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 March 31, 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

Image not found or type unknown
img199011388_0.jpg

Savara Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1717 Langhorne Newtown Road, Suite 300 Langhorne, Pennsylvania	**19047**
(Address of principal executive offices)	**(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	?	Accelerated filer	?
Non-accelerated filer	?	Smaller reporting company	?
		Emerging growth company	?

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 9, 2024, the registrant had 138,188,891 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

		Page
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	21
Item 4.	Controls and Procedures	21
PART II.	OTHER INFORMATION	22
Item 1.	Legal Proceedings	22
Item 1A.	Risk Factors	22
Item 2.	Unregistered Shares of Equity Securities and Use of Proceeds	22
Item 3.	Defaults Upon Senior Securities	22
Item 4.	Mine Safety Disclosures	22
Item 5.	Other Information	22
Item 6.	Exhibits	22
Exhibit Index		23
Signatures		24

PART I – FINANCIAL INFORMATION

Item I. Financial Information

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

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 16,785	$ 26,585
Short-term investments	126,258	135,734
Prepaid expenses and other current assets	3,144	3,628
Total current assets	146,187	165,947
Property and equipment, net	248	270
In-process R&D	10,712	10,960
Other non-current assets	1,148	387
Total assets	$ 158,295	$ 177,564
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,853	$ 3,504
Accrued expenses and other current liabilities	6,957	7,093
Total current liabilities	9,810	10,597
Long-term liabilities:		
Long-term debt	26,416	26,348
Other long-term liabilities	208	247
Total liabilities	36,434	37,192
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value, 300,000,000 authorized as of March 31, 2024 and December 31, 2023; 138,176,641 and 138,143,545 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	140	140
Additional paid-in capital	536,178	533,872
Accumulated other comprehensive loss	(742)	(271)
Accumulated deficit	(413,715)	(393,369)
Total stockholders' equity	121,861	140,372
Total liabilities and stockholders' equity	$ 158,295	$ 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 March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 16,807	$ 8,738
General and administrative	5,636	3,366
Depreciation and amortization	32	8
Total operating expenses	22,475	12,112
Loss from operations	(22,475)	(12,112)
Other income (expense)		
Interest income	1,353	765
Foreign currency exchange gain (loss)	(21)	29
Tax credit income	797	761
Total other income, net	2,129	1,555
Net loss	$ (20,346)	$ (10,557)
Net loss per share:		
Basic and diluted	$ (0.11)	$ (0.07)
Weighted-average common shares outstanding:		
Basic and diluted	182,550,109	152,781,580
Other comprehensive income (loss):		
Gain (loss) on foreign currency translation	(220)	130
Unrealized gain (loss) on short-term investments	(251)	14
Total comprehensive loss	$ (20,817)	$ (10,413)

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 March 31, 2024 and 2023
(In thousands, except share amounts)
(Unaudited)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
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**

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 March 31, 2024 and 2023
(In thousands, except share amounts)
(Unaudited)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
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**

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 three months ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (20,346)	$ (10,557)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	8
Amortization of right-of-use assets	35	15
Foreign currency gain (loss)	21	(29)
Amortization of debt issuance costs	68	68
Accretion on premium to short-term investments	(1,370)	(924)
Stock-based compensation	2,257	864
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	243	261
Non-current assets	(814)	(756)
Accounts payable and accrued expenses and other current liabilities	(770)	(976)
Net cash used in operating activities	(20,644)	(12,026)
Cash flows from investing activities:		
Purchase of property and equipment	(10)	(4)
Purchase of available-for-sale securities, net	(30,697)	(30,091)
Maturity of available-for-sale securities	41,500	24,000
Net cash provided by (used in) investing activities	10,793	(6,095)
Cash flows from financing activities:		
Proceeds from exercise of stock options, net	51	27
Repurchase of shares for minimum tax withholdings	(2)	(1)
Net cash provided by financing activities	49	26
Effect of exchange rate changes on cash and cash equivalents	2	(21)
Decrease in cash and cash equivalents	(9,800)	(18,116)
Cash and cash equivalents beginning of period	26,585	52,100
Cash and cash equivalents end of period	$ 16,785	$ 33,984
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 536	$ 464

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 March 31, 2024, the Company had an accumulated deficit of approximately $413.7 million. The Company used cash in operating activities of approximately $20.6 million during the three months ended March 31, 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 clinical trial for the Company's product candidate fails or produces unsuccessful results and the 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 $16.8 million and short-term investments of $126.3 million as of March 31, 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. 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):

	March 31, 2024	December 31, 2023
Prepaid contracted research and development costs	$ 1,566	$ 2,167
R&D tax credit receivable	796	814
Prepaid insurance	133	176
VAT receivable	146	191
Deposits and other	503	280
Total prepaid expenses and other current assets	**$ 3,144**	**$ 3,628**

Prepaid Contracted Research and Development Costs

As of March 31, 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 March 31, 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 three months ended March 31, 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):

	March 31, 2024	December 31, 2023
Accrued compensation	$ 757	$ 4,046
Accrued contracted research and development costs	4,355	2,166
Accrued general and administrative costs	1,698	738
Lease liability	147	143
Total accrued expenses and other current liabilities	**$ 6,957**	**$ 7,093**

Accrued Compensation

As of March 31, 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 March 31, 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 March 31, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments				
U.S. government securities	$ 126,319	$ 22	$ (83)	$ 126,258
Total short-term investments	**$ 126,319**	**$ 22**	**$ (83)**	**$ 126,258**

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 three months ended March 31, 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, 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 prepay the loan in whole or in part at any time, subject to a prepayment fee of 1.0% if prepaid between the first and second anniversaries of the closing date. Following the second anniversary, there is no 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,	March 31, 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	(445)	(482)
Debt issuance costs	(338)	(366)
Debt discount related to warrants	(30)	(33)
Total debt	26,416	26,348
Current portion of long-term debt	—	—
Long-term debt	$ 26,416	$ 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 three months ended March 31, 2024 and 2023, the Company experienced a decrease of approximately $0.2 million and an increase of approximately $0.2 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 March 31, 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 March 31, 2024				
Cash equivalents:				
U.S. Treasury money market funds	$ 16,027	$ —	$ —	$ 16,027
Short-term investments:				
U.S. government securities	126,258	—	—	126,258
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 three months ended March 31, 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 Common Stock and 2023 Pre-Funded Warrants were offered by the Company pursuant to its existing shelf registration statement (File No. 333-257709) filed with the SEC on July 6, 2021 and declared effective on July 16, 2021.

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 intends 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 and European Union, 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. The Sales Agreement was effective on July 16, 2021, the date the Registration Statement was declared effective by the SEC. The Shares will be offered and sold pursuant to the 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 three months ended March 31, 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:

	March 31, 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	9,794,317	9,633,067
Issued and nonvested RSUs	3,626,687	3,488,250
Total shares reserved	**57,896,173**	**57,596,486**

Warrants

The following table summarizes the outstanding warrants for the Company's common stock as of March 31, 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	$ (220)	$ (251)	$ (471)

Balance, March 31, 2024	$ (681)	$ (61)	$ (742)

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 the 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.

Similarly, the Company may become subject to additional milestone payments for the achievement of certain manufacturing protocols of molgramostim pursuant to a services agreement entered into on December 21, 2022 with a second source product manufacturer, as well as, an integrated contract research and Contract development and manufacturing organization, pursuant to a service agreement, serving as an additional source of manufacturing of molgramostim drug substances. As of March 31, 2024, the Company had no significant obligations for any such milestone payments to either of these additional source product manufacturers.

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):

	March 31, 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	540
Total manufacturing and other commitments and contingencies	**$ 1,840**

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 March 31, 2024.

Further, in February 2024, the Company entered into a master services agreement with an additional second source 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 $17.2 million of which approximately $1.4 million has been paid and/or accrued through March 31, 2024. 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 $41.5 million over the course of the IMPALA-2 clinical trial.

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

2008 Stock Option Plan

The Company adopted the Savara Inc. Stock Option Plan (the "2008 Plan"), pursuant to which the Company reserved shares for issuance to employees, directors, and consultants. The 2008 Plan includes (i) the option grant program providing for both incentive and non-qualified stock options, as defined by the Internal Revenue Code, and (ii) the stock issuance program providing for the issuance of awards that are valued based upon common stock, including restricted stock, dividend equivalents, stock appreciation rights, phantom stock, and performance units. The 2008 Plan also allows eligible persons to purchase shares of common stock at an amount determined by the plan administrator. Upon a participant's termination, the Company retains the right to repurchase nonvested shares issued in conjunction with the stock issuance program at the fair market value per share as of the date of termination.

The Company had previously issued incentive and non-qualified options and restricted stock to employees and non-employees under the 2008 Plan. The terms of the stock options, including the exercise price per share and vesting provisions, were determined by the board of directors. Stock options were granted at exercise prices not less than the estimated fair market value of the Company's common stock at the date of grant based upon objective and subjective factors including: third-party valuations, preferred stock transactions with third parties, current operating and financial performance, management estimates, and future expectations.

The Company no longer issues stock-based awards under the 2008 Plan.

Amended and Restated 2015 Omnibus Incentive Option Plan

The Company operates the Amended and Restated 2015 Omnibus Incentive Plan, as amended and restated with approval by the Company's stockholders in June 2018 and amended with approval by our stockholders in May 2020, June 2022 and June 2023 (the "2015 Plan"). The 2015 Plan provides for the grant of incentive and non-statutory stock options, as well as share appreciation rights, restricted shares, restricted stock units ("RSUs"), performance units, shares, and other stock-based awards. Share-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 March 31, 2024, the number of shares of common stock available for grant under the 2015 Plan was 1,007,502 shares.

Under both the 2008 Plan and 2015 Plan, stock options typically vest quarterly over four years and expire ten years from the grant date and RSUs typically cliff vest after two years.

2021 Inducement Equity Incentive Plan

The Company adopted the 2021 Inducement Equity Incentive Plan in May 2021 and amended it in September 2021, September 2022, December 2022, March 2023, June 2023 and February 2024 (as amended, the "Inducement Plan"). 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 March 31, 2024, the number of shares of common stock available for grant under the Inducement Plan was 475,592 shares.

Under the Inducement Plan, stock options typically vest quarterly over four years and expire ten years from the grant date and RSUs typically cliff vest after two years.

Stock-Based Awards Activity

The following table provides a summary of stock-based awards activity for the three months ended March 31, 2024:

Stock Options:

Outstanding at December 31, 2023	**9,633,067**
Granted	195,000
Exercised	(33,750)
Expired/cancelled/forfeited	—
Outstanding at March 31, 2024	**9,794,317**

The total compensation cost related to non-vested stock options not yet recognized as of March 31, 2024, was $8.3 million, which will be recognized over a weighted-average period of approximately 3.2 years**.**

RSUs:

Outstanding at December 31, 2023	**3,488,250**
Granted	140,000
Vested	(1,563)
Forfeited	—
Outstanding at March 31, 2024	**3,626,687**

The total compensation cost related to unvested RSUs not yet recognized as of March 31, 2024, was $9.3 million, which will be recognized over a weighted-average period of approximately 1.5 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 months ended March 31, 2024 and 2023 (in thousands):

	Three months ended March 31,	
	2024	**2023**
Research and development	$ 1,303	$ 255
General and administrative	954	609
Total stock-based compensation	**$ 2,257**	**$ 864**

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:

	Three months ended March 31,	
	2024	**2023**
Awards under equity incentive plan	9,794,317	8,439,119
Non-vested restricted shares and restricted stock units	3,626,687	2,140,437
Warrants to purchase common stock(*)	77,793	77,793
Total	**13,498,797**	**10,657,349**

** 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 months ended March 31, 2024 and 2023 (in thousands, except share and per share amounts):

	Three months ended March 31,	
	2024	2023
Net loss	$ (20,346)	$ (10,557)
Net loss attributable to common stockholders	(20,346)	(10,557)
Undistributed earnings and net loss attributable to common stockholders, basic and diluted	(20,346)	(10,557)
Weighted-average common shares outstanding, basic and diluted	182,550,109	152,781,580
Basic and diluted EPS	**$ (0.11)**	**$ (0.07)**

12. Subsequent Events

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 as of March 31, 2024, 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 March 31, 2024, we have raised net cash proceeds of approximately $476.7 million, primarily from public offerings of our common stock, private placements of convertible preferred 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 March 31, 2024 and 2023 were $20.3 million and $10.6 million, respectively, and the net loss for the year ended December 31, 2023 was $54.7 million. As of March 31, 2024, we had an accumulated deficit of approximately $413.7 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 March 31, 2024, we had cash and cash equivalents of $16.8 million and short-term investments of $126.3 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.

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 three months ended March 31, 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 March 31, 2024 and 2023

	For the Three Months Ended March 31,		Dollar
	2024	2023	Change
		(in thousands)	
Operating expenses:			
Research and development	$ 16,807	$ 8,738	$ 8,069
General and administrative	5,636	3,366	2,270
Depreciation and amortization	32	8	24
Total operating expenses	22,475	12,112	10,363
Loss from operations	(22,475)	(12,112)	(10,363)
Other income, net	2,129	1,555	574
Net loss	**$ (20,346)**	**$ (10,557)**	**$ (9,789)**

Research and Development

Research and development expenses increased by $8.1 million, or 92.3%, to $16.8 million for the three months ended March 31, 2024 from $8.7 million for the three months ended March 31, 2023. This increase is primarily due to the performance of tasks related to our molgramostim program, which includes approximately $4.3 million of costs related to our chemistry, manufacturing, and controls activities, primarily driven by initiatives at our second drug substance manufacturers, $1.0 million of costs related to our IMPALA-2 trial, including CRO-related activities, $0.6 million of costs related to regulatory affairs and quality assurance, and $2.2 million due to an increase in personnel and related costs.

General and Administrative

General and administrative expenses increased by $2.3 million, or 67.4%, to $5.6 million for the three months ended March 31, 2024 from $3.4 million for the three months ended March 31, 2023. The increase is due to personnel and related costs of $0.6 million, certain commercial activities of $1.1 million, and other overhead of $0.6 million primarily driven by patient advocacy activities.

Other Income, Net

Other income, net increased by $0.6 million to $2.1 million for the three months ended March 31, 2024 from $1.6 million for the three months ended March 31, 2023. The increase is primarily related to the increase in Interest income during the three months ended March 31, 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 March 31, 2024, we had $16.8 million of cash and cash equivalents, $126.3 million in short-term investments, and an accumulated deficit of approximately $413.7 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, we will continue to monitor our liquidity and capital requirements.

Cash Flows

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

	Three months ended March 31,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (20,644)	$ (12,026)
Cash provided by (used in) investing activities	10,793	(6,095)
Cash provided by financing activities	49	26

Effect of exchange rate changes on cash and cash equivalents	2	(21)
Net change in cash and cash equivalents	**$ (9,800)**	**$ (18,116)**

Cash flows from operating activities

Cash used in operating activities for the three months ended March 31, 2024 was $20.6 million, consisting of a net loss of $20.3 million and net $1.3 million in changes due to operating assets and liabilities. This was partially offset by approximately $1.0 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 $10.8 million for the three months ended March 31, 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 three months ended March 31, 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 March 31, 2024, we had cash, cash equivalents, and short-term investments of approximately $143.0 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.

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 March 31, 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 March 31, 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 three months ended March 31, 2024 and 2023. A 10% change in the Euro-to-dollar or Krone-to-dollar exchange rate on March 31, 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 Administration Officer, the effectiveness of our disclosure controls and procedures as of March 31, 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 Officer have concluded that, as of March 31, 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 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 Administration 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 March 31, 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 three months ended March 31, 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 March 31, 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	Composite Amended and Restated Certificate of Incorporation, as amended, of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-3 filed on July 6, 2021).
3.2	Amended and Restated Bylaws of Savara, Inc, dated March 28, 2023 (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 30, 2023).
10.1+	Master Services Agreement (the "Agreement"), dated February 13, 2024, by and between Fujifilm Diosynth Biotechnologies UK Limited, Fujifilm Diosynth Biotechnologies Texas, LLC, and Fujifilm Diosynth Biotechnologies U.S.A., Inc. and Savara Inc.
10.2	Savara Inc. 2021 Inducement Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on March 7, 2024).
31.1	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.
31.2	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.
32.1	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.
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)

\+ Indicates portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K.

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: May 9, 2024

By: /s/ Matthew Pauls

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

Date: May 9, 2024

By: /s/ David Lowrance

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