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 September 30, 2024

or

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

For the transition period from to

Commission File Number: 001-36694

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

Delaware	20-4580525
(State or other jurisdiction of incorporation or organization)	(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 November 7, 2024 there were 20,629,772 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	
	September 30, 2024	**December 31, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 51,757	$ 39,586
Marketable debt securities	29,742	25,994
Prepaid expenses and other current assets	3,583	3,125
Total current assets	85,082	68,705
Restricted cash, non-current	745	745
Property and equipment, net	1,109	1,296
Operating lease right-of-use asset	4,514	5,264
Other assets	2,640	2,944
Total assets	$ 94,090	$ 78,954
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,295	$ 2,434
Accrued expenses and other current liabilities	5,268	2,732
Operating lease liability	1,079	983
Total current liabilities	8,642	6,149
Operating lease liability, non-current	3,657	4,484
Total liabilities	12,299	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 September 30, 2024 and December 31, 2023, 7,991 shares issued and outstanding as of September 30, 2024 and December 31, 2023.	-	-
Common stock, $0.001 par value, authorized 100,000,000 shares:		
Common stock, 20,629,772 and 11,364,903 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.	21	11
Additional paid-in capital	313,952	268,725
Accumulated deficit	(232,211)	(200,384)
Accumulated other comprehensive income (loss)	29	(31)
Total stockholders' equity	81,791	68,321
Total liabilities and stockholders' equity	$ 94,090	$ 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 September 30,		For the Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 8,070	$ 6,218	$ 22,205	$ 18,608
General and administrative	4,260	4,482	12,637	13,964

Total operating expenses	12,330	10,700	34,842	32,572
Loss from operations	(12,330)	(10,700)	(34,842)	(32,572)
Other income (expense), net:				
Interest and investment income	1,111	840	3,015	2,373
Other income (expense), net	1,111	840	3,015	2,373
Net income (loss)	$ (11,219)	$ (9,860)	$ (31,827)	$ (30,199)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (0.50)	$ (0.87)	$ (1.74)	$ (2.67)
Weighted-average shares outstanding, basic and diluted	22,329,772	11,347,887	18,342,566	11,320,027
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities	29	171	60	523
Other comprehensive income (loss)	29	171	60	523
Comprehensive income (loss)	$ (11,190)	$ (9,689)	$ (31,767)	$ (29,676)

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	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2022	8,027	$ -	11,267,389	$ 11	$ 262,724	$ (159,964)	$ (688)	$ 102,083
Issuance of common stock upon 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
Unrealized gain (loss) on marketable debt securities	-	-	-	-	-	-	219	219
Net income (loss)	-	-	-	-	-	(9,045)	-	(9,045)
Balance at March 31, 2023	8,027	$ -	11,306,753	$ 11	$ 264,235	$ (169,009)	$ (469)	$ 94,768
Issuance of common stock upon settlement of restricted stock units	-	-	1,209	-	-	-	-	-
Stock-based compensation - restricted stock units	-	-	-	-	326	-	-	326
Stock-based compensation - stock options	-	-	-	-	1,292	-	-	1,292
Unrealized gain (loss) on marketable debt securities	-	-	-	-	-	-	133	133
Net income (loss)	-	-	-	-	-	(11,294)	-	(11,294)
Balance at June 30, 2023	8,027	$ -	11,307,962	$ 11	$ 265,853	$ (180,303)	$ (336)	$ 85,225
Issuance of common stock upon settlement of restricted stock units	-	-	21,118	-	(27)	-	-	(27)
Stock-based compensation - restricted stock units	-	-	-	-	275	-	-	275
Stock-based compensation - stock options	-	-	-	-	1,172	-	-	1,172
Conversion of Series 1 Convertible Preferred Stock to Common Stock	(36)	-	35,823	-	-	-	-	-
Unrealized gain (loss) on marketable debt securities	-	-	-	-	-	-	171	171
Net income (loss)	-	-	-	-	-	(9,860)	-	(9,860)
Balance at September 30, 2023	7,991	$ -	11,364,903	$ 11	$ 267,273	$ (190,163)	$ (165)	$ 76,956
Balance at December 31, 2023	7,991	$ -	11,364,903	$ 11	$ 268,725	$ (200,384)	$ (31)	$ 68,321
Issuance of common stock upon 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
Unrealized gain (loss) on marketable debt securities	-	-	-	-	-	-	30	30
Net income (loss)	-	-	-	-	-	(11,095)	-	(11,095)
Balance at March 31, 2024	7,991	$ -	11,433,837	$ 11	$ 269,875	$ (211,479)	$ (1)	$ 58,406
Issuance of common stock, pre-funded warrants and warrants from private placement, net of offering costs of $3,034	-	-	9,143,380	10	41,954	-	-	41,964
Issuance of common stock upon settlement of restricted stock units	-	-	4,975	-	(7)	-	-	(7)
Issuance of common stock upon exercise of stock options	-	-	47,580	-	135	-	-	135
Stock-based compensation - restricted stock units	-	-	-	-	111	-	-	111
Stock-based compensation - stock options	-	-	-	-	953	-	-	953
Unrealized gain (loss) on marketable debt securities	-	-	-	-	-	-	1	1
Net income (loss)	-	-	-	-	-	(9,513)	-	(9,513)
Balance at June 30, 2024	7,991	$ -	20,629,772	$ 21	$ 313,021	$ (220,992)	$ -	$ 92,050
Stock-based compensation - restricted stock units	-	-	-	-	109	-	-	109
Stock-based compensation - stock options	-	-	-	-	822	-	-	822
Unrealized gain (loss) on marketable debt securities	-	-	-	-	-	-	29	29
Net income (loss)	-	-	-	-	-	(11,219)	-	(11,219)
Balance at September 30, 2024	7,991	$ -	20,629,772	$ 21	$ 313,952	$ (232,211)	$ 29	$ 81,791

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 Nine Months Ended September 30,	
	2024	**2023**
Cash flows used in operating activities:		
Net income (loss)	$ (31,827)	$ (30,199)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	3,221	4,640
Operating lease right-of-use asset	750	711
Depreciation	250	234
Amortization of premium (Accretion of discount) on marketable debt securities	(406)	(331)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(458)	(1,919)
Other assets	304	(2,297)
Accounts payable	(139)	918
Accrued expenses and other current liabilities	2,536	68
Operating lease liabilities	(731)	(682)
Net cash provided by (used in) operating activities	(26,500)	(28,857)
Cash flows from investing activities:		
Purchase of marketable debt securities	(29,382)	(12,186)
Proceeds from maturity and redemption of marketable debt securities	26,100	50,820
Purchase of property and equipment	(63)	(45)
Net cash provided by (used in) investing activities	(3,345)	38,589
Cash flows from financing activities:		
Proceeds from private placement, net of offering costs of $ 3,034	41,964	-
Proceeds from exercise of stock options	135	-
Taxes paid related to net share settlement of restricted stock units	(83)	(91)
Net cash provided by (used in) financing activities	42,016	(91)
Net increase (decrease) in cash and cash equivalents and restricted cash	12,171	9,641
Cash and cash equivalents and restricted cash - beginning of year	40,331	24,872

Cash and cash equivalents and restricted cash - end of period	$ 52,502	$ 34,513
Reconciliation of cash and cash equivalents and restricted cash to the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 51,757	$ 33,768
Restricted cash, non-current	745	745
Cash and cash equivalents and restricted cash	$ 52,502	$ 34,513

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 support, or PS.

Liquidity and Capital Resources

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 September 30, 2024 and for the three and nine months ended September 30, 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 and nine months ended September 30, 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.

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.

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

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid instruments with an original maturity of three months or less when acquired to be cash equivalents. Cash and cash equivalents are held in depository, money market accounts and U.S. Treasury securities, and are reported at fair value.

The Company's restricted cash balances consist of cash deposits to collateralize letter of credit obligations.

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 and 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 governments and corporations. The Company has adopted an investment policy that includes guidelines relative to credit quality, diversification and maturities to preserve principal and liquidity.

Net Income (Loss) Per Share Attributable to Common Stockholders

Basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period plus, if dilutive, the common equivalent shares for the period from unvested restricted common stock, outstanding stock options, potential shares issuable under the 2024 ESPP, the conversion of preferred stock, and the exercise of common warrants, or the Common Warrants, issued in connection with the 2024 Private Placement, discussed further in Note 10. Stockholders' Equity.

Given the nominal exercise price associated with the Company's pre-funded warrants, or the Pre-Funded Warrants, issued in connection with the 2024 Private Placement (discussed further in Note 10. Stockholders' Equity) such Pre-Funded Warrants are included in the calculation of basic and diluted net income (loss) per share. The exercise price per warrant is deemed nonsubstantive when compared to the market value of the underlying common shares. The weighted average impact of the 1,700,000 unexercised Pre-Funded Warrants as of September 30, 2024 was included in the Company's calculation of basic and diluted loss per share.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in the Financial Accounting Standards Board, or the FASB, Accounting Standards Codification, or ASC, 480, *Distinguishing Liabilities from Equity*, or ASC 480, and ASC 815, *Derivatives and Hedging*, or ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. Finally, the Company determines if the warrants meet the definition of a derivative based on their contractual terms. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and at each balance sheet date thereafter. Changes in the estimated fair value of liability-classified warrants are recognized as a non-cash gain or loss on the consolidated statements of operations. The Company also evaluates if changes in contractual terms or other considerations would result in the reclassification of outstanding warrants from liabilities to stockholders' equity (or vice versa).

The fair market value of the warrants may be estimated using a Black-Scholes option-pricing model or potentially more complex valuation models depending on the nature of the contractual terms.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, 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. The Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

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:

(amounts in thousands, except share and per share data)

- 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 September 30, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds[(a)]	$ 41,266	$ -	$ -	$ 41,266
U.S. Treasury securities[(a)]	9,989	-	-	9,989
Restricted cash, non-current:				
Money market funds[(b)]	745	-	-	745
Marketable debt securities:				
U.S. Treasury securities[(c)]	29,742	-	-	29,742
Total	$ 81,742	$ -	$ -	$ 81,742

	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	$ 39,776	$ 25,994	$ -	$ 65,770

(a) Money market funds, U.S. Treasury securities 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) U.S. Treasury securities and 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.

Money market funds and U.S. Treasury securities 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 September 30, 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 presented within marketable debt securities were classified as available-for-sale. All marketable debt securities, including securities presented within cash and cash equivalents, consist of the following:

	As of September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities - presented in cash and cash equivalents	$ 9,988	$ 1	$ -	$ 9,989

(amounts in thousands, except share and per share data)

U.S. Treasury securities - presented in marketable debt securities	29,714	28	-	29,742
Total	$ 39,702	$ 29	$ -	$ 39,731

	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 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). For the three and nine months ended September 30, 2024 and 2023 there were no realized gains or losses. Gains, if any, would be included in investment income within the 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 90 days or less as cash equivalents. 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 remaining maturities of all debt securities held at September 30, 2024 was less than one year. 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.

As of September 30, 2024, no securities were held in a loss position. As of December 31, 2023, marketable debt securities in a loss position consist of the following:

	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	$ 21,997	$ (28)	$ 3,997	$ (3)	$ 25,994	$ (31)

As of September 30, 2024 and December 31, 2023, it was determined that there were no expected credit losses.

Interest and Investment Income

Interest and investment income consist of the following:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Interest income	$ 659	$ 710	$ 2,468	$ 2,025
Dividend income	8	2	28	6
Accretion of discount (Amortization of premium), net	444	128	519	342
Total interest and investment income	$ 1,111	$ 840	$ 3,015	$ 2,373

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	As of	
	September 30, 2024	December 31, 2023
Prepaid research and development	$ 2,640	$ 1,957
Prepaid insurance	360	659
Prepaid retention bonuses	140	-
Prepaid software	99	67
Accrued interest on marketable debt securities	-	242
Other prepaid expenses	341	163
Other current assets	3	37
Total	$ 3,583	$ 3,125

6. Other Assets

Other assets consist of the following:

(amounts in thousands, except share and per share data)

	As of	
	September 30, 2024	December 31, 2023
Prepaid research and development, non-current	$ 2,539	$ 2,661
Prepaid insurance, non-current	68	272
Other non-current assets	33	11
Total	$ 2,640	$ 2,944

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of	
	September 30, 2024	December 31, 2023
Research and development costs	3,385	440
Employee costs	1,515	2,112
Other expenses	368	180
Total	$ 5,268	$ 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 $995 during each of the nine months ended September 30, 2024 and 2023.

Lease expense consist of the following:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease expense	$ 338	$ 341	$ 1,014	$ 1,024
Total	$ 338	$ 341	$ 1,014	$ 1,024

Variable lease expenses for the three and nine months ended September 30, 2024 were $ 26 and $72, respectively. Variable lease expenses for the three and nine months ended September 30, 2023 were not material.

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

	As of September 30, 2024
Weighted-average discount rate	7.0%
Weighted-average remaining lease term – operating lease (in months)	46

As of September 30, 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 nine months ended September 30, 2024)	$ 332
2025	1,395
2026	1,429
2027	1,429
2028	718
Thereafter	87
Total operating lease payments	5,390
Less: imputed interest	(654)
Present value of future minimum lease payments	$ 4,736

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 September 30, 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 20,629,772 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.

Preferred Stock

As of September 30, 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 September 30, 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.

April 2024 Equity Financing

On April 5, 2024, the Company entered into a subscription agreement with certain purchasers, or the Purchasers, pursuant to which the Company agreed to sell and issue to the Purchasers, in a private placement, or the 2024 Private Placement, an aggregate of 9,143,380 shares of the Company's common stock, or the Shares, and, for certain purchasers, pre-funded warrants, or the Pre-Funded Warrants, to purchase an aggregate of 1,700,000 shares of the Company's common stock. In each case, the Shares or Pre-Funded Warrants were issued with warrants, or the Common Warrants, to purchase an aggregate of up to 10,843,380 shares of the Company's common stock. Each Share, 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. The closing date of the 2024 Private Placement was April 10, 2024. The 2024 Private Placement resulted in gross proceeds of approximately $ 44,998 and net proceeds of approximately $42,964, reflecting approximately $ 3,034 of placement agent's fees, legal costs and other expenses connected with the transaction.

The Pre-Funded Warrants are exercisable at any time after April 10, 2024, at an exercise price of $ 0.001 per share. The Common Warrants are exercisable on or prior to the earlier of (i) April 10, 2027 and (ii) 90 days after the public announcement that the Company has demonstrated a six-month complete response rate of minimum 42% from at least 25 Bacillus Calmette-Guérin (BCG)-Unresponsive patients in the ADVANCED-2 (Cohort B) clinical trial, at an exercise price of $5.25 per share.

The Pre-Funded Warrants and the Common Warrants are exercisable so long as the aggregate number of shares of the Company's common stock beneficially owned by the holder (together with its affiliates) would not exceed 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of such Pre-Funded Warrant or Common Warrant, as applicable. Such percentage may be increased or decreased to any number not in excess of 19.99% at the holder's election upon notice to the Company, any such increase not to take effect until the sixty-first day after notice to the Company.

Both the Pre-Funded Warrants and the Common Warrants contain standard adjustments to the exercise price, inclusive of stock splits, stock dividends and pro rata distributions and contain customary terms regarding the treatment of such Pre-Funded Warrants or Common Warrants in the event of a fundamental transaction, which include but are not limited to a merger or consolidation involving the Company, a sale of all or substantially all of the assets of the Company or a business combination resulting in any person acquiring more than 50% of the outstanding shares of Common Stock of the Company.

The Company concluded that the Pre-Funded Warrants and Common Warrants met the requirements to be classified in stockholders' equity.

The fair market value of the Pre-Funded Warrants was estimated as the difference between the share price of our stock on the agreement date and the exercise price of the Pre-Funded Warrant.

The fair market value of the Common Warrants at their issuance was estimated using the Black-Scholes option-pricing model. The assumed dividend yield was based upon the Company's expectation of not paying dividends in the foreseeable future. Expected volatility for the Company's common stock was determined based on the historical volatility of the Company over the full term of the warrant. The risk-free interest rate was based upon the U.S. Treasury yield curve commensurate with the expected term at the time of grant. The expected term of the Common Warrants was calculated utilizing the three-year expiration date, taking into consideration the possibility of an accelerated expiration date pursuant to the terms of the Common Warrants.

The estimated fair market values of the Shares, Pre-Funded Warrants and Common Warrants have been recorded in additional paid in capital. As of September 30, 2024, no warrants have expired or been exercised.

11. Stock-Based Compensation

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. 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.

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. Following the approval of the Company's 2024 Equity Incentive Plan, or 2024 EIP, by the stockholders of the Company on June 7, 2024, no additional awards will be made under the 2014 Equity Incentive Plan.

As of September 30, 2024, there were 3,700,664 shares of common stock subject to outstanding awards.

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 total number of shares authorized under the 2017 Equity Incentive Plan was 2,000,000 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.

As of September 30, 2024, there were 134,328 shares of common stock subject to outstanding awards.

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 total number of shares authorized under the 2020 Inducement Plan is 600,000 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 September 30, 2024, there were 512,900 shares of common stock subject to outstanding awards and 87,100 shares of common stock available for future issuance under the 2020 Inducement Plan.

2024 Equity Incentive Plan

On June 7, 2024, the stockholders approved the 2024 EIP. The 2024 EIP provides for the grant of 1,500,000 shares of common stock for stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, performance shares and other stock and cash awards.

Terms of the stock awards, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the plan.

As of September 30, 2024, there were 72,000 shares of common stock subject to outstanding awards and 1,428,000 shares of common stock available for future issuance under the 2024 EIP.

2024 Employee Stock Purchase Plan

On June 7, 2024, the stockholders of the Company approved the 2024 Employee Stock Purchase Plan, or 2024 ESPP. The number of shares authorized under the 2024 ESPP is 1,000,000.

As of September 30, 2024, the number of shares available for issuance was 1,000,000. During the three and nine months ended September 30, 2024, no shares were issued under the 2024 ESPP.

(amounts in thousands, except share and per share data)

Restricted Stock Units

The following table summarizes restricted stock unit, or RSU, activities for the nine months ended September 30, 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	(39,886)	2.89
Vested	(111,579)	10.45
Non-vested as of September 30, 2024	295,914	$ 2.69

The fair value of RSUs is amortized on a straight-line basis over the requisite service period of the respective awards. As of September 30, 2024, the unamortized value of RSUs was $485. As of September 30, 2024, the weighted average remaining amortization period was 1.83 years. As of September 30, 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 nine months ended September 30, 2024, the Company issued 73,909 shares of the Company's common stock from the net settlement of 111,579 RSUs. The Company paid $ 83 in connection with the net share settlement of these RSUs.

Stock Options

The following table summarizes stock option activities for the nine months ended September 30, 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	1,373,700	1.99	-	-
Exercised	(47,580)	2.83	-	23
Forfeited	(302,137)	3.14	-	-
Expired	(89,710)	12.97	-	-
Outstanding as of September 30, 2024	3,834,478	$ 7.31	7.92	$ 2
Vested and expected to vest at September 30, 2024	3,834,478	$ 7.31	7.92	$ 2
Exercisable as of September 30, 2024	1,819,217	12.17	6.89	-

(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 September 30, 2024, respectively.

The weighted average grant date fair value per share of the options granted during the nine months ended September 30, 2024 and 2023 was $ 1.58 and $2.40, respectively. As of September 30, 2024, there was approximately $ 4,274 of unrecognized share-based compensation for unvested stock option grants, which is expected to be recognized over a weighted average period of 2.58 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 September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Restricted stock units	$ 109	$ 275	$ 371	$ 915
Stock options	822	1,172	2,850	3,725
Total	$ 931	$ 1,447	$ 3,221	$ 4,640

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 228	$ 419	$ 839	$ 1,233
General and administrative	703	1,028	2,382	3,407
Total	$ 931	$ 1,447	$ 3,221	$ 4,640

12. Net Income (Loss) per Common Share

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator				
Net income (loss) attributable to common stockholders	$ (11,219)	$ (9,860)	$ (31,827)	$ (30,199)
Denominator				
Weighted-average shares of common stock outstanding, basic and diluted	22,329,772	11,347,887	18,342,566	11,320,027
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (0.50)	$ (0.87)	$ (1.74)	$ (2.67)

The Pre-Funded Warrants for the purchase of 1,700,000 shares of common stock with an exercise price of $ 0.001 per share have been included in the computation of the net loss per share attributable to common stockholders – basic and diluted, as the exercise price was deemed non-substantive.

Since the Company was in a net loss position for all periods presented, net income (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 income (loss) per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of September 30,	
	2024	2023
Stock options issued and outstanding	3,834,478	2,933,525
Restricted stock units issued and outstanding	585,414	526,479
Series 1 Convertible Preferred Stock issued and outstanding	7,993,217	7,993,217
Common Warrants, issued and outstanding	10,843,380	-
Total potentially dilutive shares	23,256,489	11,453,221

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 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 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, which has been in shortage for several decades creating a need for new therapies. The mechanism of action of TARA-002 is similar in some ways to that of BCG. Mechanistically, TARA-002 and BCG are similar in that in that they are both intravesically administered broad-spectrum immune potentiators that drive a TH-1 pro-inflammatory response and have a preference to M1 polarization. We found several important differences when we compared the two drugs in pre-clinical studies that we believe make TARA-002 a potentially compelling new therapy. We found that TARA-002 is a NOD2/TLR 2 agonist (NOD2 is defined as Nucleotide-binding oligomerization domain 2; TLR 2 is defined as toll-like receptor 2) and BCG is a toll-like receptor 4, or TLR4, agonist. When we compared TARA-002 directly to BCG, in a cytotxcitiy assay, we found that TARA-002 resulted in significantly stronger tumor cell killing compared to BCG. We also found that TARA-002 resulted in significantly higher upregulation of key pro-inflammatory cytokines and chemokines, including tumor necrosis factor alpha, or TNF-α, and interferon gamma, or interferon-γ. It's worth noting that TARA-002 meaningfully down-regulates Interleukin-8, or IL-8, which at prolonged elevations is thought to increase risk for tumor recurrence in bladder cancer after BCG therapy.

We conducted 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 was 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.

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 (10KE, 20KE, and 40KE), and no dose limiting toxicities were observed. A maximum tolerated dose was not determined, and the

Company 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, or TEAEs, 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. An exploratory cohort of dose escalation at the 80KE was also completed demonstrating similar safety to the 40KE dose. The 80KE dose could potentially be used as we continue to explore priming doses with TARA-002.

Additionally, we completed an open-label expansion clinical trial, or ADVANCED-1EXP, evaluating intravesical TARA-002 at the 40KE dose in CIS patients, including BCG-Naïve, BCG-Unresponsive, and BCG-Experienced patients and are conducting an open-label Phase 2 clinical trial, or ADVANCED-2, assessing intravesical TARA-002 in NMIBC patients with CIS (± Ta/T1) who are BCG-Naïve (n=27) and BCG-Unresponsive (n≈100).

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 TEAEs. TEAEs 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 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	-	-%
	7	3	43%
BCG-Naïve			
CIS-only	2	2	100%
CIS +Ta/T1	7	1	14%
	9	3	33%
	16	6	38%
By Stage of Disease at Baseline			
CIS-only	8	5	63%
CIS +Ta/T1	8	1	13%
	16	6	38%
By Study			
Phase 1a	3	1	33%
Phase 1b-EXP	8	3	38%
Phase 2 Naïve	5	2	40%
	16	6	38%

Data cutoff date: March 19, 2024

We expect to share preliminary results from a pre-planned interim analysis of the ongoing ADVANCED-2 trial in the fourth quarter of 2024. The analysis is expected to include at least 10 patients who are six-month evaluable. The BCG-Unresponsive cohort has been designed to be registrational aligned with the United States Food and Drug Administration's, or FDA's, 2024 BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment Draft 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, we anticipate sharing interim 12-month results from the ADVANCED-2 trial in the middle 2025.

In addition to the ADVANCED-2 trial, we will continue to explore systemic priming prior to initiation of intravesical administration to assess the anti-tumor activity of TARA-002. We continue to believe that combination therapy may play a meaningful role in the NMIBC treatment paradigm and intend to prioritize trials assessing TARA-002 in combination with other therapies. Given TARA-002's mechanism of action and safety profile, we believe it has strong potential as a combination agent and we continue to evaluate the best potential combination therapy options for our clinical program.

We also 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 support, or PS, which includes both nutrition and fluids. 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. PS patients are unable to synthesize choline from enteral nutrition sources, and there are currently no available PS formulations containing choline. Every year in the U.S. there are approximately 90,000 people who require PS at home and of those approximately

30,000 are on long-term PS. IV Choline Chloride has the potential to become the first FDA approved IV choline formulation for PS patients.

In April 2024, we announced alignment with the FDA on a registrational path forward for IV Choline Chloride in patients dependent on PS. 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 adult and adolescent patients on PS for whom oral or enteral nutrition is not possible, insufficient, or contraindicated. The FDA has also granted IV Choline Chloride Fast Track designation for this indication. Feedback from the FDA on our IV Choline Chloride program indicated that a single study with an endpoint of restoring choline levels in PS patients could serve as the basis for a regulatory filing for IV Choline Chloride. We plan to advance the development of IV Choline Chloride as a source of choline for adult and adolescent patients on long-term PS and intend to initiate THRIVE-3, a registrational Phase 3 trial in the first quarter of 2025.

Choline is recommended for patients on parenteral nutrition, or 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. The U.S. Patent and Trademark Office has issued us a U.S. patent claiming a choline composition and a U.S. patent claiming a method for treating choline deficiency with a choline composition, each with a term expiring in 2041.

In September 2024, we presented the results of THRIVE-1, a prospective, observational study evaluating the prevalence of choline deficiency and liver injury in patients dependent on PS at the ESPEN Congress. The study found that 78% of patients who are dependent on PS were choline deficient, and that 63% of choline deficient participants had liver dysfunction, including steatosis, cholestasis and hepatobiliary injury, underscoring the need for IV choline supplementation in this patient population.

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 (≥ 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 completed enrollment in the first 3-patient safety cohort and are enrolling the second safety cohort.

In September 2024, we announced interim data from the first safety cohort in the STARBORN-1 trial. Of three patients treated in the first cohort, which enrolled individuals six years to less than 18 years of age, two patients treated with TARA-002 achieved a complete response after receiving one injection of TARA-002; the responses were seen in a patient with a macrocystic lymphatic malformation and a patient with a maxillofacial cyst called a ranula. The safety and tolerability seen in this cohort was consistent with that of the historical experience with OK-432 and included TEAEs of pain, swelling, fatigue and body temperature increases. All TEAEs were mild to moderate and resolved.

We believe TARA-002 may also have the potential to be used to treat other maxillofacial cysts based on the historical literature from the TARA-002 predecessor, OK-432, as well as recent data in the one pediatric patient with a ranula, which resolved nearly 100% after a single 1KE injection of TARA-002. While completing STARBORN-1 in LMs is our priority, we believe there may be an opportunity in the future to explore the potential of TARA-002 to treat different types of maxillofacial cysts.

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 September 30, 2024, we had an accumulated deficit of approximately $232.2 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 September 30, 2024, we had approximately $81.5 million in cash, cash equivalents and marketable debt securities. On April 10, 2024, we completed a private placement, or the 2024 Private Placement, pursuant to which we sold 9,143,380 shares of our common stock, or the Shares, and, for certain purchasers, pre-funded warrants, or the Pre-Funded Warrants, to purchase an aggregate of 1,700,000 shares of our common stock. In each case, the Shares and Pre-Funded Warrants were accompanied by common warrants, or the Common Warrants, to purchase an aggregate of up to 10,843,380 shares of common stock at a price of $5.25. Each Share, along with its attached Common Warrant, has a purchase price of $4.15, and each Pre-Funded Warrant, along with its attached Common Warrant, has a purchase price of $4.149. We received gross proceeds of approximately $45.0 million and net proceeds of approximately $42.0 million, reflecting approximately $3.0 million of placement agent's fees, legal costs and other expenses in connection with the transaction.

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 September 30, 2024 and 2023

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

	For The Three Months Ended September 30,		Period-to-Period
	2024	2023	Change
Operating expenses:			
Research and development	$ 8,070	$ 6,218	$ 1,852
General and administrative	4,260	4,482	(222)
Total operating expenses	12,330	10,700	1,630
Loss from operations	(12,330)	(10,700)	(1,630)
Other income (expense), net:			
Interest and investment income	1,111	840	271
Other income (expense), net	1,111	840	271
Net income (loss)	$ (11,219)	$ (9,860)	$ (1,359)

Research and development expenses. During the three months ended September 30, 2024, our research and development expenses were approximately $8.1 million, which represented an increase of approximately $1.9 million as compared to the three months ended September 30, 2023. This increase was primarily due to an increase in clinical and non-clinical study costs related to TARA-002 of $1.5 million and IV Choline Chloride of $0.4 million.

General and administrative expenses. During the three months ended September 30, 2024, our general and administrative expenses were approximately $4.3 million, which represented a decrease of approximately $0.2 million as compared to the three months ended September 30, 2023. This decrease was primarily due to a reduction of $0.6 million in personnel-related expenses (inclusive of $0.3 million of stock-based compensation), offset partially by increases in market development, business development and investor relations activities of $0.3 million.

Other income (expense), net. During the three months ended September 30, 2024, our other income (expense), net was approximately $1.1 million, which represented an increase of approximately $0.3 million as compared to the three months ended September 30, 2023, due primarily to higher investment return on a higher invested balance.

Comparison of the Nine Months Ended September 30, 2024 and 2023

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

	For The Nine Months Ended September 30,	Period-to-Period

	2024	2023	Change
Operating expenses:			
Research and development	$ 22,205	$ 18,608	$ 3,597
General and administrative	12,637	13,964	(1,327)
Total operating expenses	34,842	32,572	2,270
Loss from operations	(34,842)	(32,572)	(2,270)
Other income (expense), net:			
Interest and investment income	3,015	2,373	642
Other income (expense), net	3,015	2,373	642
Net income (loss)	$ (31,827)	$ (30,199)	$ (1,628)

Research and development expenses. During the nine months ended September 30, 2024, our research and development expenses were approximately $22.2 million, which represented an increase of approximately $3.6 million as compared to the nine months ended September 30, 2023. This increase was primarily due to an increase in clinical and non-clinical study costs related to TARA-002 of $2.4 million and IV Choline Chloride of $0.2 million. There was also an increase in personnel-related expenses of $1.0 million (inclusive of an $0.4 million reduction of stock-based compensation).

General and administrative expenses. During the nine months ended September 30, 2024, our general and administrative expenses were approximately $12.6 million, which represented a decrease of approximately $1.3 million as compared to the nine months ended September 30, 2023. This decrease was primarily due to a reduction of $1.4 million in personnel-related expenses (inclusive of $1.0 million of stock-based compensation).

Other income (expense), net. During the nine months ended September 30, 2024, our other income (expense), net was approximately $3.0 million, which represented an increase of approximately $0.6 million as compared to the nine months ended September 30, 2023, due primarily to higher investment return on a higher invested balance.

Liquidity and Capital Resources

Overview

As of September 30, 2024 and December 31, 2023, our cash, cash equivalents and marketable debt securities were $81.5 million and $65.6 million, respectively. We have not generated revenues since our inception and have incurred net losses of $31.8 million and $30.2 million for the nine months ended September 30, 2024 and 2023, respectively, and $11.2 million and $9.9 million for the three months ended September 30, 2024 and 2023 respectively. As of September 30, 2024, we had working capital of $76.4 million and stockholder's equity of $81.8 million. During the nine months ended September 30, 2024, net cash flows used in operating activities were $26.5 million, consisting primarily of a net loss of $31.8 million including non-cash expenses of $3.8 million, as well as working capital adjustments of $1.5 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 our 2024 Private Placement, pursuant to which we sold 9,143,380 Shares, 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 Common 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, prevailing market interest rates, general economic uncertainty or other factors, we may need to curtail planned development activities. A recession or market correction, continued supply chain disruptions and/or inflation could materially affect our business and the value of our common stock.

Cash Flows

The following table summarizes our sources and uses of cash for the nine months ended September 30, 2024 and 2023 (in thousands):

	For The Nine Months Ended September 30,		Period-to-Period
	2024	2023	Change
Net cash provided by (used in) operating activities	$ (26,500)	$ (28,857)	$ 2,357
Net cash provided by (used in) investing activities	(3,345)	38,589	(41,934)
Net cash provided by (used in) financing activities	42,016	(91)	42,107
Net increase (decrease) in cash and cash equivalents, and restricted cash	$ 12,171	$ 9,641	$ 2,530

Comparison of the Nine Months Ended September 30, 2024 and 2023

Net cash used in operating activities was $26.5 million for the nine months ended September 30, 2024 compared to $28.9 million for the nine months ended September 30, 2023. The decrease of $2.4 million in cash used in operating activities was primarily driven by a $5.4 million decrease in working capital adjustments, primarily related to changes in prepaid expenses and other current assets and accrued expenses resulting from the timing of payments to our service providers, offset partially by an increase in net loss of $1.6 million which includes a $1.4 million decrease in non-cash items

including stock-based compensation, operating lease right-of-use asset, depreciation and amortization of premium (accretion of discount) on marketable debt securities.

Net cash provided by (used in) investing activities was $(3.3) million for the nine months ended September 30, 2024 compared to $38.6 million for the nine months ended September 30, 2023. The decrease of $41.9 million resulted primarily from a decrease of $24.7 million of marketable debt securities matured as well as an increase of $17.2 million of marketable debt securities purchased.

Net cash provided by (used in) financing activities was $42.0 million for the nine months ended September 30, 2024 compared to $(0.1) million for the nine months ended September 30, 2023. The increase of $42.1 million resulted primarily from the net proceeds of the 2024 Private Placement transaction, which took place in April 2024.

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 September 30, 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 September 30, 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 September 30, 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

There were no material changes to the risk factors previously disclosed 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 and "Part II, Item 1A —Risk Factors" of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on May 2, 2024.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

During the three months ended September 30, 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	Subscription Agreement, dated April 5, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
10.2	Form of Pre-Funded Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
10.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).

10.4	Registration Rights Agreement, dated April 5, 2024 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 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.

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: November 12, 2024

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

Date: November 12, 2024

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

Exhibit 31.1

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 September 30, 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 Rules13a-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: November 12, 2024

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

Exhibit 31.2

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 September 30, 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 Rules13a-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: November 12, 2024

/s/ Patrick Fabbio
Patrick Fabbio
Chief Financial Officer
(*Principal Financial Officer)*

Exhibit 32.1

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 September 30, 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: November 12, 2024

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

Date: November 12, 2024

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

A signed original of this written statement required by Section906 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.