Interest income (expense)* line item in our consolidated statement of operations.

Summary of Carrying Value

The following table summarizes the components of the long-term debt carrying value, which approximates the fair value (in thousands):

Future minimum payments due during the year ended December 31,	June 30, 2024	December 31, 2023
2024	\$ —	\$ —
2025	—	—
2026	17,667	17,667
2027	9,562	9,562
Total future minimum payments	27,229	27,229
Unamortized end of term charge	(408)	(482)
Debt issuance costs	(309)	(366)
Debt discount related to warrants	(28)	(33)
Total debt	26,484	26,348
Current portion of long-term debt	—	—
Long-term debt	\$ 26,484	\$ 26,348

7. Fair Value Measurements

The Company measures and reports certain financial instruments at fair value on a recurring basis and evaluates its financial instruments subject to fair value measurements on a recurring and nonrecurring basis to determine the appropriate level in which to classify them in each reporting period.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

Certain assets and liabilities are measured at fair value on a nonrecurring basis. These assets and liabilities are not measured at fair value on an ongoing basis, but are subject to fair value adjustments annually or whenever events or circumstances indicate that the carrying value of those assets may not be recoverable. These assets and liabilities can include acquired in-process research and development ("IPR&D") and other long-lived assets that are written down to fair value if they are impaired.

During the six months ended June 30, 2024 and 2023, the Company experienced a decrease of approximately \$0.3 million and an increase of approximately \$0.1 million, respectively, in the carrying value of IPR&D due to foreign currency translation.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company determined that certain investments in debt securities classified as available-for-sale securities were Level 1 financial instruments.

Additional investments in corporate debt securities, commercial paper, and asset-backed securities are considered Level 2 financial instruments because the Company has access to quoted prices but does not have visibility to the volume and frequency of trading for all of these investments. For the Company's investments, a market approach is used for recurring fair value measurements and the valuation techniques use inputs that are observable, or can be corroborated by observable data, in an active marketplace.

The fair value of these instruments as of June 30, 2024 and December 31, 2023 was as follows (in thousands):

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
As of June 30, 2024				
Cash equivalents:				
U.S. Treasury money market funds	\$ 23,310	\$ —	\$ —	\$ 23,310
Short-term investments:				
U.S. government securities	97,652	—	—	97,652
As of December 31, 2023				
Cash equivalents:				
U.S. Treasury money market funds	\$ 17,270	\$ —	\$ —	\$ 17,270
Short-term investments:				
U.S. government securities	135,734	—	—	135,734

The Company did not transfer any assets measured at fair value on a recurring basis to or from Level 1, Level 2, and Level 3 during the six months ended June 30, 2024 and 2023.

8. Stockholders' Equity

Registered Direct Offering of Common Stock

On July 17, 2023, the Company sold (i) an aggregate of 21,000,000 shares of the Company's common stock (the "Common Stock") for \$3.00 per share which represented a 1% premium over the closing price on that date and (ii) pre-funded warrants to purchase an aggregate of 5,666,667 shares of Common Stock at an exercise price of \$0.001 per share (the "2023 Pre-Funded Warrants") for \$2.999 per warrant pursuant to a registered direct offering (the "July 2023 Offering").

The Company determined that the securities issued in the July 2023 Offering were free-standing and that the 2023 Pre-Funded Warrants meet the equity classification requirements pursuant to ASC 480, *Distinguishing Liability from Equity*, ASC 815, *Derivatives and Hedging* and Subtopic 815-40, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. The 2023 Pre-Funded Warrants were sold at the same price as the underlying common stock, less \$0.001 (which represents the exercise price of the warrants).

The July 2023 Offering resulted in net proceeds to the Company of approximately \$74.9 million, after deducting final underwriting discounts, commissions, and other estimated offering expenses, as follows (in thousands):

Financial instruments	Proceeds
Common stock	\$ 63,000
2023 Pre-funded warrants	16,994
Total	79,994
Offering expenses	\$ (5,120)
Net proceeds	\$ 74,874

The Company has used and intends to continue to use the net proceeds for working capital and general corporate purposes, which include, but are not limited to, the funding of clinical development of and pursuing regulatory approval for molgramostim, investing in our commercialization infrastructure, commercial launch preparation activities in the United States, initiating pre-commercial work in Europe, and administrative expenses.

Evercore Common Stock Sales Agreement

On July 6, 2021, the Company entered into a Common Stock Sales Agreement with Evercore Group L.L.C. ("Evercore"), as sales agent (the "Sales Agreement"), pursuant to which the Company may offer and sell, from time to time, through Evercore, shares of Savara's common stock, par value \$0.001 per share (the "Shares"), having an aggregate offering price of not more than \$60.0 million which has been increased to not more than \$100.0 million as of May 21, 2024. The Sales Agreement was effective on July 16, 2021, the date the 2021 Registration Statement was declared effective by the SEC. The Sales Agreement currently operates in accordance with Form S-3 (File No. 333-279274), which was previously filed with the SEC on May 9, 2024 and declared effective on May 21, 2024 (the "2024 Registration Agreement"). Prospectively, the Shares will be offered and sold pursuant to the 2024 Registration Statement. Subject to the terms and conditions of the Sales Agreement, Evercore will use commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions. The Company has provided Evercore with customary indemnification rights, and Evercore will be entitled to a commission at a fixed commission rate equal to 3% of the gross proceeds per Share sold. Sales of the Shares, if any, under the Sales Agreement may be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. The Company has no obligation to sell any of the Shares and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement.

During the six months ended June 30, 2024 and 2023, the Company did not sell any shares of common stock under the Sales Agreement.

Common Stock Reserved for Issuance

The Company's shares of common stock reserved for issuance as of the periods indicated were as follows:

	June 30, 2024	December 31, 2023
April 2017 Warrants	24,725	24,725
June 2017 Warrants	41,736	41,736
December 2018 Warrants	11,332	11,332
2017 Pre-funded Warrants	775,000	775,000
Pre-funded PIPE Warrants	5,780,537	5,780,537
2021 Pre-funded Warrants	32,175,172	32,175,172
2023 Pre-funded Warrants	5,666,667	5,666,667
Stock options outstanding	9,735,019	9,633,067
Issued and nonvested RSUs	3,560,125	3,488,250
Total shares reserved	57,770,313	57,596,486

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of June 30, 2024:

Expiration Date	Shares Underlying Outstanding Warrants	Exercise Price
October 2024	775,000	\$ 0.01
April 2027	24,725	\$ 2.87
June 2027	41,736	\$ 2.87
December 2028	11,332	\$ 2.87
None	43,622,376	\$ 0.001
	44,475,169	

Accumulated Other Comprehensive Income (Loss) Information

The components of accumulated other comprehensive income (loss) as of the dates indicated and the change during the period were (in thousands):

	Foreign Exchange Translation Adjustment	Unrealized Gain (Loss) on ST Investments	Total Accumulated Other Comprehensive Income (Loss)
Balance, December 31, 2022	\$ (594)	\$ (11)	\$ (605)
Change	\$ 133	\$ 201	\$ 334
Balance, December 31, 2023	\$ (461)	\$ 190	\$ (271)
Change	\$ (333)	\$ (276)	\$ (609)
Balance, June 30, 2024	\$ (794)	\$ (86)	\$ (880)

9. Commitments and Contingencies

Manufacturing and Other Commitments and Contingencies

The Company is subject to various royalties and manufacturing and development payments related to its product candidate, molgramostim. Under a manufacture and supply agreement with an active pharmaceutical ingredients ("API") manufacturer for molgramostim, as amended on December 7, 2022 and December 13, 2023, the Company must make certain payments to the API manufacturer upon achievement of the milestones outlined in the table set forth below. Additionally, upon first receipt of marketing approval by the Company from a regulatory authority in a country for a product containing the API for therapeutic use in humans and ending the earlier of (i) ten (10) years thereafter or (ii) the date a biosimilar of such product is first sold in such country, the Company shall pay the API manufacturer a royalty equal to low-single digits of the net sales in that country.

Additionally, the Company is subject to a purchase requirement under which for ten years following the date of receipt of approval by a regulatory authority of the first regulatory filing for the marketing and sale of the first molgramostim product in any country, each year, the Company will purchase from the API manufacturer the API required to produce a percentage of such molgramostim product it sells (the "Purchase Requirement"); provided, however, that the Purchase Requirement will no longer apply if (i) the price charged by the API manufacturer exceeds a certain price charged by an alternative supplier, (ii) there is a shortage of supply, or (iii) API manufacturer at any time fails to materially fulfill a purchase order of the Company.

The Company is also subject to certain contingent milestone payments, disclosed in the following table, payable to the manufacturer of the nebulizer used to administer molgramostim. In addition to these milestones, the Company will owe a royalty of three-and one-half percent (3.5%) to the manufacturer of the nebulizer based on net sales.

The following table summarizes manufacturing commitments and contingencies as of the period indicated (in thousands):

	June 30, 2024
Molgramostim manufacturer:	
Achievement of certain milestones related to validation of API and regulatory approval of molgramostim	\$ 1,300
Molgramostim nebulizer manufacturer:	
Achievement of various development activities and regulatory approval of nebulizer utilized to administer molgramostim	536
Total manufacturing and other commitments and contingencies	\$ 1,836

The milestone commitments disclosed above reflect the activities that have (i) not been met or incurred; (ii) not been remunerated; and (iii) not accrued, as the activities are not deemed probable or reasonably estimable, as of June 30, 2024.

Further, in February 2024, the Company entered into a master services agreement with an additional manufacturer to provide development and manufacturing services related to API for the Company's molgramostim product candidate in accordance with the terms of separate scope of work agreements to be entered into by the parties and to perform a manufacturing campaign for process performance qualification of the API of molgramostim. Under that master services agreement, work orders and subsequent change orders, the Company is currently obligated to pay the second source manufacturer, in total, estimated fees of \$20.0 million. These costs are subject to various cancellation fees ranging from ten percent (10%) to one hundred percent (100%) of the cost of the respective activity based upon the timing of the commencement date and status of the activity.

Contract Research

As part of its development of molgramostim for the treatment of aPAP, the Company entered into a Master Services Agreement ("MSA") with Parexel International (IRL) Limited ("Parexel") pursuant to which Parexel will provide contract research services related to clinical trials. Contemporaneously with entering the MSA, a work order was executed with Parexel, under which they will provide services related to the IMPALA-2 trial. Under that work order and subsequent change orders, the Company will pay Parexel service fees, pass-through expenses, and investigator fees estimated to be approximately \$42.5 million over the course of the IMPALA-2 clinical trial and trial close-out activities.

In the second quarter of 2024, the Company initiated an open-label, multicenter clinical trial of inhaled molgramostim in pediatric subjects with aPAP ("Pediatric Study") under a separate work order with Parexel. Pursuant to the Pediatric Study, Parexel has the opportunity to earn up to approximately \$3.6 million in various milestone payments primarily dependent upon patient enrollment, site management, project oversight and the compliance with defined study protocols.

Risk Management

The Company maintains various forms of insurance that the Company's management believes are adequate to reduce the exposure to certain risks associated with operating the Company's business to an acceptable level.

10. Stock-Based Compensation

Equity Incentive Plans

The Company's 2024 Omnibus Incentive Plan (the "2024 Plan") was adopted by the Company's board of directors in March 2024, was approved by the Company's stockholders on June 6, 2024, and became effective on June 7, 2024. The 2024 Plan was intended to replace the Company's Amended and Restated 2015 Omnibus Incentive Plan (the "2015 Plan"), and upon the effectiveness of the 2024 Plan, no further grants may be made under the 2015 Plan. All outstanding awards under the 2015 Plan will continue in accordance with the 2015 Plan and any award agreement executed in connection with such outstanding awards. The 2024 Plan provides for the grant of stock options (both incentive stock options and non-statutory stock options), stock appreciation rights, restricted stock, restricted stock units ("RSUs"), performance units, shares, and other stock-based awards. Stock-based awards are subject to terms and conditions established by the board of directors or the compensation committee of the board of directors. As of June 30, 2024, the number of shares of common stock available for grant under the 2024 Plan was 12,815,139 shares (which is comprised of 11,700,000 shares as approved by the Company's shareholders upon adoption of the 2024 Plan, plus 1,115,139 shares remaining available for issuance under the 2015 Plan as of the effectiveness of the 2024 Plan). As of June 30, 2024, no awards were granted under the 2024 Plan.

The Company's 2021 Inducement Equity Incentive Plan (the "Inducement Plan") was adopted by the Company's board of directors in May 2021 and subsequently amended to increase the shares available for grant. The Inducement Plan provides for the grant of non-statutory stock options, restricted stock, RSUs, stock appreciation rights, performance units, and performance shares. Each award under the Inducement Plan is intended to qualify as an employment inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4). As of June 30, 2024, the number of shares of common stock available for grant under the Inducement Plan was 486,217 shares.

The Savara Inc. Stock Option Plan (the "2008 Plan") was adopted in 2008, and the Company no longer issues awards under the 2008 Plan. As of June 30, 2024, the Company had options outstanding to purchase 144,606 shares of common stock under the 2008 Plan. The outstanding awards granted under the 2008 Plan are fully vested and generally have a maximum contractual term of ten years.

Stock-Based Awards Activity

The following table provides a summary of stock-based awards activity for the six months ended June 30, 2024:

Stock Options:

Outstanding at December 31, 2023	9,633,067
Granted	230,000
Exercised	(62,736)
Expired/cancelled/forfeited	(65,312)
Outstanding at June 30, 2024	9,735,019

The total compensation cost related to non-vested stock options not yet recognized as of June 30, 2024, was \$7.6 million, which will be recognized over a weighted-average period of approximately 3.0 years.

RSUs:

Outstanding at December 31, 2023	3,488,250
Granted	142,500
Vested	(3,125)
Forfeited	(67,500)
Outstanding at June 30, 2024	3,560,125

The total compensation cost related to unvested RSUs not yet recognized as of June 30, 2024, was \$7.6 million, which will be recognized over a weighted-average period of approximately 1.3 years.

Stock-Based Compensation

Stock-based compensation expense is included in the following line items in the accompanying statements of operations and comprehensive loss for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Research and development	\$ 600	\$ 280	\$ 1,903	\$ 534
General and administrative	1,596	678	2,550	1,288
Total stock-based compensation	\$ 2,196	\$ 958	\$ 4,453	\$ 1,822

11. Net Loss per Share

Basic and diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common stock and pre-funded warrants outstanding during the period without consideration of common stock equivalents. For periods in which the Company generated a net loss, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.

The following equity instruments were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	Six months ended June 30,	
	2024	2023
Awards under equity incentive plan	9,735,019	8,530,680
Non-vested restricted shares and restricted stock units	3,560,125	2,388,625
Warrants to purchase common stock(*)	77,793	77,793
Total	13,372,937	10,997,098

* Pre-funded warrants are excluded herein.

The following table calculates basic earnings per share of common stock and diluted earnings per share of common stock for the three and six months ended June 30, 2024 and 2023 (in thousands, except share and per share amounts):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Net loss	\$ (22,243)	\$ (11,443)	\$ (42,589)	\$ (22,000)
Net loss attributable to common stockholders	(22,243)	(11,443)	(42,589)	(22,000)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	(22,243)	(11,443)	(42,589)	(22,000)
Weighted-average common shares outstanding, basic and diluted	182,584,078	152,796,617	182,567,091	152,778,031
Basic and diluted EPS	\$ (0.12)	\$ (0.07)	\$ (0.23)	\$ (0.14)

12. Subsequent Events

July 2024 Offering

On July 1, 2024, the Company sold an aggregate of 26,246,720 shares of the Company's common stock, par value \$0.001 per share, pursuant to the July 2024 Offering at an offering price of \$3.81 per share. The July 2024 Offering resulted in gross proceeds of approximately \$100.0 million. The Company estimates approximately \$93.7 million of net proceeds from the July 2024 Offering after taking into consideration underwriter commissions, legal fees, and other customary closing costs.

The July 2024 Offering was made pursuant to the Company's 2024 Registration Statement. The Company intends to use the net proceeds for working capital and general corporate purposes, which include, but are not limited to, funding of clinical development of and the pursuit of regulatory approval for molgramostim, investing in our chemistry, manufacturing, and controls activities, developing commercialization infrastructure in the United States, initiating pre-commercial work in Europe, and general and administrative expenses.

The Company has evaluated subsequent events through the date these condensed consolidated financial statements were issued and determined there were no additional events that required disclosure or recognition in these condensed consolidated financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Statement Concerning Forward-Looking Statements

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements contained herein that involve risks and uncertainties, such as Savara's plans, objectives, expectations, intentions, and beliefs should be considered forward-looking statements. Savara's actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to the following: the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the risks associated with the process of conducting clinical trials and developing, obtaining regulatory approval for and commercializing drug candidates that are safe and effective for use as human therapeutics, the timing and ability to raise additional capital as needed to fund continued operations, natural disasters, pandemics, geopolitical events (including the war between Russia and Ukraine and the war in the Middle East), and those discussed in the section entitled "Risk Factors" in this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on March 7, 2024, all of which are difficult to predict.

Statements made herein are as of the date of the filing of this Quarterly Report with the SEC and should not be relied upon as of any subsequent date. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

The following discussion and analysis of the financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report and the consolidated financial statements and related notes in our Annual Report on Form 10-K for the year ended December 31, 2023.

Overview

Savara Inc. (together with its subsidiaries "Savara," the "Company," "we," "our" or "us") is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. Our sole program, molgramostim, is an inhaled biologic, specifically, inhaled granulocyte-macrophage colony-stimulating factor in Phase 3 development for aPAP. Savara, together with its wholly-owned subsidiaries, which include Aravas Inc. and Savara ApS, operate in one segment with its principal office in Langhorne, Pennsylvania, though a majority of our employees work remotely.

Since inception, we have devoted our efforts and resources to identifying and developing our product candidates, recruiting personnel, and raising capital. We have incurred operating losses and negative cash flow from operations and have no product revenue from inception to date. From inception to June 30, 2024, we have raised net cash proceeds of approximately \$476.7 million, primarily from underwritten offerings of our common stock, private placements of common stock, and debt financings.

We have never been profitable and have incurred operating losses every year since inception. Our net losses for the three months ended June 30, 2024 and 2023 were \$22.2 million and \$11.4 million, respectively, and the net loss for the year ended December 31, 2023 was \$54.7 million. As of June 30, 2024, we had an accumulated deficit of approximately \$436.0 million. Our operating losses primarily resulted from expenses attributed to our research and development programs and from general and administrative costs associated with our operations.

We have chosen to operate by outsourcing our manufacturing and most of our clinical operations. We expect to incur significant additional expenses and continue to incur operating losses for at least the next several years as we continue the clinical development of, and seek regulatory approval for, our primary product candidate. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to the timing of clinical development programs and efforts to achieve regulatory approval.

As of June 30, 2024, we had cash and cash equivalents of \$23.9 million and short-term investments of \$97.7 million. We will continue to require additional capital to continue our clinical development and potential commercialization activities. Although we have sufficient capital to fund many of our planned activities, we may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, our product candidate and begin to commercialize any approved product. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidate.

Recent Events

July 2024 Offering

On July 1, 2024, the Company sold an aggregate of 26,246,720 shares of the Company's common stock, par value \$0.001 per share, pursuant to a registered direct offering (the "July 2024 Offering") at an offering price of \$3.81 per share. The July 2024 Offering resulted in gross proceeds of approximately \$100.0 million. The Company estimates approximately \$93.7 million of net proceeds from the July 2024 Offering after taking into consideration underwriter commissions, legal fees, and other customary closing costs. The July 2024 Offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-279274), which was previously filed with the SEC on May 9, 2024 and declared effective on May 21, 2024 ("2024 Registration Statement").

Financial Operations Overview

Research and Development Expenses

The largest component of our operating expenses has historically been our investment in research and development activities. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- expenses incurred under agreements with contract research organizations ("CROs"), consultants, and clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of our clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies; and
- internal costs that are associated with activities performed by our research and development organization and generally benefit our molgramostim product candidate and program. Where appropriate, such internal costs consist primarily of:
 - personnel costs, which include salaries, benefits, and stock-based compensation expense;
 - facilities and other expenses, which include expenses for maintenance of facilities and depreciation expense; and
 - regulatory expenses and technology license fees related to development activities.

We expect research and development expenses will remain significant in the future as we advance our molgramostim product candidate through clinical trials and pursue regulatory approvals, which will require a significant increased investment in regulatory support and contract manufacturing activities, including investing in the development of a second source manufacturer and clinical supplies.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidate. The probability of success of our product candidate may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability, and commercial viability. As a result, we are unable to accurately determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of molgramostim.

General and Administrative Expenses

G&A expenses consist primarily of salaries, benefits, and related costs for personnel in executive, finance and accounting, legal, and investor relations; as well as professional and consulting fees for accounting, legal, investor relations, business development, human resources, and information technology services. Other G&A expenses include facility lease and insurance costs.

Other Income (Expense), Net

Other income (expense) includes amortization expense related to capitalized debt issuance costs and debt discount under our Amended Loan Agreement executed with Silicon Valley Bank during April 2022 (the "Amended Loan Agreement"). Refer to [Note 6. Long-term Debt](#) in the notes to the condensed consolidated financial statements included in this Quarterly Report. Interest expense is typically reported net of interest income which includes interest earned on our cash, cash equivalent, and short-term investment balances. Other income (expense) also includes net unrealized and realized gains and losses from foreign currency transactions, foreign exchange derivatives not designated as hedging, refundable tax credits generated by some of our foreign subsidiaries, and securities subject to fair value accounting as well as any other non-operating gains and losses.

Critical Accounting Policies and Estimates

There have not been any material changes during the six months ended June 30, 2024, to the methodology applied by management for critical accounting policies previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023. Please read *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates* in our Annual Report on Form 10-K for the year ended December 31, 2023, for further description of our critical accounting policies.

Results of Operations – Comparison of Three Months Ended June 30, 2024 and 2023

	For the Three Months Ended June 30,		Dollar
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	\$ 17,617	\$ 8,911	\$ 8,706
General and administrative	5,540	3,302	2,238
Depreciation and amortization	33	8	25
Total operating expenses	23,190	12,221	10,969
Loss from operations	(23,190)	(12,221)	(10,969)
Other income, net	947	778	169
Net loss	\$ (22,243)	\$ (11,443)	\$ (10,800)

Research and Development

Research and development expenses increased by \$8.7 million, or 97.7%, to \$17.6 million for the three months ended June 30, 2024 from \$8.9 million for the three months ended June 30, 2023. This increase is primarily due to the performance of tasks related to our molgramostim program, which includes approximately \$4.8 million of costs related to our chemistry, manufacturing, and controls activities, primarily driven by initiatives to establish our second drug substance manufacturer, \$1.2 million of costs related to our IMPALA-2 trial and Pediatric Study, including CRO-related activities, \$1.3 million of costs related to regulatory affairs and quality assurance, and \$1.4 million due to an increase in personnel including related costs and other departmental overhead.

General and Administrative

General and administrative expenses increased by \$2.2 million, or 67.8%, to \$5.5 million for the three months ended June 30, 2024 from \$3.3 million for the three months ended June 30, 2023. The increase is due to personnel and related costs of \$1.1 million, certain commercial activities of \$0.8 million, and other overhead of \$0.3 million primarily driven by consultant costs.

Other Income, Net

There was no significant changes in Other income, net for the three months ended June 30, 2024 and the three months ended June 30, 2023.

Results of Operations – Comparison of Six Months Ended June 30, 2024 and 2023

	Six months ended June 30,		Dollar
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	\$ 34,424	\$ 17,649	\$ 16,775
General and administrative	11,176	6,668	4,508
Depreciation and amortization	65	16	49
Total operating expenses	45,665	24,333	21,332
Loss from operations	(45,665)	(24,333)	(21,332)
Other income, net	3,076	2,333	743
Net loss	\$ (42,589)	\$ (22,000)	\$ (20,589)

Research and Development

Research and development expenses increased by \$16.8 million, or 95.0%, to \$34.4 million for the six months ended June 30, 2024 from \$17.6 million for the six months ended June 30, 2023. This increase is primarily due to the performance of tasks related to our molgramostim program, which includes approximately \$9.2 million of costs related to our chemistry, manufacturing, and controls activities, primarily driven by initiatives to establish our second drug substance manufacturer, \$2.1 million of costs related to our IMPALA-2 trial and Pediatric Study, including CRO-related activities, \$1.9 million of costs related to regulatory affairs and quality assurance, and \$3.6 million due to an increase in personnel including related costs and other departmental overhead.

General and Administrative

General and administrative expenses increased by \$4.5 million, or 67.6%, to \$11.2 million for the six months ended June 30, 2024 from \$6.7 million for the six months ended June 30, 2023. The increase is due to personnel and related costs of \$1.7 million, certain commercial activities of \$1.9 million, and other overhead of \$0.9 million primarily driven by patient advocacy activities and consultant costs.

Other Income, Net

Other income, net increased by approximately \$0.7 million to \$3.1 million for the six months ended June 30, 2024 from \$2.3 million for the six months ended June 30, 2023. The increase is primarily related to the increase in *Interest income* during the six months ended June 30, 2024 as a result of both an increase in our short-term investments following various equity financings and an increase in market interest rates.

Liquidity and Capital Resources

As of June 30, 2024, we had \$23.9 million of cash and cash equivalents, \$97.7 million in short-term investments, and an accumulated deficit of approximately \$436.0 million. As discussed in [Note 6. Long-term Debt](#) in the notes to the condensed consolidated financial statements included in this Quarterly Report, during April 2022, we entered into an Amended Loan Agreement with Silicon Valley Bank that provided for a \$26.5 million term loan facility, the proceeds of which were used to refinance all outstanding obligations under our pre-existing loan agreement with Silicon Valley Bank.

We have used and intend to use our liquidity and capital for working capital and general corporate purposes, which include, but are not limited to, the funding of clinical development of and pursuing regulatory approval for our product candidate and general and administrative expenses. As we continue to progress on the IMPALA-2 trial, pursue regulatory approval, and invest in pre-commercial activities, we will continue to monitor our liquidity and capital requirements.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six months ended June 30,	
	2024	2023
	(in thousands)	
Cash used in operating activities	\$ (43,139)	\$ (22,298)
Cash provided by (used in) investing activities	40,331	(7,101)
Cash provided by financing activities	104	130
Effect of exchange rate changes on cash and cash equivalents	(17)	(86)
Net change in cash and cash equivalents	\$ (2,721)	\$ (29,355)

Cash flows from operating activities

Cash used in operating activities for the six months ended June 30, 2024 was \$43.1 million, consisting of a net loss of \$42.6 million and net \$2.9 million in changes due to operating assets and liabilities. This was partially offset by approximately \$2.4 million of net noncash charges (comprised of depreciation and amortization including right-of-use assets, accretion on premium to short-term investments, amortization of debt issuance costs, foreign currency, and stock-based compensation).

Cash flows from investing activities

Cash provided by investing activities of \$40.3 million for the six months ended June 30, 2024 was primarily associated with proceeds from the maturities of short-term investments partially offset by cash used for purchases of short-term investments.

Cash flows from financing activities

Cash provided by financing activities was minimal for the six months ended June 30, 2024.

Future Funding Requirements

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize our product candidate. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture, and clinical trials of, and seeking regulatory approval for, our product candidate. In addition, subject to obtaining regulatory approval of our product candidate, we anticipate we may need additional funding in connection with our continuing operations.

As of June 30, 2024, we had cash, cash equivalents, and short-term investments of approximately \$121.5 million. Although we have sufficient capital to fund our planned activities, including those discussed in [Note 9. Commitments – Manufacturing and Other Commitments and Contingencies](#), in the notes to the condensed consolidated financial statements included in this Quarterly Report, we may need to continue to raise additional capital to further fund the development of, and seek regulatory approvals for, our product candidate and to begin commercialization of any approved product. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidate.

On July 1, 2024, the Company sold an aggregate of 26,246,720 shares of the Company's common stock, par value \$0.001 per share, pursuant to the July 2024 Offering at an offering price of \$3.81 per share. The July 2024 Offering resulted in gross proceeds of approximately \$100.0 million. The Company estimates approximately \$93.7 million of net proceeds from the July 2024 Offering after taking into consideration underwriter commissions, legal fees, and other customary closing costs. The July 2024 Offering was made pursuant to the Company's 2024 Registration Statement.

Although we believe we are well capitalized based on our current operations, until we can generate a sufficient amount of product revenue to finance our cash requirements, we may finance our future cash needs primarily through the issuance of additional equity securities and potentially through borrowings, grants, and strategic alliances with partner companies. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts or grant rights to develop and market our product candidate to third parties that we would otherwise prefer to develop and market ourselves.

Recent Accounting Pronouncements

See [Note 2. Summary of Significant Accounting Policies – Recent Accounting Pronouncements](#), of the condensed consolidated financial statements in this Quarterly Report for a discussion of recent accounting pronouncements and their effect, if any, on us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We have market risk exposure related to our cash, cash equivalents, and short-term investment securities. Such interest-earning instruments carry a degree of interest rate risk; however, we have not been exposed, nor do we anticipate being exposed, to material risks due to changes in interest rates. A hypothetical 1% change in interest rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements. Additionally, our investment securities are fixed income instruments denominated and payable in U.S. dollars and have short-term maturities, typically less than twelve months, and typically carry credit ratings of "A" at a minimum by two of three Nationally Recognized Statistical Rating Organizations, specifically Moody's, Standard & Poor's, or Fitch. As such, we do not believe that our cash, cash equivalents, and short-term investment securities have significant risk of default or illiquidity.

We also have interest rate exposure related to our long-term debt. Refer to [Note 6. Long Term Debt](#) of the unaudited condensed consolidated financial statements in this quarterly report on Form 10-Q for additional discussion. The Amended Loan Agreement with Silicon Valley Bank bears interest equal to the greater of (i) 3% and (ii) the prime rate reported in The Wall Street Journal, minus a spread of 0.5%, which was 8.0% on June 30, 2024. Changes in the prime rate would have impacted our interest expense associated with our secured term loan. If a 10% change in interest rates from the interest rates on June 30, 2024, were to have occurred, this change would not have had a material effect on our interest expense with respect to outstanding borrowed amounts.

We have ongoing operations in Europe and pay those vendors in local currency, including Euros or Danish Krone. At times, we seek to limit the impact of foreign currency fluctuations through the use of derivative instruments and short-term foreign currency forward exchange contracts not designated as hedging instruments. We did not recognize any significant exchange rate losses during the six months ended June 30, 2024 and 2023. A 10% change in the Euro-to-dollar or Krone-to-dollar exchange rate on June 30, 2024, would not have had a material effect on our results of operations or financial condition.

Additionally, inflation generally affects us by increasing our cost of labor, supplies and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management has evaluated, under the supervision and with the participation of our Chief Executive Officer and Chief Financial and Administrative Officer, the effectiveness of our disclosure controls and procedures as of June 30, 2024, pursuant to and as required by Rule 13a-15(b) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial and Administrative Officer have concluded that, as of June 30, 2024, our disclosure controls and procedures, as defined by Rule 13a-15(e) under the Exchange Act, were effective and designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act (i) is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (ii) information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial and Administrative Officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial and Administrative Officer, we assessed the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). As a result of that assessment, management concluded that our internal control over financial reporting was effective as of June 30, 2024 based on criteria in *Internal Control – Integrated Framework* (2013) issued by the COSO.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the six months ended June 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors. We are not currently a party to any material pending litigation or other material legal proceeding.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report, you should carefully consider the risk factors and other cautionary statements described under the heading “Item 1A. Risk Factors” included in the Annual Report on Form 10-K for the year ended December 31, 2023, and the risk factors and other cautionary statements contained in our other filings with the SEC, which could materially affect our business, financial condition or future results. 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, or future results. There have been no material changes in our risk factors from those described in the Annual Report on Form 10-K for the year ended December 31, 2023, or our other SEC filings.

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.

Rule 10b5-1 Trading Plans

During the quarter ended June 30, 2024, no officer or director of the Company adopted or terminated any contract, instruction, or written plan for the purchase or sale of securities of the Company’s common stock that is intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement as defined in 17 CFR § 229.408(c).

Item 6. Exhibits.

An Exhibit Index has been attached as part of this report and is incorporated by reference.

Exhibit Index

Exhibit Number	Description
3.1	<u>Savara Inc. Certificate of Amendment to Amended and Restated Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 7, 2024).</u>
3.2	<u>Amended and Restated Bylaws of Savara Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 30, 2023).</u>
10.1	<u>Savara Inc. 2024 Omnibus Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A (Amendment No. 1) filed on June 10, 2024).</u>
31.1	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Savara Inc.

Date: August 12, 2024

By: /s/ Matthew Pauls

Matthew Pauls
Chief Executive Officer and Chair of the Board of Directors
(Principal Executive Officer)

Date: August 12, 2024

By: /s/ David Lowrance

David Lowrance
Chief Financial and Administrative Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Matthew Pauls, certify that:

1. I have reviewed this Form 10-Q of Savara 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(s) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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(s) 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.

Date: August 12, 2024

/s/ Matthew Pauls

Matthew Pauls

Chief Executive Officer and Chair of the Board of Directors
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David Lowrance, certify that:

1. I have reviewed this Form 10-Q of Savara 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(s) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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(s) 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.

Date: August 12, 2024

/s/ David Lowrance

David Lowrance
Chief Financial and Administrative Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER 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 Quarterly Report of Savara Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew Pauls, principal executive officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 12, 2024

/s/ Matthew Pauls

Matthew Pauls

Chief Executive Officer and Chair of the Board of Directors
(Principal Executive Officer)

In connection with the Quarterly Report of Savara Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Lowrance, principal financial officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 12, 2024

/s/ David Lowrance

David Lowrance

Chief Financial and Administrative Officer
(Principal Financial and Accounting Officer)
