

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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: 001-36694

Protara Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

20-4580525

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

345 Park Avenue South
3rd Floor
New York, NY
(Address of principal executive offices)

10010
(Zip Code)

(646) 844-0337
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	TARA	The Nasdaq Capital 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 April 30, 2024 there were 20,589,976 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

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CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify these forward-looking statements by terminology such as “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seek,” “approximately,” “predict,” “intend,” “plans,” “estimates,” “anticipates” or the negative version of these terms or other comparable terminology. These forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements.

These forward-looking statements include, but are not limited to, statements about:

- estimates regarding our financial performance, including future revenue, expenses and capital requirements;
- our expected cash position and ability to obtain financing in the future on satisfactory terms or at all;
- expectations regarding our plans to research, develop and commercialize our current and future product candidates, including TARA-002, and Intravenous, or IV, Choline Chloride;
- expectations regarding the safety and efficacy of our product candidates;
- expectations regarding the timing, costs and outcomes of our planned clinical trials;
- expectations regarding potential market size;
- expectations regarding the timing of the availability of data from our clinical trials;
- expectations regarding the clinical utility, potential benefits and market acceptance of our product candidates;
- expectations regarding our commercialization, marketing and manufacturing capabilities and strategy;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- expectations regarding our ability to identify additional products or product candidates with significant commercial potential;

- developments and projections relating to our competitors and industry;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to remain listed on the Nasdaq Capital Market, or Nasdaq;
- the impact of government laws and regulations;
- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to prevent system failures, data breaches or violations of data protection laws;
- the timing or likelihood of regulatory filings and approvals;
- our ability to protect our intellectual property position; and
- the impact of general U.S., foreign and global economic, industry, market, regulatory, political or public health conditions.

All forward-looking statements in this Quarterly Report on Form 10-Q involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, the risk factors set forth below in Part II, Item 1A, *Risk Factors*, and elsewhere in this Quarterly Report on Form 10-Q. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain medical conditions, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

PROTARA THERAPEUTICS, INC. AND SUBSIDIARIES
Unaudited Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	As of	
	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 52,231	\$ 39,586
Marketable debt securities	2,992	25,994
Prepaid expenses and other current assets	2,690	3,125
Total current assets	57,913	68,705
Restricted cash, non-current	745	745
Property and equipment, net	1,213	1,296
Operating lease right-of-use asset	5,018	5,264
Other assets	3,245	2,944
Total assets	\$ 68,134	\$ 78,954
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 972	\$ 2,434
Accrued expenses and other current liabilities	3,529	2,732
Operating lease liability	1,000	983
Total current liabilities	5,501	6,149
Operating lease liability, non-current	4,227	4,484
Total liabilities	9,728	10,633
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, \$0.001 par value, authorized 10,000,000 shares: Series 1 Convertible Preferred Stock, 8,028 shares authorized at March 31, 2024 and December 31, 2023, 7,991 shares issued and outstanding as of March 31, 2024 and December 31, 2023.	-	-
Common stock, \$0.001 par value, authorized 100,000,000 shares: Common stock, 11,433,837 and 11,364,903 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively.	11	11
Additional paid-in capital	269,875	268,725
Accumulated deficit	(211,479)	(200,384)
Accumulated other comprehensive income (loss)	(1)	(31)
Total stockholders' equity	58,406	68,321
Total liabilities and stockholders' equity	\$ 68,134	\$ 78,954

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

PROTARA THERAPEUTICS, INC. AND SUBSIDIARIES
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	For the Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 7,748	\$ 5,143
General and administrative	4,103	4,589
Total operating expenses	<u>11,851</u>	<u>9,732</u>
Loss from operations	<u>(11,851)</u>	<u>(9,732)</u>
Other income (expense), net:		
Interest and investment income	756	687
Other income (expense), net	<u>756</u>	<u>687</u>
Net loss	<u>\$ (11,095)</u>	<u>\$ (9,045)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.97)</u>	<u>\$ (0.80)</u>
Weighted-average shares outstanding, basic and diluted	<u>11,420,948</u>	<u>11,303,869</u>
Other comprehensive income (loss):		
Net unrealized gain (loss) on marketable debt securities	30	219
Other comprehensive income (loss)	<u>30</u>	<u>219</u>
Comprehensive loss	<u>\$ (11,065)</u>	<u>\$ (8,826)</u>

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

PROTARA THERAPEUTICS, INC. AND SUBSIDIARIES
Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except share and per share data)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	8,027	\$ -	11,267,389	\$ 11	\$ 262,724	\$ (159,964)	\$ (688)	\$ 102,083
Settlement of restricted stock units	-	-	39,364	-	(64)	-	-	(64)
Stock-based compensation - restricted stock units	-	-	-	-	314	-	-	314
Stock-based compensation - stock options	-	-	-	-	1,261	-	-	1,261
Net unrealized (loss) gain on marketable debt securities	-	-	-	-	-	-	219	219
Net loss	-	-	-	-	-	(9,045)	-	(9,045)
Balance at March 31, 2023	<u>8,027</u>	<u>\$ -</u>	<u>11,306,753</u>	<u>\$ 11</u>	<u>\$ 264,235</u>	<u>\$ (169,009)</u>	<u>\$ (469)</u>	<u>\$ 94,768</u>
Balance at December 31, 2023	7,991	\$ -	11,364,903	\$ 11	\$ 268,725	\$ (200,384)	\$ (31)	\$ 68,321
Settlement of restricted stock units	-	-	68,934	-	(76)	-	-	(76)
Stock-based compensation - restricted stock units	-	-	-	-	151	-	-	151
Stock-based compensation - stock options	-	-	-	-	1,075	-	-	1,075
Net unrealized (loss) gain on marketable debt securities	-	-	-	-	-	-	30	30
Net loss	-	-	-	-	-	(11,095)	-	(11,095)
Balance at March 31, 2024	<u>7,991</u>	<u>\$ -</u>	<u>11,433,837</u>	<u>\$ 11</u>	<u>\$ 269,875</u>	<u>\$ (211,479)</u>	<u>\$ (1)</u>	<u>\$ 58,406</u>

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

PROTARA THERAPEUTICS, INC. AND SUBSIDIARIES
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	For the Three Months Ended March 31,	
	2024	2023
Cash flows used in operating activities:		
Net loss	\$ (11,095)	\$ (9,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,226	1,575
Operating lease right-of-use asset	246	341
Depreciation	83	77
Amortization of premium (Accretion of discount) on marketable debt securities	(68)	(71)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	435	(6,145)
Other assets	(301)	58
Accounts payable	(1,462)	2,495
Accrued expenses and other current liabilities	797	(1,841)
Operating lease liabilities	(240)	(332)
Net cash used in operating activities	<u>(10,379)</u>	<u>(12,888)</u>
Cash flows from investing activities:		
Purchase of marketable debt securities	-	(12,186)
Proceeds from maturity and redemption of marketable debt securities	23,100	22,052
Purchase of property and equipment	-	(6)
Net cash provided by investing activities	<u>23,100</u>	<u>9,860</u>
Cash flows from financing activities:		
Repurchase of shares in connection with settlement of RSUs	(76)	(64)
Net cash used in financing activities	<u>(76)</u>	<u>(64)</u>
Net increase (decrease) in cash and cash equivalents and restricted cash	12,645	(3,092)
Cash and cash equivalents and restricted cash - beginning of year	40,331	24,872
Cash and cash equivalents and restricted cash - end of period	<u>\$ 52,976</u>	<u>\$ 21,780</u>
Reconciliation of cash and cash equivalents and restricted cash to the condensed consolidated balance sheets:		
Cash and cash equivalents	\$ 52,231	\$ 21,035
Restricted cash, non-current	745	745
Cash and cash equivalents and restricted cash	<u>\$ 52,976</u>	<u>\$ 21,780</u>
Supplemental schedule of noncash financing activities:		
Accrued financing fees	<u>\$ 385</u>	<u>\$ -</u>

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

Protara Therapeutics, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
(amounts in thousands, except share and per share data)

1. Organization and Nature of the Business

Overview

Protara Therapeutics, Inc., and its consolidated subsidiaries (“Protara” or the “Company”), is a clinical-stage biopharmaceutical company committed to advancing transformative therapies for the treatment of cancer and rare diseases. Protara’s portfolio includes two development programs utilizing TARA-002, an investigational cell therapy in development for the treatment of non-muscle invasive bladder cancer, or NMIBC, and lymphatic malformations, or LMs. Additionally, the Company’s portfolio includes Intravenous, or IV, Choline Chloride, an investigational phospholipid substrate replacement therapy in development for patients receiving parenteral nutrition, or PN.

Liquidity and Capital Resources

On April 5, 2024, the Company entered into a subscription agreement with certain purchasers and subsequently closed a private placement transaction, or the Private Placement, on April 10, 2024. Pursuant to the Private Placement the Company sold 9,143,380 shares of common stock and, for certain purchasers, pre-funded warrants to purchase an aggregate of 1,700,000 shares of common stock. In each case, the shares of common stock and pre-funded warrants were accompanied by warrants to purchase an aggregate of up to 10,843,380 shares of common stock at a price of \$5.25.

Each share of common stock along with its attached common warrant, had a purchase price of \$4.15 and each pre-funded warrant, along with its attached common warrant, had a purchase price of \$4.149.

At the close of the Private Placement on April 10, 2024, the Company received total net proceeds of approximately \$41,963 after deducting placement agent fees and offering expenses.

The Company is in the business of developing biopharmaceuticals and has no current or near-term revenues. The Company has incurred substantial clinical and other costs in its drug development efforts. The Company will need to raise additional capital in order to fully realize management’s plans.

The Company believes that its current financial resources are sufficient to satisfy the Company’s estimated liquidity needs for at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

The Company’s significant accounting policies are disclosed in the audited consolidated financial statements and the notes thereto in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, filed with the United States Securities and Exchange Commission, or SEC, on March 13, 2024. Except as reflected below, there were no changes to the Company’s significant accounting policies as described in the Annual Report on Form 10-K. Reflected in this note are updates to accounting policies, including the impact of the adoption of new policies.

Basis of Presentation

The accompanying condensed consolidated financial statements and the related disclosures as of March 31, 2024 and for the three months ended March 31, 2024 and 2023 are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, and the rules and regulations of the SEC for interim financial statements. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the 2023 and 2022 audited consolidated financial statements and notes included in the Annual Report on Form 10-K. The December 31, 2023 consolidated balance sheet included herein was derived from the audited financial statements as of that date but does not include all disclosures including notes required by GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements reflect all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of the Company’s financial position and results of operations for the three months ended March 31, 2024 and 2023. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or any other interim period or future year or period.

Protara Therapeutics, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
(amounts in thousands, except share and per share data)

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in the accompanying condensed consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements. Significant items subject to such estimates include but are not limited to research and development accruals as well as contingencies.

On an ongoing basis, the Company's management evaluates its estimates based on historical and anticipated results, trends, and various other assumptions believed to be reasonable. Actual results could differ from those estimates. The results of any changes in accounting estimates are reflected in the financial statements of the period in which the change becomes evident.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consists principally of cash, cash equivalents, restricted cash and investments in marketable debt securities.

The Company currently invests its excess cash primarily in money market funds and high quality investment grade marketable debt securities of corporations. The Company has adopted an investment policy that includes guidelines relative to credit quality, diversification and maturities to preserve principal and liquidity.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standards Board, or the FASB, issued ASU 2023-07 – Improvements to Reportable Segment Disclosures, which enhances the disclosures required for reportable segments in annual and interim consolidated financial statements, including additional, more detailed information about a reportable segment's expenses. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is available. The Company is still evaluating the full extent of the potential impact of the adoption of ASU 2023-07, but believes it will not have a material impact on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09 – Improvements to Income Tax Disclosures, which enhances the transparency and decision usefulness of income tax disclosures. The standard is effective for public companies for annual periods beginning after December 15, 2024. Early adoption is available. The Company is still evaluating the full extent of the potential impact of the adoption of ASU 2023-09, but believes it will not have a material impact on its consolidated financial statements and disclosures.

Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were available to be issued. Other than the disclosure of the Private Placement described above in the Liquidity and Capital Resources section of Note 1. Organization and Nature of the Business, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

Protara Therapeutics, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
(amounts in thousands, except share and per share data)

3. Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value. Fair value is determined based upon the exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as determined by either the principal market or the most advantageous market.

Inputs used in the valuation techniques to derive fair values are classified based on a three-level hierarchy, as follows:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

The following tables present the Company's financial assets and liabilities that are measured and carried at fair value and indicate the level within the fair value hierarchy of valuation techniques it utilizes to determine such fair value:

	As of March 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds ^(a)	\$ 51,781	\$ -	\$ -	\$ 51,781
Restricted cash, non-current:				
Money market funds ^(b)	745	-	-	745
Marketable debt securities:				
Corporate bonds ^(c)	-	2,992	-	2,992
Total	<u>\$ 52,526</u>	<u>\$ 2,992</u>	<u>\$ -</u>	<u>\$ 55,518</u>
	As of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds ^(a)	\$ 39,031	\$ -	\$ -	\$ 39,031
Restricted cash, non-current:				
Money market funds ^(b)	745	-	-	745
Marketable debt securities:				
Corporate bonds ^(c)	-	23,495	-	23,495
Agency bonds ^(c)	-	2,499	-	2,499
Total	<u>\$ 39,776</u>	<u>\$ 25,994</u>	<u>\$ -</u>	<u>\$ 65,770</u>

(a) Money market funds and bonds with original maturities of 90 days or less are included within Cash and cash equivalents in the condensed consolidated balance sheets.

(b) Restricted money market funds are included within Restricted cash, non-current in the condensed consolidated balance sheets.

(c) Bonds with original maturities greater than 90 days are included within Marketable debt securities in the condensed consolidated balance sheets and classified as current or non-current based upon whether the maturity of the financial asset is less than or greater than 12 months.

Protara Therapeutics, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
(amounts in thousands, except share and per share data)

Money market funds are classified as Level 1 within the fair value hierarchy, because they are valued using quoted prices in active markets. Corporate and agency bonds classified as Level 2 within the fair value hierarchy are valued on the basis of prices from an orderly transaction between market participants provided by reputable dealers or pricing services. Prices of these securities are obtained through independent, third-party pricing services and include market quotations that may include both observable and unobservable inputs. In determining the value of a particular investment, pricing services may use certain information with respect to transactions in such investments, quotations from dealers, pricing matrices and market transactions in comparable investments and various relationships between investments. There were no transfers of financial instruments among Level 1, Level 2, and Level 3 during the period presented.

Cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities at March 31, 2024 and December 31, 2023 are carried at amounts that approximate fair value due to their short-term maturities.

4. Marketable Debt Securities

Marketable debt securities, all of which were classified as available-for-sale, consist of the following:

	As of March 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate bonds - presented in marketable debt securities	\$ 2,993	\$ -	\$ (1)	\$ 2,992
Total	\$ 2,993	\$ -	\$ (1)	\$ 2,992

	As of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate bonds - presented in marketable debt securities	\$ 23,525	\$ -	\$ (30)	\$ 23,495
Agency bonds - presented in marketable debt securities	2,500	-	(1)	2,499
Total	\$ 26,025	\$ -	\$ (31)	\$ 25,994

The amount of realized gains and losses reclassified into earnings for the three months ended March 31, 2024 and 2023 was \$0. Gains, if any, would be included in investment income within the condensed consolidated statements of operations and comprehensive loss.

The Company has recorded the securities at fair value in its condensed consolidated balance sheets and unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss). The amount of realized gains and losses reclassified into earnings are based on the specific identification of the securities sold or securities that reached maturity date. The amount of realized gains and losses reclassified into earnings have not been material to the Company's condensed consolidated statements of operations and comprehensive loss.

At the time of purchase, the Company determines the appropriate classification of investments based upon its intent with regard to such investments. The Company classifies investments in marketable debt securities with remaining maturities when purchased of greater than three months as available-for-sale. Investments with a remaining maturity date greater than one year are classified as non-current. The contractual maturities of all securities held at March 31, 2024 was 1 month or less. There were no sales of securities in the periods presented.

Credit Losses

Securities with an amortized cost basis in excess of estimated fair value are assessed to determine what amount of the excess, if any, is caused by expected credit losses. For the period ended March 31, 2024, it was determined that none of the unrealized loss is related to expected credit losses as the Company has the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery. Further, the entire portfolio is held with investment grade high credit quality institutions. The Company intends to continue investing only in such securities. Expected credit losses, if they existed, would be recognized in other income (expense), net within the Company's condensed consolidated statements of operations and comprehensive loss. The remaining unrealized losses, not related to credit losses, net of taxes, are included in accumulated other comprehensive loss in stockholders' equity within the Company's condensed consolidated balance sheets.

Protara Therapeutics, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
(amounts in thousands, except share and per share data)

Marketable debt securities in a loss position consist of the following:

	As of March 31, 2024					
	In Continuous Loss Position Less Than 12 Months		In Continuous Loss Position Greater Than 12 Months		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Corporate bonds – presented in marketable debt securities	\$ 1,993	\$ (1)	\$ -	\$ -	\$ 1,993	\$ (1)
Total	<u>\$ 1,993</u>	<u>\$ (1)</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 1,993</u>	<u>\$ (1)</u>

	As of December 31, 2023					
	In Continuous Loss Position Less Than 12 Months		In Continuous Loss Position Greater Than 12 Months		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Corporate bonds – presented in marketable debt securities	\$ 19,498	\$ (27)	\$ 3,997	\$ (3)	\$ 23,495	\$ (30)
Agency bonds – presented in marketable debt securities	2,499	(1)	-	-	2,499	(1)
Total	<u>\$ 21,997</u>	<u>\$ (28)</u>	<u>\$ 3,997</u>	<u>\$ (3)</u>	<u>\$ 25,994</u>	<u>\$ (31)</u>

Investment Income

Interest and investment income consist of the following:

	For the Three Months Ended March 31,	
	2024	2023
Interest income	\$ 679	\$ 605
Accretion/(Amortization) of discount/premium, net	68	82
Dividend income	9	-
Total interest and investment income	<u>\$ 756</u>	<u>\$ 687</u>

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	As of	
	March 31, 2024	December 31, 2023
Prepaid research and development	\$ 1,539	\$ 1,957
Prepaid insurance	572	659
Prepaid retention bonuses	240	-
Prepaid software	117	67
Accrued interest on marketable debt securities	23	242
Other prepaid expenses	196	163
Other current assets	3	37
Total	<u>\$ 2,690</u>	<u>\$ 3,125</u>

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6. Other Assets

Other assets consist of the following:

	As of	
	March 31, 2024	December 31, 2023
Prepaid research and development, non-current	\$ 2,625	\$ 2,661
Deferred offering costs	385	-
Prepaid insurance, non-current	204	272
Other non-current assets	31	11
Total	\$ 3,245	\$ 2,944

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of	
	March 31, 2024	December 31, 2023
Research and development costs	\$ 1,814	\$ 440
Employee costs	1,065	2,112
Accrued financing fees	385	-
Other expenses	265	180
Total	\$ 3,529	\$ 2,732

8. Leases

Operating leases

Leases classified as operating leases are included in operating lease right-of use, or ROU, assets, operating lease liabilities and operating lease liabilities, non-current, in the Company's condensed consolidated balance sheets. Cash paid for operating lease liabilities was \$332 during each of the three months ended March 31, 2024 and 2023.

Lease expense consist of the following:

	For the Three Months Ended March 31,	
	2024	2023
Lease cost		
Operating lease cost	\$ 338	\$ 341
Total	\$ 338	\$ 341

Variable lease expenses for the three months ended March 31, 2024 were \$20. Variable lease expenses for the three months ended March 31, 2023 were not material.

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The weighted-average remaining lease term and the weighted average discount rate for operating leases were:

	As of March 31, 2024
Weighted-average discount rate	7.0%
Weighted-average remaining lease term – operating lease (in months)	52

As of March 31, 2024, the expected annual minimum lease payments of the Company’s operating lease liabilities were as follows:

For Years Ending December 31,	Operating Lease Payments
2024 (excluding the three months ended March 31, 2024)	\$ 995
2025	1,395
2026	1,429
2027	1,429
2028	718
Thereafter	87
Total operating lease payments	6,053
Less: imputed interest	(826)
Present value of future minimum lease payments	\$ 5,227

9. Commitments and Contingencies

Commitments

The Company has commitments under certain license and collaboration agreements, lease agreements, and employment agreements. Commitments under certain license agreements primarily include annual payments, payments upon the achievement of certain milestones, and royalty payments based on net sales of licensed products. Commitments under lease agreements consist of future minimum lease payments for operating leases which are further described in Note 8 of this Quarterly Report on Form 10-Q.

Contingencies

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Management is of the opinion that the ultimate outcome of these matters would not have a material adverse impact on the financial position of the Company or the results of its operations.

In the normal course of business, the Company enters into contracts in which it makes representations and warranties regarding the performance of its services and that its services will not infringe on third-party intellectual rights. There have been no significant events related to such representations and warranties in which the Company believes the outcome could result in losses or penalties in the future.

10. Stockholders’ Equity

Common Stock

As of March 31, 2024 and December 31, 2023, the Company had 100,000,000 shares of common stock authorized for issuance, \$0.001 par value per share, of which 11,433,837 and 11,364,903 shares were issued and outstanding, respectively.

The holders of the Company’s common stock are entitled to one vote per share.

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Preferred Stock

As of March 31, 2024 and December 31, 2023, the Company had 10,000,000 shares of preferred stock authorized for issuance, \$0.001 par value per share, of which 8,028 shares of Series 1 Convertible Preferred Stock were authorized for issuance and 7,991 shares were issued and outstanding as of March 31, 2024 and December 31, 2023. Each share of Series 1 Convertible Preferred Stock is convertible into approximately 1,000 shares of common stock, at a conversion price initially equal to approximately \$7.01 per common share, subject to certain adjustments as described in the certificate of designation of preferences, rights and limitations of Series 1 Convertible Preferred Stock.

During August 2023, approximately 36 shares of Series 1 Convertible Preferred Stock were converted into 35,823 shares of common stock.

The holders of Series 1 Convertible Preferred Stock are not entitled to vote.

11. Stock-Based Compensation

2020 Inducement Plan

On March 26, 2020, the Compensation Committee of the Board of Directors, or the Compensation Committee, approved the 2020 Inducement Plan in order to award nonstatutory stock options, restricted stock awards, restricted stock unit awards and other stock-based awards to persons not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company.

The 2020 Inducement Plan provides for a total of 600,000 shares for the issuance of the Company's common stock. The Compensation Committee also adopted a form of stock option grant notice and stock option agreement and forms of restricted stock unit grant notice and restricted stock unit agreement for use with the Inducement Plan.

As of March 31, 2024, there were 409,000 shares of common stock subject to outstanding awards and 191,00 shares of common stock available for future issuance under the 2020 Inducement Plan.

2017 Equity Incentive Plan

On August 10, 2017, Private ArTara (a predecessor entity of the Company), its Board of Directors and its stockholders approved the ArTara Therapeutics, Inc. 2017 Equity Incentive Plan to enable Private ArTara and its affiliates to recruit and retain highly qualified personnel and to incentivize personnel for productivity and growth.

The 2017 Equity Incentive Plan provided for the grant of a total of 2,000,000 shares for the issuance of stock options, stock appreciation rights, restricted stock and restricted stock units to among others, members of the Board of Directors, employees, consultants and service providers to the Company and its affiliates. As of January 9, 2020, no additional awards will be made under the 2017 Equity Incentive Plan.

2014 Equity Incentive Plan

On October 3, 2014, the stockholders approved the 2014 Equity Incentive Plan. On June 20, 2017, the Company's Board of Directors amended the 2014 Equity Incentive Plan, or the Amended and Restated 2014 Plan. On July 31, 2017, the stockholders approved this amendment. On January 1, 2020, Protara Therapeutics, Inc. amended its Amended and Restated 2014 Equity Incentive Plan.

The Amended and Restated 2014 Plan, as amended, provides for the grant of incentive and non-statutory stock options, stock appreciation rights, restricted stock and stock unit awards, performance units, stock grants and qualified performance-based awards. The Amended and Restated 2014 Plan, as amended, provides that the number of shares reserved and available for issuance will automatically increase each January 1, by four percent of the Company's common stock on the immediately preceding December 31, adjusted for the number of shares of the Company's common stock issuable upon conversion of any security that the Company may issue that is convertible into or exchangeable for the Company's common stock, or such lesser number of shares as determined by the Company's Board of Directors.

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On January 1, 2024, pursuant to the annual evergreen feature of the Amended and Restated 2014 Plan, as amended, the number of shares authorized under the Amended and Restated 2014 Plan, as amended, was increased by 911,380 shares to 4,474,683 shares. As of March 31, 2024, there were 4,090,945 shares of common stock subject to outstanding awards and 181,939 shares of common stock available for future issuance under the Amended and Restated 2014 Plan.

Terms of the stock awards, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the plans. Certain awards provide for accelerated vesting if there is a change in control as defined in the plan.

2014 Employee Stock Purchase Plan

On October 3, 2014, the stockholders approved the 2014 Employee Stock Purchase Plan, or the 2014 ESPP. The 2014 ESPP initially authorized the issuance of up to 3,513 shares of the Company's common stock. The number of shares increases each January 1, commencing on January 1, 2015 and ending on (and including) January 1, 2024, by an amount equal to the lesser of one percent of the outstanding shares as of the end of the immediately preceding fiscal year, 7,025 shares or any lower amount determined by the Company's Board of Directors prior to each such January 1st.

On January 1, 2024, pursuant to the increase per the 2014 ESPP, the number of shares authorized under the 2014 ESPP was increased by 7,025 shares to 46,112 shares. As of March 31, 2024, the authorized number of shares under the 2014 ESPP was 46,112 and the number of shares available for issuance was 46,112. During the three months ended March 31, 2024 and 2023, no shares were issued under the 2014 ESPP.

Restricted Stock Units

The following table summarizes restricted stock unit, or RSU, activities for the three months ended March 31, 2024:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested as of December 31, 2023	236,679	\$ 7.07
Granted	210,700	1.91
Forfeited	-	-
Vested	(104,484)	10.57
Non-vested as of March 31, 2024	<u>342,895</u>	<u>\$ 2.84</u>

The fair value of RSUs is amortized on a straight-line basis over the requisite service period of the respective awards. As of March 31, 2024, the unamortized value of RSUs was \$821. As of March 31, 2024, the weighted average remaining amortization period was 2.32 years. As of March 31, 2024 and December 31, 2023, 289,500 RSUs have vested that have not yet been settled into shares of the Company's common stock.

During the three months ended March 31, 2024, the Company issued 68,934 shares of the Company's common stock from the net settlement of 104,484 RSUs. The Company paid \$76 in connection with the net share settlement of these RSUs.

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Stock Options

The following table summarizes stock option activities for the three months ended March 31, 2024:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (1)
Outstanding as of December 31, 2023	2,900,205	\$ 9.50	8.03	\$ 20
Granted	1,102,300	1.91	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	(627)	3.20	-	-
Outstanding as of March 31, 2024	<u>4,001,878</u>	\$ 7.41	7.45	\$ 3,675
Vested and expected to vest at March 31, 2024	4,001,878	\$ 7.41	7.45	\$ 3,675
Exercisable as of March 31, 2024	1,648,715	12.90	6.71	429

(1) Aggregate intrinsic value represents the difference between the exercise price of the option and the closing market price of our common stock on December 31, 2023 and March 31, 2024, respectively. The intrinsic value of options exercised during the period ended March 31, 2024 was \$0 and no options were exercised.

The weighted average grant date fair value per share of the options granted during the three months ended March 31, 2024 and 2023 was \$1.52 and \$2.42 respectively. As of March 31, 2024, there was approximately \$6,301 of unrecognized share-based compensation for unvested stock option grants, which is expected to be recognized over a weighted average period of 2.86 years. The total unrecognized stock-based compensation cost will be adjusted for actual forfeitures as they occur.

Summary of Stock-Based Compensation Expense

The following tables summarize total stock-based compensation costs recognized:

	For the Three Months Ended March 31,	
	2024	2023
Restricted stock units	\$ 151	\$ 314
Stock options	1,075	1,261
Total	<u>\$ 1,226</u>	<u>\$ 1,575</u>

Stock-based compensation expense was reflected within the condensed consolidated statements of operations and comprehensive loss as:

	For the Three Months Ended March 31,	
	2024	2023
Research and development	\$ 374	\$ 400
General and administrative	852	1,175
Total	<u>\$ 1,226</u>	<u>\$ 1,575</u>

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12. Net Loss per Common Share

The following table sets forth the computation of the net loss per share attributable to common stockholders, basic and diluted:

	For the Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	\$ (11,095)	\$ (9,045)
Denominator:		
Weighted-average shares of common stock outstanding, basic and diluted	11,420,948	11,303,869
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.97)	\$ (0.80)

Since the Company was in a net loss position for all periods presented, net loss per share attributable to common stockholders was the same, on a basic and diluted basis, as the inclusion of all potential common equivalent shares outstanding would have been anti-dilutive. The Company excluded the following potential shares of common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of March 31,	
	2024	2023
Stock options issued and outstanding	4,001,878	2,973,531
Restricted stock units issued and outstanding	632,395	586,061
Conversion of Series 1 Convertible Preferred Stock	7,993,217	8,029,039
Total potentially dilutive shares	12,627,490	11,588,631

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

Overview

We are a New York City based clinical-stage biopharmaceutical company committed to advancing transformative therapies for the treatment of cancer and rare diseases. We were founded on the principle of applying modern scientific, regulatory or manufacturing advancements to established mechanisms in order to create new development opportunities. We prioritize creativity, diverse perspectives, integrity and tenacity to expedite our goal of bringing life-changing therapies to people with limited treatment options.

Our portfolio includes two development programs utilizing TARA-002, an investigational cell therapy based on the broad immunopotentiator, OK-432, which was originally granted marketing approval by the Japanese Ministry of Health and Welfare as an immunopotentiating cancer therapeutic agent. This cell therapy is currently approved in Japan and Taiwan for lymphatic malformations, or LMs, and multiple oncologic indications. We have secured worldwide rights to the asset excluding Japan and Taiwan and are exploring its use in oncology and rare disease indications. TARA-002 was developed from the same master cell bank of genetically distinct group A *Streptococcus pyogenes* as OK-432 (marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd., or Chugai Pharmaceutical). We are currently developing TARA-002 in non-muscle invasive bladder cancer, or NMIBC, and in LMs.

Our lead oncology program is TARA-002 in NMIBC, which is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle. Bladder cancer is the sixth most common cancer in the United States, with NMIBC representing approximately 80% of bladder cancer diagnoses. Approximately 65,000 patients are diagnosed with NMIBC in the United States each year. Very few new therapeutics have been approved for NMIBC since the 1990s and the current standard of care for NMIBC includes intravesical Bacillus Calmette–Guérin, or BCG. The mechanism of action of TARA-002 is similar in some ways to that of BCG. TARA-002 and BCG are both intravesically administered, elicit a Th1 type immune response and produce a generally similar array of locally activated cytokines and immune cells.

We are conducting a Phase 1 open-label clinical trial to evaluate TARA-002 in treatment-naïve and treatment-experienced NMIBC patients with carcinoma in situ, or CIS, and high-grade papillary tumors, or Ta, known as the ADVANCED-1 trial. In the initial dose escalation phase of the trial, patients received six weekly intravesical doses of TARA-002, evaluating the 10KE, 20KE and 40KE doses (Klinische Einheit, or KE, is a German term indicating a specified weight of dried cells in vial). The primary objective of the trial is to evaluate the safety, tolerability and preliminary signs of anti-tumor activity of TARA-002, with the goal of establishing a recommended Phase 2 dose. In April 2023, we announced positive preliminary data from the Phase 1a dose escalation component of the ongoing ADVANCED-1 trial through the 40KE dose, in which TARA-002 indicated favorable tolerability and anti-tumor activity in NMIBC patients. A maximum tolerated dose was not determined, and dose escalation at the 80KE dose remains ongoing in an exploratory cohort.

Preliminary data from the ADVANCED-1 trial suggested that intravesical TARA-002 was generally well tolerated at the three dose levels evaluated in the initial phase of the trial, and no dose limiting toxicities were observed. The Company has selected the 40KE dose for use in subsequent clinical trials. The majority of reported adverse events were Grades 1 and 2 across all dose levels, and treatment emergent adverse events, as assessed by study investigators, were in line with typical responses to bacterial immunopotentiation and included fatigue, headache, fever and chills. The most common urinary symptoms were urinary urgency, urinary frequency, urinary tract pain/burning, incomplete emptying, and bladder spasm. Most bladder irritations resolved soon after administration, or in a few hours to a few days. A total of nine patients were enrolled in the dose escalation portion of the study through the 40KE dose. Of those, three patients with CIS, one of whom was a heavily pre-treated BCG-unresponsive patient, achieved a complete response, or CR, at the 20KE dose, and tumor regression was observed in the other two patients. Results from six patients with high-grade, non-invasive papillary, or HGTA, tumors showed five of six patients with high-grade recurrence free survival, or HGRFS, at week 12. The patient who did not achieve HGRFS was dosed at 10KE, the lowest dose of TARA-002 offered in the trial.

The ongoing open-label expansion trial, or ADVANCED-1EXP, is evaluating intravesical TARA-002 at the 40KE dose in up to 12 CIS patients, including BCG-naïve, BCG-unresponsive, and BCG-inadequately treated patients. In April 2024, we announced positive data from three-month evaluable NMIBC patients with CIS pooled across our clinical studies, including ADVANCED-1 Phase 1a, ADVANCED-1 EXP Phase 1b and ADVANCED-2 Phase 2 trials of TARA-002 in patients with high-risk NMIBC, including BCG-Unresponsive, BCG-Experienced and BCG-Naïve patients. The overall three-month CR rate prior to reinduction for the 16 evaluable patients was 38%, with a CR rate of 63% in CIS-only patients and 13% in patients with CIS +Ta/T1 (T1 is defined as carcinoma invading the lamina propria). A 43% CR rate was observed in BCG-Unresponsive/Experienced patients. TARA-002 demonstrated a favorable safety and tolerability profile. The majority of reported adverse events were Grades 1 and 2 across all dose levels, and there were no Grade 3 or higher treatment emergent adverse events, or TEAEs. TEAEs as assessed by study investigators, were in line with typical responses to bacterial immunopotentialiation, and included fatigue, headache, fever, and chills. The most common urinary symptoms were urinary urgency, urinary frequency, urinary tract pain/burning, incomplete emptying, and bladder spasm. Most bladder irritations resolved in a few hours to a few days. Additional details regarding the data, which support the potential for TARA-002 in treating high risk patients can be found in the following table:

	Three Month Evaluable Patients		
	# Patients	# of CRs	CR %
BCG-Unresponsive/ Experienced			
CIS-only	6	3	50%
CIS +Ta/T1	1	-	-%
	<u>7</u>	<u>3</u>	<u>43%</u>
BCG-Naïve			
CIS-only	2	2	100%
CIS +Ta/T1	7	1	14%
	<u>9</u>	<u>3</u>	<u>33%</u>
	<u>16</u>	<u>6</u>	<u>38%</u>
By Stage of Disease at Baseline			
CIS-only	8	5	63%
CIS +Ta/T1	8	1	13%
	<u>16</u>	<u>6</u>	<u>38%</u>
By Study			
Phase 1a	3	1	33%
Phase 1b-EXP	8	3	38%
Phase 2 Naïve	5	2	40%
	<u>16</u>	<u>6</u>	<u>38%</u>

Data cutoff date: March 19, 2024

We expect to share preliminary results from a pre-planned risk-benefit analysis of the ongoing Phase 2 open-label ADVANCED-2 trial in the second half of 2024. The analysis is expected to include approximately 10 patients who are six-month evaluable. The ongoing ADVANCED-2 trial is assessing intravesical TARA-002 in NMIBC patients with CIS (\pm Ta/T1) who are BCG-Naïve (n=27) and BCG-Unresponsive (n=75-100). The BCG-Unresponsive cohort has been designed to be registrational aligned with the United States Food and Drug Administration's, or FDA's, 2018 BCG-Unresponsive Non-muscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry. Trial subjects will receive an induction course of six weekly intravesical instillations, and following mandatory biopsy at three months, will either receive a reinduction course of six weekly intravesical instillations of TARA-002, or the first maintenance course of three weekly installations every three months, for an additional 12 months.

In addition to the ADVANCED-2 trial, we intend to assess higher dosing at an 80KE dose and systemic priming prior to initiation of intravesical administration, in each case to assess anti-tumor activity, as well as the combination of TARA-002 with a checkpoint inhibitor in NMIBC patients with CIS.

In addition, we continue to conduct non-clinical studies on TARA-002 to better characterize the mechanism of action to help us understand how TARA-002 may perform in potential combinations with other agents used to treat NMIBC. We use non-clinical data to help us define other cancer targets for TARA-002, both within urothelial cancer and other types of cancer affecting different parts of the body.

We are also pursuing intravenous, or IV, Choline Chloride, an investigational phospholipid substrate replacement therapy, for patients receiving parenteral nutrition, or PN. Choline is a known important substrate for phospholipids that are critical for healthy liver function and also plays an important role in modulating gene expression, cell membrane signaling, brain development and neurotransmission, muscle function, and bone health. PN patients are unable to synthesize choline from enteral nutrition sources, and there are currently no available PN formulations containing choline. Approximately 80 percent of PN-dependent patients are choline-deficient and have some degree of liver damage, which can lead to hepatic failure. There are currently no available PN formulations containing choline. In the U.S. alone, there are approximately 40,000 patients on long-term PN who would benefit from an IV formulation of choline. IV Choline Chloride has the potential to become the first FDA approved IV choline formulation for PN patients.

Choline is recommended for patients on PN by the American Society for Parenteral and Enteral Nutrition, or ASPEN, in their Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi-Trace Element Products, as well as by the European Society for Clinical Nutrition and Metabolism, or ESPEN, in their Guideline on Home Parenteral Nutrition. IV Choline Chloride has been granted Orphan Drug Designation by the FDA for the prevention of choline deficiency in PN patients. We have been issued a U.S. patent by the U.S. Patent and Trademark Office claiming a choline composition with a term expiring in 2041.

In April 2024, we announced alignment with the FDA on a registrational path forward for IV Choline Chloride in patients dependent on PN. Previously, we had been pursuing an indication in intestinal failure-associated liver disease, or IFALD, and following feedback from the FDA, are pursuing a broader indication in patients on PN who are or may become unable to synthesize choline from oral or enteral nutrition sources. Feedback from the FDA on our IV Choline Chloride program indicated that a single study with an endpoint of restoring choline levels in PN patients could serve as the basis for a regulatory filing for IV Choline Chloride. We intend to advance the development of IV Choline Chloride as a source of choline for adult and adolescent patients on long-term PN.

We are also pursuing TARA-002 in LMs, which are rare, non-malignant cysts of the lymphatic vascular system that primarily form in the head and neck region of children before the age of two. In July 2020, the FDA granted Rare Pediatric Disease designation for TARA-002 for the treatment of LMs and in May 2022 the European Medicines Agency granted orphan drug designation to TARA-002 for the treatment of LMs. In addition to the clinical experience in Japan, we have secured the rights to a dataset from one of the largest ever conducted Phase 2 trials in LMs, in which OK-432 was administered via a compassionate use program led by the University of Iowa to over 500 pediatric and adult patients. We have an investigational new drug application for LMs with the Vaccines and Related Products Division of the FDA, or Vaccines Division.

In October 2023, we initiated STARBORN-1, which is a Phase 2 single-arm, open-label, prospective clinical trial to evaluate the safety and efficacy of intracystic injection of TARA-002 for the treatment of macrocystic and mixed-cystic LMs ($\geq 50\%$ macrocystic disease) in participants six months to less than 18 years of age. Including an age de-escalation safety lead-in, the trial will enroll approximately 30 patients who will receive up to four injections of TARA-002 spaced approximately six weeks apart.

The primary endpoint of the trial is the proportion of participants with macrocystic LMs and mixed-cystic LMs who demonstrated clinical success, defined as having either a complete response (90% to 100% reduction from baseline in total LM volume) or substantial response (60% to less than 90% reduction in total LM volume) as measured by axial imaging.

We have devoted substantial efforts to the development of these programs and do not have any approved products and have not generated any revenue from product sales. Neither TARA-002 nor IV Choline Chloride have been approved for use for any indications. We do not expect to generate revenues in the near-term, and it is possible we may never generate revenues in the future. To finance our current strategic plans, including the conduct of ongoing and future clinical trials and further research and development costs, we will need to raise additional capital. See “—Liquidity and Capital Resources” for additional information about our liquidity and capital resource needs.

Since inception, we have incurred significant operating losses. As of March 31, 2024, we had an accumulated deficit of approximately \$211.5 million. We expect to continue to incur significant and increasing expenses and operating losses for at least the next few years as we continue our development of, and seek marketing approvals for, our product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States.

As a clinical-stage company, our expenses and results of operations are likely to fluctuate significantly from quarter-to-quarter and year-to-year. We believe that our period-to-period comparisons of our results of operations should not be relied upon as indicative of our future performance.

As of March 31, 2024, we had approximately \$55.2 million in cash, cash equivalents, and marketable debt securities. On April 10, 2024, we completed a private placement where we sold 9,143,380 shares of common stock and, for certain purchasers, pre-funded warrants to purchase an aggregate of 1,700,000 shares of common stock. In each case, the shares and pre-funded warrants were accompanied by warrants to purchase an aggregate of up to 10,843,380 shares of common stock at a price of \$5.25. We received total net proceeds of approximately \$42.0 million after deducting placement agent fees and offering expenses.

Financial Overview

Research and Development

Research and development expenses consist primarily of costs incurred for the development of TARA-002 and IV Choline Chloride, which include personnel-related expenses, including salaries, benefits, travel and stock-based compensation expense, expenses incurred under agreements with clinical research organizations, or CROs, contract development and manufacturing organizations, or CDMOs, the cost of acquiring, developing and manufacturing clinical trial materials, clinical and non-clinical related costs, costs associated with regulatory operations and facilities, depreciation and other expenses, which include expenses for rent and maintenance of facilities and other supplies.

General and Administrative

General and administrative expenses consist principally of personnel-related expenses, including salaries, benefits, travel and stock-based compensation expense, in executive and other administrative functions. Other general and administrative expenses also include professional fees for legal, intellectual property matters, consulting and accounting services, facility related costs, as well as expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with our Nasdaq listing and SEC requirements, director and officer liability insurance premiums and investor relations costs associated with being a public company.

Other Income (Expense), net

Interest and investment income consists of interest and dividend income on our cash, cash equivalents and marketable debt securities and amortization of premiums and/or accretion of discounts.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial position and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

Our critical accounting policy is the accounting for accrued research and development expenses. We record accruals for estimated costs of research, preclinical, clinical and manufacturing development within accrued expenses which are significant components of research and development expenses. A substantial portion of our ongoing research and development activities are conducted by third-party service providers. We accrue costs incurred under these third-party arrangements based on estimates of actual work completed in accordance with the respective agreements. We determine the estimated costs to accrue through discussions with internal personnel and our external service providers as to the percentage of completion of the services and the agreed-upon fees to be paid for such services. Payments made to third parties under these arrangements in advance of performance of the related services are recorded as prepaid expenses until the services are rendered.

It is important that the discussion of our operating results that follow be read in conjunction with these critical accounting policies which have been disclosed in our Annual Report on Form 10-K filed with the SEC on March 13, 2024.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023 (in thousands):

	For The Three Months Ended March 31,		Period-to- Period Change
	2024	2023	
Operating expenses:			
Research and development	\$ 7,748	\$ 5,143	\$ 2,605
General and administrative	4,103	4,589	(486)
Total operating expenses	11,851	9,732	2,119
Loss from operations	(11,851)	(9,732)	(2,119)
Other income (expense), net:			
Interest and investment income	756	687	69
Other income (expense), net	756	687	69
Net loss	\$ (11,095)	\$ (9,045)	\$ (2,050)

Research and development expenses. During the three months ended March 31, 2024, our research and development expenses were approximately \$7.7 million, which represented an increase of approximately \$2.6 million as compared to the three months ended March 31, 2023. This increase was primarily due to an increase in expenses related to clinical trial and non-clinical activities for TARA-002 of \$1.8 million as well as an increase of \$1.1 million in personnel-related expenses partially offset by a reduction in clinical development activities for Choline of \$0.3 million.

General and administrative expenses. During the three months ended March 31, 2024, our general and administrative expenses were approximately \$4.1 million, which represented a decrease of approximately \$0.5 million as compared to the three months ended March 31, 2023. This decrease was primarily due to a reduction of \$0.5 million in personnel-related expenses (inclusive of \$0.3 million of stock-based compensation).

Other income (expense), net. During the three months ended March 31, 2024, our other income (expense), net was approximately \$0.8 million, which represented an increase of approximately \$0.1 million as compared to the three months ended March 31, 2023, due primarily to higher market interest rates obtained from money market funds.

Liquidity and Capital Resources

Overview

As of March 31, 2024 and December 31, 2023, our cash, cash equivalents, and marketable debt securities were \$55.2 million and \$65.6 million, respectively. We have not generated revenues since our inception and have incurred net losses of \$11.1 million and \$9.0 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had working capital of \$52.4 million and stockholder's equity of \$58.4 million. During the three months ended March 31, 2024, net cash flows used in operating activities were \$10.4 million, consisting primarily of a net loss of \$11.1 million including non-cash expenses of \$1.5 million, as well as working capital adjustments of \$0.7 million. Since inception, we have met our liquidity requirements principally through the sale of our common stock and preferred stock in private placements. More recently, on April 10, 2024, we completed a private placement where we sold 9,143,380 shares of common stock and, for certain purchasers, pre-funded warrants to purchase an aggregate of 1,700,000 shares of common stock. In each case, the shares and pre-funded warrants were accompanied by warrants to purchase an aggregate of up to 10,843,380 shares of common stock at a price of \$5.25. We received total net proceeds of approximately \$42.0 million after deducting placement agent fees and offering expenses.

We are in the business of developing biopharmaceuticals and have no current or near-term revenues. We have incurred substantial clinical and other costs in our drug development efforts. We will need to raise additional capital in order to fully realize management's plans.

We believe that our current financial resources, as of the date of the issuance of our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, are sufficient to satisfy our estimated liquidity needs for at least twelve months from the date of filing this quarterly report on Form 10-Q.

As a result of volatility in the capital markets, economic conditions, general global economic uncertainty, political change, global pandemics, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development activities. Specifically, higher, and potentially increasing interest rates could impact our access to capital, and could in the future negatively affect our liquidity. A recession or market correction, continued supply chain disruptions and/or inflation could materially affect our business and the value of our common stock. Further, recent rises in interest rates have had, and may continue to have, a negative effect on market prices for common stock of public companies, especially those in the pharmaceutical industry and those that have no current or near-term revenue.

Cash Flows

The following table summarizes our sources and uses of cash for the three months ended March 31, 2024 and 2023 (in thousands):

	For The Three Months Ended March 31,		Period-to- Period
	2024	2023	Change
Net cash provided by (used in) operating activities	\$ (10,379)	\$ (12,888)	\$ 2,509
Net cash provided by (used in) investing activities	23,100	9,860	13,240
Net cash provided by (used in) financing activities	(76)	(64)	(12)
Net increase (decrease) in cash and cash equivalents, and restricted cash	<u>\$ 12,645</u>	<u>\$ (3,092)</u>	<u>\$ 15,737</u>

Comparison of the Three Months Ended March 31, 2024 and 2023

Net cash used in operating activities was \$10.4 million for the three months ended March 31, 2024 compared to \$12.9 million for the three months ended March 31, 2023. The decrease of \$2.5 million in cash used in operating activities was primarily driven by a \$5.0 million decrease in working capital adjustments, primarily related to changes in prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities resulting from the timing of payments to our service providers offset partially by an increase in net loss of \$2.1 million which includes a \$0.4 million decrease in non-cash items including stock-based compensation, operating lease right-of-use asset, depreciation, and amortization of premium on marketable debt securities.

Net cash provided by investing activities was \$23.1 million for the three months ended March 31, 2024 compared to \$9.9 million for the three months ended March 31, 2023. The increase of \$13.2 million resulted primarily from an increase in proceeds from the maturity of marketable debt securities.

Net cash used in financing activities was approximately \$0.1 million for the three months ended March 31, 2024 and 2023.

Contractual and Other Obligations

Operating lease obligations

Our operating lease obligations primarily consist of lease payments on our corporate headquarters in New York, New York, as well as lease payments for our development laboratory, a manufacturing facility and an additional manufacturing space, all located in North America which are described in further detail in Note 8 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Other obligations

From time to time, we enter into certain types of contracts that contingently require us to indemnify parties against third-party claims, supply agreements, and agreements with directors and officers. The terms of such obligations vary by contract and in most instances a maximum dollar amount is not explicitly stated therein. Generally, amounts under these contracts cannot be reasonably estimated until a specific claim is asserted, thus no liabilities have been recorded for these obligations on our condensed consolidated balance sheet for the periods presented.

We enter into contracts in the normal course of business with CROs, CDMOs, and clinical sites for the conduct of clinical trials, non-clinical research studies, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts generally provide for termination on notice, and therefore are cancelable contracts.

Certain of these agreements require us to pay milestones to such third parties upon achievement of certain development, regulatory or commercial milestones as further described in Note 9 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones, which may not be achieved.

We also have obligations to make future payments to third parties that become due and payable on the achievement of certain milestones, including future payments to third parties with whom we have entered into research, development and commercialization agreements. We have not included these commitments on our condensed consolidated balance sheet for the periods presented because the achievement and timing of these milestones is not fixed and determinable.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the applicable regulations of the SEC.

Item 3. Qualitative and Quantitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of March 31, 2024, our management, with the participation of our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2024, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, 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 be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

In addition to the other information set forth in this Form 10-Q, including under the heading “Cautionary Note Regarding Forward-Looking Statements,” the risks and uncertainties which could adversely affect our business, financial condition, results of operations and future growth prospects that we believe are most important for you to consider are discussed in “Part II, Item 1A—Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 13, 2024. The risks described in our Annual Report on Form 10-K for the year ended December 31, 2023 are not the only risks we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Except as set forth below, there are no material changes to the Risk Factors described in our Annual Report on Form 10-K for the year ended December 31, 2023.

We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

We will require substantial additional funds to conduct the costly and time-consuming preclinical studies and clinical trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of TARA-002 and IV Choline Chloride in new indications or uses. Our future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders’ ownership interests and divert our management’s focus on achieving our business objectives. As a result of economic conditions, general global economic uncertainty, U.S. and foreign political conditions, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. Further, rising inflation has, in part, caused a disruption in the capital markets and an increase in interest rates, which may lead to a recession or market correction that could impact our access to capital, increase the cost of capital, and could in the future negatively affect our liquidity. A recession or market correction, inflation and/or further increases in interest rates could materially affect our business and the value of our common stock.

In April 2024, we entered into a Subscription Agreement to sell (i) 9,143,380 shares of common stock, (ii) pre-funded warrants to purchase 1,700,000 shares of common stock (the “Pre-Funded Warrants”) and (iii) warrants to purchase an aggregate of 10,843,380 shares of common stock (the “Common Warrants”). The Pre-Funded Warrants are immediately exercisable upon issuance at an exercise price of \$0.001 per share and do not expire. The Common Warrants are exercisable upon issuance at an exercise price of \$5.25 per share and may be exercised at any time on or prior to the earlier of (i) April 10, 2027 and (ii) the date that is 90 days after the public announcement that the Company has demonstrated a six-month complete response rate of minimum 42% from at least 25 BCG-Unresponsive patients in the ADVANCED-2 (Cohort B) clinical trial. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interests of our common stockholders will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

The Common Warrants are speculative in nature.

The Common Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, the Common Warrants are exercisable upon issuance at an exercise price of \$5.25 per share and may be exercised at any time on or prior to the earlier of (i) April 10, 2027 and (ii) the date that is 90 days after the public announcement that the Company has demonstrated a six-month complete response rate of minimum 42% from at least 25 BCG-Unresponsive patients in the ADVANCED-2 (Cohort B) clinical trial. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the Common Warrants and consequently, whether it will ever be profitable for holders of the Common Warrants to exercise the warrants.

Further, if the Common Warrants are exercised in full, we would be entitled to receive the cash exercise price of \$5.25 per warrant, or an aggregate of \$56,927,745. We would be able to use these additional proceeds to fund our operations. To the extent the market price of our common stock does not equal or exceed the exercise price of the Common Warrants before they expire, we would not be entitled to these proceeds, and we may be required to pursue additional financing alternatives.

We will not receive a significant amount, or potentially any, additional funds upon the exercise of our Pre-Funded Warrants; however, any exercise would increase the number of shares eligible for future resale in the public market and result in substantial dilution to our stockholders.

In April 2024, we issued Pre-Funded Warrants to purchase a total of 1,700,000 shares of our common stock, all of which are outstanding as of the date of this report. Each Pre-Funded Warrant is exercisable for \$0.001 per share of common stock underlying such Pre-Funded Warrant. Accordingly, we will not receive a significant amount of additional funds upon the exercise of the Pre-Funded Warrants. To the extent such Pre-Funded Warrants are exercised, additional shares of common stock will be issued for nominal consideration, which will result in dilution to the then existing holders of our common stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of the common stock, causing our stock price to decline.

The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders would receive.

In April 2024, we issued the Pre-Funded Warrants and the Common Warrants. Each Common Warrant is exercisable solely by means of a cash exercise, except that the Common Warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of the shares of common stock underlying the common stock warrants under the Securities Act of 1933, as amended, is not then effective. The Common Warrants include certain rights upon “fundamental transactions” as described in the Common Warrants. Additionally, each holder of warrants will not be entitled to exercise any portion of any Pre-Funded Warrant or Common Warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 9.99%, or for certain holders, 4.99%, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise. However, any holder may increase or decrease such percentage to any other percentage (not in excess of 19.99%) upon prior notice from the holder to us.

Although these warrants are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, entrench our management and our board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us and the holders of these warrants concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly.

We will register the issuance of shares upon exercise of these warrants under a registration statement. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

During the three months ended March 31, 2024, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 27, 2014).
3.2	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
3.3	Second Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2020).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
3.5	Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 23, 2020).
3.6	Composite Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.6 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 8, 2023).
3.7	Second Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 of Current Report on Form 8-K, filed with the SEC on August 3, 2017).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
4.2	Registration Rights Agreement, dated as of September 23, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
10.1†*	Amended and Restated Non-Employee Director Compensation Policy.
10.2†*	Retention Bonus, effective as of January 25, 2024, by and between Registrant and Jacqueline Zummo, Ph.D, MPH, MBA.
10.3†	Separation and Consulting Agreement and Release, dated as of March 18, 2024, by and between the Company and Jathin Bandari, M.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 18, 2024).
31.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
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*	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL")
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Exhibits filed herewith.

** Exhibits furnished herewith.

† Indicates management contract or compensatory plan or arrangement.

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.

PROTARA THERAPEUTICS, INC.

Date: May 2, 2024

By: /s/ Jesse Shefferman
Jesse Shefferman
Chief Executive Officer
(Principal Executive Officer)

Date: May 2, 2024

By: /s/ Patrick Fabbio
Patrick Fabbio
Chief Financial Officer
(Principal Financial Officer)

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the “**Board**”) who is not also serving as an employee of or consultant to Protara Therapeutics, Inc. (the “**Company**”) or any of its subsidiaries (each such member, an “**Eligible Director**”) will receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy is effective as of March 21, 2021 (the “**Effective Date**”), as amended on March 12, 2024, and may be further amended at any time in the sole discretion of the Board or the Compensation Committee of the Board. This policy supersedes any prior agreement that provides for compensation terms as of the Effective Date.

Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

For Eligible Directors who are serving on the Board as of the Effective Date the annual cash compensation shall be deemed effective as of the later of (i) October 1, 2019 or (ii) the date such member of the Board was appointed or elected to the Board or to the board of directors of a wholly- owned subsidiary of the Company.

1. Annual Board Service Retainer:

- a. All Eligible Directors: \$40,000
- b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): \$115,000

2. Annual Committee Chair Service Retainer:

- a. Chairman of the Audit Committee: \$15,000
- b. Chairman of the Compensation Committee: \$12,000
- c. Chairman of the Nominating and Corporate Governance Committee: \$9,000
- d. Chairman of the Scientific Advisory Committee: \$50,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):

- a. Member of the Audit Committee: \$7,500
 - b. Member of the Compensation Committee: \$6,000
 - c. Member of the Nominating and Corporate Governance Committee: \$5,000
 - d. Member of the Scientific Advisory Committee: \$25,000
-

Equity Compensation

The equity compensation set forth below will be granted under the Company's Amended and Restated 2014 Equity Incentive Plan (as amended from time to time, the "**Plan**"). All stock options granted under this policy will be non-statutory stock options, with an exercise price per share equal to 100% of the Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for death, disability or cause, the post-termination exercise period will be 12 months from the date of termination).

1. **Initial Grant:** On the date of the Eligible Director's initial appointment or election to the Board, for each Eligible Director who is first appointed or elected to the Board following the Effective Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 20,000 shares (the "**Initial Grant**"). The shares subject to each Initial Grant will vest in equal monthly installments over a three-year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's continuous service as a member of the Board through each such vesting date and will vest in full upon a Change of Control (as defined in the Plan).
2. **Annual Grant:** On the date of each Company annual stockholder meeting held on or after the Effective Date, for each Eligible Director who continues to serve as a non-employee member of the Board (or who is first appointed or elected to the Board at such annual stockholder meeting), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 10,000 shares (the "**Annual Grant**"). In addition, each Eligible Director who is first appointed or elected to the Board following the Effective Date and other than at an annual stockholder meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted an Annual Grant, pro-rated for the number of months remaining until the next annual stockholder meeting. The shares subject to the Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will, in any case, be fully vested on the date of the Company's next annual stockholder meeting, subject to the Eligible Director's continuous service as a member of the Board through such vesting date and will vest in full upon a Change of Control.

Annual Compensation Limits

Notwithstanding anything in this policy to the contrary, no Eligible Director may be granted (in any calendar year) compensation with a value in excess of \$750,000 (or \$1,000,000 solely with respect to the calendar year in which an Eligible Director is first appointed or elected to the Board) with the value of any Initial Grant or Annual Grant measured based on the accounting grant date fair value.



January 24, 2024

Jacqueline Zummo, Ph.D.
c/o Protara Therapeutics, Inc.
345 Park Avenue South
3rd Floor
New York, NY 10010

Via E-Mail

Re: Retention Award Opportunity

Dear Jackie:

Recognizing the vital role you play at Protara Therapeutics, Inc. (the "Company") and acknowledging the importance of your contributions to the Company over the course of the next year, the Company is pleased to offer you a cash retention award (the "Retention Award") on the terms and conditions contained in this letter agreement (this "Agreement"), which shall be effective as of the date you execute and return a copy of this Agreement.

1. Retention Bonus. You will receive a cash lump sum payment in the amount of \$150,000 (the "Retention Award"), payable on or about January 31, 2024, subject to your continued employment through the payment date and the other terms and conditions set forth herein. You agree that in the event of (i) your voluntary termination of your employment with the Company or (ii) your termination for Cause (as such term is defined in that certain Executive Employment Agreement between the Company and you dated as of December 17, 2019), on or before April 30, 2025, you will be required to repay the Retention Award, net of any taxes withheld, in full to the Company within thirty (30) days of such termination.
2. Tax Withholding. Payment of the Retention Award will be subject to applicable federal, state and local tax withholding.
3. Effect on Other Benefits. You acknowledge that payment of the Retention Award is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, pension or retirement benefits, matching contributions or similar payments.
4. No Right to Continued Employment. Nothing in this Agreement will confer upon you any right to continued employment with the Company (or its subsidiaries or their respective successors) or interfere in any way with the right of the Company (or its subsidiaries or their respective successors) to terminate your employment at any time.
5. Governing Law. Any dispute arising under this Agreement shall be decided by applying the laws of the State of New York, without regard to conflicts of law principles.
6. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument.
7. Entire Agreement; Amendment. This Agreement constitutes the entire agreement between you and the Company with respect to the Retention Award and supersedes any and all prior agreements or understandings between you and the Company with respect to the Retention Award, whether written or oral. This Agreement may be amended or modified only by a written instrument executed by you and the Company.

345 Park Avenue South
3rd Floor
New York, NY 10010
+1 646-844-0337
info@protaratx.com
www.protaratx.com



We hope this arrangement encourages your continued commitment to the Company. Please acknowledge your agreement to the terms of this Agreement by countersigning it in the space below and returning it to me.

Sincerely yours,

PROTARA THERAPEUTICS, INC.

By: /s/ Jesse Shefferman

Name: Jesse Shefferman

Title: Chief Executive Officer

Accepted and agreed:

/s/ Jacqueline Zummo

Jacqueline Zummo, Ph.D.

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

I, Jesse Shefferman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of Protara Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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 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: May 2, 2024

/s/ Jesse Shefferman
Jesse Shefferman
Chief Executive Officer
(Principal Executive Officer)

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

I, Patrick Fabbio, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2024 of Protara Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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 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: May 2, 2024

/s/ Patrick Fabbio

Patrick Fabbio
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Protara Therapeutics, Inc. (the "Corporation") on Form 10-Q for the fiscal quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jesse Shefferman, as Chief Executive Officer of the Corporation, and I, Patrick Fabbio, as Chief Financial Officer of the Corporation, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

Date: May 2, 2024

By: /s/ Jesse Shefferman
Jesse Shefferman
Chief Executive Officer
(Principal Executive Officer)

Date: May 2, 2024

By: /s/ Patrick Fabbio
Patrick Fabbio
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Corporation and will be retained by the Corporation and furnished to the Securities and Exchange Commission or its staff upon request. This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Corporation specifically incorporates it by reference.