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, 2021
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)

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 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 ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting 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 ☒

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

As of November 3, 2021 there were 11,235,731 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. You can identify these forward-looking statements by the use of words such as “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seek,” “approximately,” “predict,” “intend,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words. 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:

- the impact of the novel coronavirus disease, or COVID-19, pandemic on our business and operations as well as the business or operations of our manufacturers, research partners, other third parties with whom we conduct business and regulatory agencies;
- 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 remain listed on the Nasdaq Capital Market;
- the impact of government laws and regulations;
- the timing or likelihood of regulatory filings and approvals; and
- our ability to protect our intellectual property position.

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 and the risk factors set forth in Part I, Item 1A Risk Factors, within our Form 10-K filed on March 11, 2021. 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.

SUMMARY OF RISKS AFFECTING OUR BUSINESS

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, and other risks and uncertainties that we face, are set forth in Part II, Item 1A, Risk Factors, and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the United States Securities and Exchange Commission, or SEC, before making investment decisions regarding our securities.

- We have a very limited operating history and have never generated any revenues.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- The COVID-19 pandemic could adversely impact our business, including our clinical development plans.
- We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.
- Our business depends on the successful clinical development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride.
- We have never made a biologics license application, or BLA, or new drug application, or NDA, submission or conducted a clinical trial and may be unable to successfully do so for TARA-002 or IV Choline Chloride.
- TARA-002 is an immunopotentiator, and one indication for which we plan to pursue is the treatment of lymphatic malformations, or LMs. There are no therapies for the treatment of LMs approved by the United States Food and Drug Administration, or the FDA. It is difficult to predict the timing and costs of clinical development for TARA-002 with respect to LMs.
- Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.
- Our product candidates, if approved, will face significant competition, and may face competition sooner than anticipated, and their failure to compete effectively may prevent them from achieving significant market penetration.
- We currently have limited marketing capabilities and no sales organization. If we are unable to grow our sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.
- We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.
- Certain stockholders have the ability to control or significantly influence certain matters submitted to our stockholders for approval.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

PROTARA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	As of	
	September 30, 2021	**December 31, 2020**
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 40,742	$ 168,598
Restricted cash	-	50
Marketable debt securities, current	53,016	-
Prepaid expenses and other current assets	1,937	787
Total current assets	95,695	169,435
Non-current assets:		
Restricted cash, non-current	745	745
Marketable debt securities, non-current	44,652	-
Property and equipment, net	1,729	1,240
Operating lease right-of-use asset	7,413	1,060
Goodwill	29,517	29,517
Other assets, non-current	946	1,160
Total assets	$ 180,697	$ 203,157
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 928	$ 914
Accrued expenses	1,920	1,913
Operating lease liability, current	840	88
Total current liabilities	3,688	2,915
Non-current liabilities:		
Operating lease liability, non-current	6,603	999
Total liabilities	10,291	3,914
Commitments and Contingencies (Note 6)		
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, 2021 and December 31, 2020, 8,027 shares issued and outstanding as of September 30, 2021 and December 31, 2020.	-	-
Common Stock, $0.001 par value, authorized 100,000,000 shares:		
Common Stock, 11,235,731 and 11,211,840 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively.	11	11
Additional Paid in Capital	254,218	245,992
Accumulated Deficit	(83,784)	(46,760)
Accumulated Other Comprehensive Income (Loss)	(39)	-
Total Stockholders' Equity	170,406	199,243
Total Liabilities and Stockholders' Equity	$ 180,697	$ 203,157

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

PROTARA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expense:				
Research & development	$ 4,093	$ 2,796	$ 17,020	$ 8,330
General & administrative	6,737	5,266	20,182	17,157
Total operating expenses	10,830	8,062	37,202	25,487
Operating loss	(10,830)	(8,062)	(37,202)	(25,487)
Other income, net				
Interest income, net	(53)	(92)	(178)	(317)
Total other income, net	(53)	(92)	(178)	(317)
Net loss	(10,777)	(7,970)	(37,024)	(25,170)
Other comprehensive gain (loss):				
Unrealized gains (losses) on available-for-sale marketable debt securities	62	-	(39)	-
Total other comprehensive gain (loss)	62	-	(39)	-
Comprehensive Loss	$ (10,715)	$ (7,970)	$ (37,063)	$ (25,170)
Weighted Average Shares Outstanding, basic and diluted	11,235,507	6,324,295	11,231,513	5,910,849
Net loss per share, basic and diluted	$ (0.96)	$ (1.26)	$ (3.30)	$ (4.26)

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

PROTARA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020
(unaudited)
(in thousands, except share and per share data)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balance at January 1, 2020	-	$ -	2,627,533	$ 3	$ 10,651	$ (12,782)	$ -	$ (2,128)
Issuance of Common Stock in ArTara Private Placement, net of offering costs	-	-	284,875	-	1,867	-	-	1,867
Issuance of Common Stock in Proteon Private Placement, net of offering costs	-	-	1,896,888	2	12,411	-	-	12,413
Issuance of Series 1 Convertible Preferred Stock in Proteon Private Placement, net of offering costs	3,879	-	-	-	25,319	-	-	25,319
Reverse business combination	-	-	1,033,907	1	34,532	-	-	34,533
Stock-based compensation - restricted stock units	-	-	-	-	2,430	-	-	2,430
Stock-based compensation - stock options	-	-	-	-	368	-	-	368
Net loss	-	-	-	-	-	(10,060)	-	(10,060)
Balance at March 31, 2020	3,879	$ -	5,843,203	$ 6	$ 87,578	$ (22,842)	$ -	$ 64,742
Stock-based compensation - restricted stock units	-	-	-	-	1,315	-	-	1,315
Stock-based compensation - stock options	-	-	-	-	514	-	-	514
Net loss	-	-	-	-	-	(7,140)	-	(7,140)
Balance at June 30, 2020	3,879	$ -	5,843,203	$ 6	$ 89,407	$ (29,982)	$ -	$ 59,431
Settlement of RSUs	-	-	20,870	-	-	-	-	-
Exercise of stock options	-	-	57,767	-	530	-	-	530
Issuance of Common Stock in public offering, net of offering costs	-	-	4,600,000	5	73,566	-	-	73,571
Issuance of Series 1 Convertible Preferred in public offering, net of offering costs	4,148	-	-	-	66,283	-	-	66,283
Stock-based compensation - stock options	-	-	-	-	1,474	-	-	1,474
Stock-based compensation - restricted stock units	-	-	-	-	1,307	-	-	1,307
Net loss	-	-	-	-	-	(7,970)	-	(7,970)
Balance at September 30, 2020	8,027	$ -	10,521,840	$ 11	$ 232,567	$ (37,952)	$ -	$ 194,626
Balance at January 1, 2021	8,027	$ -	11,211,840	$ 11	$ 245,992	$ (46,760)	$ -	$ 199,243
Settlement of restricted stock units	-	-	16,766	-	(228)	-	-	(228)
Stock-based compensation - restricted stock units	-	-	-	-	1,303	-	-	1,303
Stock-based compensation - stock options	-	-	-	-	1,437	-	-	1,437
Unrealized losses on available-for-sale marketable debt securities	-	-	-	-	-	-	(164)	(164)
Net loss	-	-	-	-	-	(13,465)	-	(13,465)
Balance at March 31, 2021	8,027	$ -	11,228,606	$ 11	$ 248,504	$ (60,225)	$ (164)	$ 188,126
Settlement of restricted stock units	-	-	5,250	-	-	-	-	-
Stock-based compensation - restricted stock units	-	-	-	-	1,360	-	-	1,360
Stock-based compensation - stock options	-	-	-	-	1,638	-	-	1,638
Unrealized gains on available-for-sale marketable debt securities	-	-	-	-	-	-	63	63
Net loss	-	-	-	-	-	(12,782)	-	(12,782)
Balance at June 30, 2021	8,027	$ -	11,233,856	$ 11	$ 251,502	$ (73,007)	$ (101)	$ 178,405
Settlement of restricted stock units	-	-	1,875	-	-	-	-	-
Stock-based compensation - restricted stock units	-	-	-	-	1,307	-	-	1,307
Stock-based compensation - stock options	-	-	-	-	1,409	-	-	1,409
Unrealized gains on available-for-sale marketable debt securities	-	-	-	-	-	-	62	62
Net loss	-	-	-	-	-	(10,777)	-	(10,777)
Balance at September 30, 2021	8,027	$ -	11,235,731	$ 11	$ 254,218	$ (83,784)	$ (39)	$ 170,406

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

PROTARA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	For the nine months ended September 30,	
	2021	**2020**
Cash flows used in operating activities:		
Net loss	$ (37,024)	$ (25,170)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	8,454	7,407
Operating lease right-of-use asset	712	61
Depreciation	63	71
Amortization of premium on marketable debt securities	1,280	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(605)	1,107
Other Assets, non-current	213	(42)
Accounts payable	14	1,197
Accrued expenses	5	(1,236)
Operating lease liabilities	(707)	(36)
Net cash used in operating activities	(27,595)	(16,641)
Cash flows (used in)/provided by investing activities:		
Cash and restricted cash acquired in connection with the reverse merger with ArTara Therapeutics, Inc.	-	3,719
Purchase of marketable debt securities, available-for-sale	(115,959)	-
Proceeds from maturity of marketable debt securities, available-for-sale	2,600	-
Proceeds from redemption of marketable debt securities, available-for-sale	13,828	-
Purchase of property and equipment	(552)	(373)
Net cash (used in)/provided by investing activities	(100,083)	3,346
Cash flows (used in)/provided by financing activities:		
Proceeds from - ArTara Private Placement, net of offering costs	-	1,867
Proceeds from - Common Stock in Proteon Private Placement, net of offering costs	-	12,413
Proceeds from - Series 1 Convertible Preferred Stock in Proteon Private Placement, net of offering costs	-	25,319
Proceeds from September Series 1 Convertible Preferred, net of offering costs	-	66,284
Proceeds from September Common Stock, net of offering costs	-	73,571
Repayments under short-term debt	-	(1,298)
Proceeds from the exercise of stock options	-	530
Repurchase of shares in connection with settlement of RSUs	(228)	-
Net cash (used in)/provided by financing activities	(228)	178,686
Net (decrease)/increase in cash and cash equivalents and restricted cash	(127,906)	165,391
Cash and cash equivalents and restricted cash - beginning of year	169,393	564
Cash and cash equivalents and restricted cash - end of period	$ 41,487	$ 165,955
Supplemental cash flow information		
Cash paid for:		
Interest	$ -	$ 26
Income Taxes	$ -	$ -
Non-cash investing and financing activities:		
Deferred offering costs recognized that were previously recorded in accrued expenses	$ -	$ 122
Purchase of insurance agreement with notes payable	$ -	$ 1,669
Common stock issued in connection with the reverse merger with ArTara Therapeutics, Inc.	$ -	$ 34,533

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

NOTE 1 – BUSINESS, LIQUIDITY AND CAPITAL RESOURCES

Overview

Protara Therapeutics, Inc., and its consolidated subsidiaries ("Protara" or the "Company"), is a clinical-stage biopharmaceutical company committed to identifying and advancing transformative therapies for the treatment of cancer and rare diseases with significant unmet needs. Protara's portfolio includes two development programs utilizing TARA-002, an investigational cell therapy in development for the treatment of lymphatic malformations ("LMs") and non-muscle invasive bladder cancer ("NMIBC"). The third program in the portfolio is Intravenous ("IV") Choline Chloride, an investigational phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition ("PN") who have intestinal failure associated liver disease ("IFALD"). The fourth program in the portfolio is Vonapanitase, a recombinant human elastase.

Liquidity, Capital Resources and Management Plans

As of September 30, 2021 and December 31, 2020, the Company's cash, cash equivalents, and marketable debt securities were $138,410 and $168,598, respectively. The Company has not generated revenues since its inception and has incurred net losses of $10,777 and $7,970 for the three months ended September 30, 2021 and 2020, respectively, and $37,024 and $25,170 for the nine months ended September 30, 2021 and 2020, respectively. During the nine months ended September 30, 2021, cash flows used in operating activities were $27,595, consisting primarily of a net loss of $37,024 which includes non-cash stock-based compensation charges of $8,454. Since inception, the Company has met its liquidity requirements principally through the sale of its common stock ("Common Stock") and series 1 convertible preferred stock ("Series 1 Convertible Preferred Stock"). The Company manages its capital resources to ensure the Company will continue as a going concern.

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.

Impact of the COVID-19 Pandemic

The impact of the COVID-19 pandemic has been and is expected to continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Severe and/or long-term disruptions in the Company's operations as a result of COVID-19, including in response to related public health directives and orders, will negatively impact its business, operating results and financial condition. Specifically, the Company anticipates that the stress of COVID-19 on healthcare systems around the globe may negatively impact its ability to conduct clinical trials in the near term due primarily to the lack of resources at clinical trial sites and the resulting inability to enroll patients in the trials. The Company also anticipates that the global impact of COVID-19 will negatively impact its ability to conduct nonclinical studies due primarily to laboratory closures and limited availability of personnel. In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit the Company's ability to access capital, which could in the future negatively affect its liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business and the value of its Common Stock.

NOTE 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, 2020 filed with the United States Securities and Exchange Commission ("SEC") on March 11, 2021 (the "2020 Annual Report"). Except as reflected below, there were no changes to the Company's significant accounting policies as described in the 2020 Annual Report. 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, 2021 and for the three and nine months ended September 30, 2021 and 2020 are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. 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 U.S. GAAP for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the 2020 and 2019 audited consolidated financial statements and notes included in the 2020 Annual Report. The December 31, 2020 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 U.S. GAAP for complete financial statements. In the opinion of management, the unaudited interim 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, 2021 and 2020. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or any other interim period or future year or period.

Principles of Consolidation

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

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those which result from using such estimates. Management also utilizes various other estimates, including but not limited to the recoverability of the Company's net deferred tax assets and related valuation allowance, operating lease right-of-use assets and liabilities, determining the fair value and evaluation for impairment of goodwill and stock-based compensation. The results of any changes in accounting estimates are reflected in the financial statements of the period in which the change becomes evident. Estimates and assumptions are reviewed periodically and the effects of revisions are reflected in the period that they are determined to be necessary. Actual results may differ materially from those estimates or assumptions.

Reclassification

Certain amounts in prior periods related to the classification of operating right-of-use assets have been reclassified to conform to current period presentation.

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 and money market accounts and are reported at fair value. The Company's restricted cash balances consist of cash deposits to collateralize letter of credit obligations.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash in the condensed consolidated balance sheets to the total amount shown in the condensed consolidated statements of cash flows:

	As of September 30,	
	2021	**2020**
Cash and cash equivalents	$ 40,742	$ 165,905
Restricted cash, current	-	50
Restricted cash, non-current	745	-
Total cash, cash equivalents, and restricted cash	$ 41,487	$ 165,955

Investments in marketable debt securities

At the time of purchase, the Company determines the appropriate classification of investments based upon its intent with regard to such investments. The Company classifies investments in marketable debt securities with remaining maturities when purchased of greater than three months as available-for-sale. Investments with a remaining maturity date greater than one year are classified as non-current. All of the Company's non-current investments have a maturity date that is within two years of the balance sheet date.

The Company records investments at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss), net in the condensed consolidated statements of operations and comprehensive loss. Of the 36 securities in a loss position held by the Company, there were no securities with an other-than-temporary impairment at September 30, 2021. There were no securities in a continuous unrealized loss position for greater than twelve months at September 30, 2021. The Company has the ability to hold such securities with an unrealized loss until its forecasted recovery. The Company determined that there was no material change in the credit risk of the above investments.

Leases

Under ASC 842, lease expense is recognized as a single lease cost on a straight-line basis over the lease term. The lease term consists of non-cancelable periods and may include options to extend or terminate the lease term, when it is reasonably certain such options will be exercised.

The Company enters into contracts in the normal course of business and assesses whether any such contracts contain a lease. The Company determines if an arrangement is a lease at inception if it conveys the right to control the identified asset for a period of time in exchange for consideration. The Company classifies leases as operating or financing in nature and records the associated lease liability and right-of-use asset on its balance sheet. The lease liability represents the present value of future lease payments, net of lease incentives, discounted using an incremental borrowing rate, which is a management estimate based on the information available at the commencement date of a lease arrangement. With respect to operating lease arrangements, the Company accounts for lease components, and non-lease components that are fixed, as a single lease component. Non-lease components that are variable are expensed as incurred as in the statement of operations and comprehensive loss. The Company recognizes costs associated with lease arrangements having an initial term of 12 months or less ("short-term leases") on a straight-line basis over the lease term; such short-term leases are not recorded on the balance sheet.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Concentrations of Credit Risk

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

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

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. The Company recognizes forfeitures at the time forfeitures occur.

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same way the payroll costs or service payments are classified for the related stock-based award recipient. The fair value of the Company's stock options are estimated using the Black Scholes option-pricing model. The Company lacks company specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly-traded set of peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded stock price.

Research and Development Costs

Research and development costs are expensed as incurred. These expenses include the costs of the Company's proprietary research and development efforts, as well as costs incurred in connection with certain licensing arrangements. Before a compound receives regulatory approval, the Company records upfront and milestone payments made to third parties under licensing arrangements as expense. Upfront payments are recorded when incurred, and milestone payments are recorded when the specific milestone or progress has been achieved. Once a compound receives regulatory approval, the Company records any milestone payments in identifiable intangible assets, less accumulated amortization and, unless the asset is determined to have an indefinite life, the Company amortizes the payments on a straight-line basis over the remaining agreement term or the expected product life cycle, whichever is shorter.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2019-12 - *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in ASU 2019-12 remove certain exceptions to the general principles in Accounting Standards Codification Topic 740. The amendments also clarify and amend existing guidance to improve consistent application. The amendments became effective for annual reporting periods beginning after December 15, 2020. On January 1, 2021, the Company adopted ASU 2019-12. The adoption of this standard did not have a material effect on the Company's financial position, results of operations, or cash flows.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13 - *Measurement of Credit Losses on Financial Statements*. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. In November 2019, the FASB issued ASU 2019-10 – *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which amended the effective date for certain companies. The standard is effective for public companies eligible to be smaller reporting companies for annual and interim periods beginning after December 15, 2022. Early adoption is available. The Company is currently evaluating the potential impact ASU 2016-13, and related updates, will have on its consolidated financial statements and disclosures.

The Company has evaluated other recently issued accounting pronouncements and has concluded that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

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.

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

NOTE 3 – FAIR VALUE MEASUREMENTS

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

	September 30, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate Bonds - presented in marketable debt securities, current	$ 53,018	$ -	$ (2)	$ 53,016
Corporate Bonds - presented in marketable debt securities, non-current	44,689	-	(37)	44,652
Total	$ 97,707	$ -	$ (39)	$ 97,668

As of December 31, 2020, the Company did not have any marketable debt securities.

The Company has recorded the securities at fair value in its condensed consolidated balance sheet and unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss). The amount of realized gains and losses reclassified into earnings are based on the specific identification of the securities sold or securities that reached maturity date. Cash proceeds realized from maturities and redemptions of securities available-for-sale as of September 30, 2021 were $2,600 and $13,828, respectively. There were no sales or maturities of securities in the periods presented.

Gross realized gains and losses on the redemptions of investments have not been material to the Company's consolidated statement of operations.

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

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

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

The following table presents the Company's financial assets measured and recorded at fair value on a recurring basis using the above input categories as of September 30, 2021:

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds - presented in cash and cash equivalents	$ 29,942	$ -	$ -	$ 29,942
Corporate bonds - presented in marketable debt securities, current	-	53,016	-	53,016
Corporate bonds - presented in marketable debt securities, non-current	-	44,652	-	44,652
Total assets	$ 29,942	$ 97,668	$ -	$ 127,610

As of December 31, 2020, the Company did not have any marketable debt securities or money market funds.

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

NOTE 4 – ACCRUED EXPENSES

Included in the Company's accrued expenses within the condensed consolidated financial statements are:

	As of,	
	September 30, 2021	**December 31, 2020**
Payroll	$ 1,455	$ 1,530
Taxes	30	159
Legal fees	26	156
Research and development costs	142	37
Other expenses	267	31
Total	$ 1,920	$ 1,913

NOTE 5 – LEASES

Operating leases

In December 2020, the Company entered into an agreement to lease approximately 10.3 square feet of office space in New York, New York ("Office Lease"), which commenced in April 2021. The office space is owned by an affiliate of Deerfield Management Company, L.P., which together with its affiliates beneficially owned more than 5% of the Company's voting securities at the time the lease was executed. Management determined that the lease terms were on an arms-length basis. Annual rent is approximately $1,117. The Office Lease has a term of approximately seven years, commenced on April 2, 2021, and contains provisions for a free-rent period, annual rent increases, and an allowance for tenant improvements. The Company is responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises. The landlord was deemed to be the accounting owner of the tenant improvements, which were not material for the Office Lease. In conjunction with the Office Lease, the Company established a letter of credit of approximately $745 secured by cash balances included in restricted cash. Variable lease expenses based on our portion of the operating expenses, including real estate taxes and insurance, are recorded as a period expense when incurred. The Company has an option to extend the term by five years, however, the Company determined at the lease commencement date that it was not reasonably certain to exercise the renewal option and such renewal was excluded from the operating lease right-of-use ("ROU") asset and operating lease liability recorded for this lease.

In June 2021, the Company amended the existing agreement with its Contract Development and Manufacturing Organization ("CDMO"), establishing a term of eight-years from the amendment date. These lease terms apply to the leased spaces which prior to the amendment, were leased under a quarter-to quarter arrangement.

Leases classified as operating leases are included in operating lease ROU assets, current operating lease liabilities and non-current operating lease liabilities in the Company's condensed consolidated balance sheets. The operating lease ROU assets and operating lease liabilities represents the Office Lease and the CDMO leased spaces. Cash paid for operating lease liabilities was $707 and $61 during the nine months ended September 30, 2021 and 2020, respectively, which is included in operating cash flows. The ROU asset obtained in exchange for operating lease liabilities related to the Office Lease was $6,549.

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

NOTE 5 – LEASES (Continued)

Operating leases, continued

Supplemental balance sheet information related to the Company's leases was as followed:

	As of	
Operating leases:	**September 30, 2021**	**December 31, 2020**
Operating ROU assets	$ 7,413	$ 1,060
Operating lease liability, current	$ 840	$ 88
Operating lease liability, non-current	$ 6,603	$ 999

The components of lease expense for the three and nine months ended September 30, 2021 and 2020 were as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
Lease cost	**2021**	**2020**	**2021**	**2020**
Operating lease cost	$ 367	$ 21	$ 712	$ 61
Short-term lease cost	4	3	92	151
Total	$ 371	$ 24	$ 804	$ 212

Variable lease expense for the three and nine months ended September 30, 2021 were not material. The Company did not incur variable lease expense for the three and nine months ended September 30, 2020.

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

	As of September 30, 2021	**As of December 31, 2020**
Weighted-average discount rate	7.0%	12.0%
Weighted-average remaining lease term – operating lease (in months)	82	87

As of September 30, 2021, the expected annual minimum lease payments of the Company's operating lease liabilities were as follows:

For Years Ending December 31,	**Operating lease**
2021 (excluding the nine months ended September 30, 2021)	$ 332
2022	1,327
2023	1,327
2024	1,327
2025	1,395
Thereafter	3,664
Total operating lease payments	9,372
Less: imputed interest	1,929
Present value of future minimum lease payments	$ 7,443

NOTE 6 – 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 5 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.

NOTE 7 – STOCKHOLDERS' EQUITY

Authorized Common Stock

As of September 30, 2021 and December 31, 2020, the Company has 100,000,000 shares of Common Stock authorized for issuance, $0.001 par value per share, of which 11,235,731 and 11,211,840 shares were issued and outstanding as of September 30, 2021 and December 31, 2020, respectively.

The holders of Common Stock are entitled to one vote per share.

Authorized Preferred Stock

As of September 30, 2021 and December 31, 2020, the Company has 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 are authorized for issuance and 8,027 shares were issued and outstanding. 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.

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

NOTE 8 – STOCK-BASED COMPENSATION

2020 Inducement Plan

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

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

As of September 30, 2021, 353,734 shares remain available to be issued under the 2020 Inducement Plan.

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

NOTE 8 – STOCK-BASED COMPENSATION (Continued)

2014 Equity Incentive Plan

On October 3, 2014, the stockholders approved the 2014 Plan. On June 20, 2017, the Company's Board of Directors amended the 2014 Plan (the "Amended 2014 Plan"). On July 31, 2017, the stockholders approved this amendment.

The Amended 2014 Plan 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 2014 Plan provides that the number of shares reserved and available for issuance under the 2014 Plan will automatically increase each January 1, beginning January 1, 2015 by four percent of the outstanding shares of Common Stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's Board of Directors prior to each such January 1st. The Amended 2014 Plan clarifies that the number of shares for purposes of calculating the evergreen feature includes the number of shares of Common Stock issuable upon conversion of any security that the Company may issue that is convertible into or exchangeable for Common Stock, including, but not limited to, preferred stock or warrants. On January 1, 2021, pursuant to the Amended 2014 Plan's annual evergreen feature, the number of shares authorized under the Amended 2014 Plan was increased by 812,889 shares to 1,861,189 shares. As of September 30, 2021, 436,154 shares remain available to be issued under the Amended 2014 Plan.

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

2014 Employee Stock Purchase Plan

On October 3, 2014, the stockholders approved the 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP initially authorized the issuance of up to 3,513 shares of Common Stock. The number of shares increases each January 1, commencing on January 1, 2015 and ending on (and including) January 1, 2024, by an amount equal to the lesser of one percent of the outstanding shares as of the end of the immediately preceding fiscal year, 7,025 shares or any lower amount determined by the Company's Board of Directors prior to each such January 1st. On January 1, 2021, pursuant to the increase per the 2014 ESPP, the number of shares authorized under the 2014 ESPP was increased by 7,025 shares to 25,037 shares. As of September 30, 2021, the authorized number of shares under the 2014 ESPP is 25,037 and the number of shares available for issuance is 20,365. During the nine months ended September 30, 2021 and 2020, no shares were issued under the 2014 ESPP.

Restricted Stock Units

The following table summarizes restricted stock unit ("RSU") activities for the nine months ended September 30, 2021:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested 1/1/2021	274,616	$ 29.95
Granted	10,500	-
Forfeited	-	-
Vested	(171,686)	29.40
Non-vested 9/30/2021	113,430	$ 29.04

NOTE 8 – STOCK-BASED COMPENSATION (Continued)

The fair value of restricted stock units is amortized on a straight-line basis over the requisite service periods of the respective awards. As of September 30, 2021, the unamortized value of RSUs was $2,385. As of September 30, 2021, the weighted average remaining amortization period was 2.27 years. As of September 30, 2021 and December 31, 2020, 269,689 and 132,709 RSUs, respectively, have vested that have not yet been settled into shares of Common Stock.

During the nine months ended September 30, 2021, the Company issued 23,891 shares of Common Stock from the net settlement of 34,706 RSUs. The Company paid $228 in connection with the net share settlement of these RSUs.

Stock Option Grants

Options to Directors

During the nine months ended September 30, 2021, the Board of Directors granted options for the purchase of 121,750 shares of Common Stock to members of the board of directors. These options were granted under the Company's 2014 Equity Incentive Plan, had exercise prices ranging from $10.51 to $17.98 per share and a term of 10 years. These options vest ratably over one to three years. The options had a grant date fair value of $1,059.

Options to Employees

During the nine months ended September 30, 2021, the Company granted options for the purchase of 658,550 shares of Common Stock to employees of the Company. These options were granted under the Company's 2014 Equity Incentive Plan and the 2020 Inducement Plan, had exercise prices ranging from $8.23 to $19.82 per share and a term of 10 years. These options vest ratably over approximately four years. The options had a grant date fair value of $9,380.

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

NOTE 8 – STOCK-BASED COMPENSATION (Continued)

Stock Options

The Company determined the fair value of stock options granted based upon the assumptions as provided below.

	For the nine months ended September 30,	
	2021	**2020**
Exercise price	$ 8.23 - $ 19.82	$ 20.51 - $ 51.12
Dividend yield	0.00%	0.00%
Expected volatility	91.00% - 98.00%	95.00% - 101.00%
Risk-free interest rate	0.45% - 1.14%	0.28% - 1.69%
Expected life (in years)	5.27 - 6.08	5.27 - 6.08

Expected Term — The expected term represents the period that the stock-based awards are expected to be outstanding. As the Company does not have sufficient historical experience for determining the expected term of the stock option awards granted, the Company based its expected term for awards issued to employees and directors using the simplified method, which is presumed to be the midpoint between the vesting date and the end of the contractual term.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.

Expected Volatility — Since the Company does not have sufficient trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that the Company considers to be comparable to its business over a period equivalent to the expected term of the stock-based awards.

Dividend Rate — The expected dividend rate is zero as the Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Fair Value of Common Stock — The fair value of the Common Stock is determined by the public market on the date of grant.

The following table summarizes stock option activities for the nine months ended September 30, 2021:

	Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (years)**	**Aggregate Intrinsic Value**
Outstanding 1/1/2021	674,039	$ 25.23	9.06	$ 2,311
Granted	780,300	17.31	-	-
Exercised	-	-	-	-
Forfeited	(60,696)	21.74	-	-
Expired	(7,788)	25.29	-	-
Outstanding 9/30/2021	1,385,855	$ 20.92	8.89	$ -
Exercisable as of 9/30/2021	329,046	$ 22.76	8.13	$ -

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

NOTE 8 – STOCK-BASED COMPENSATION (Continued)

Stock Options, continued

The weighted average grant date fair value of the options granted during the nine months ended September 30, 2021 and 2020 was $13.38 per share and $23.23 per share, respectively. The fair value of stock options is amortized on a straight-line basis over the requisite service periods of the respective awards. As of September 30, 2021, the unamortized value of stock options was $14,892. As of September 30, 2021, the weighted average remaining amortization period was 2.88 years.

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,	
	2021	2020	2021	2020
Restricted Stock Units	$ 1,307	$ 1,307	$ 3,970	$ 5,051
Stock options	1,409	1,474	4,484	2,356
Total	$ 2,716	$ 2,781	$ 8,454	$ 7,407

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,	
	2021	2020	2021	2020
Research and development	$ 392	$ 158	$ 1,114	$ 568
General and administrative	2,324	2,623	7,340	6,839
Total	$ 2,716	$ 2,781	$ 8,454	$ 7,407

NOTE 9 – EMPLOYEE BENEFIT PLAN

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code covering substantially all qualified employees of the Company (the “401(k) Plan”). Under the 401(k) Plan, the Company matches 100% up to a 4% contribution. The 401(k) Plan was implemented in June of 2020. For the three months ended September 30, 2021 and 2020, the Company recorded expense of $50 and $34, respectively, and for the nine months ended September 30, 2021 and 2020, the Company recorded expense of $185 and $42, respectively, representing employer contributions under the 401(k) Plan.

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

NOTE 10 – NET LOSS PER COMMON SHARE

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the basic weighted-average number of shares of common stock outstanding during the period and if dilutive, the weighted-average number of potential shares of common stock, including outstanding stock options, unsettled restricted stock units, and convertible preferred stock. All potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share, and thus they are considered "anti-dilutive." Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	September 30,	
	2021	**2020**
Stock options issued and outstanding	1,385,855	622,339
Restricted stock units issued and outstanding	383,119	407,325
Conversion of Series 1 Convertible Preferred Stock	8,029,039	8,029,039
Total potentially dilutive shares	9,798,013	9,058,703

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

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 identifying and advancing transformative therapies for the treatment of cancer and rare diseases with significant unmet needs. 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 LMs and multiple oncologic indications. It has never been approved outside Japan and Taiwan and we have secured worldwide rights to the asset excluding Japan and Taiwan and have begun to explore its use in rare disease and oncology indications. We are developing TARA-002 in non-muscle invasive bladder cancer, or NMIBC, and in LMs.

TARA-002's lead oncology program is 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-Guerin, or BCG. The mechanism of TARA-002 is similar to BCG. Both TARA-002 and BCG are intravesically administered and elicit a Th1 type immune response and locally activated generally similar array of cytokines and immune cells.

On October 12, 2021, we announced that the Office of Tissues and Advanced Therapies Division, or the OTAT Division, of the FDA's Center for Biologics Evaluation and Research, or CBER, cleared our Investigational New Drug, or IND, application for TARA-002 in NMIBC, including confirmatory, Good Manufacturing Practice, or GMP, -scale comparability data for TARA-002 in relation to OK-432. We plan to commence a Phase 1 dose-finding, open-label clinical trial by year-end to evaluate TARA-002 in treatment-naïve and treatment-experienced NMIBC patients with high-grade carcinoma in situ and high-grade papillary tumors (Ta). In the initial dose escalation phase of the trial, patients will receive six weekly intravesical doses of TARA-002. The primary objective of the trial is to evaluate the safety, tolerability and preliminary signs of anti-tumor activity of TARA-002, with the goal of establishing a maximum tolerated dose and recommended dose for a future Phase 2 clinical trial.

Our most advanced clinical program for TARA-002 is for 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. OK-432, the originator compound to TARA-002, has been the standard of care in LMs in Japan for over 20 years. 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. The IND for TARA-002 for LMs was originally opened under the Vaccines and Related Products Division of the FDA, or Vaccines Division. We have recently submitted to the Vaccines Division an updated IND with the completed confirmatory, GMP-scale comparability data for TARA-002 in relation to OK-432. We plan to engage the FDA on the design, and subsequently initiate a clinical trial in pediatric LM patients.

TARA-002 was developed from the same master cell bank of genetically distinct group A Streptococcus pyogenes as OK-432 (marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd., or Chugai Pharmaceutical). Following a pre-IND interaction with the OTAT Division, it was agreed that we have successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432. The confirmatory, GMP-scale comparability data were reviewed by the OTAT Division as part of the clearance of the IND for TARA-002 in NMIBC.

The third development program in our portfolio is intravenous, or IV, Choline Chloride, an investigational phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition, or PN, who have intestinal failure associated liver disease, or IFALD. IV Choline Chloride has been granted Orphan Drug Designation by the FDA for this indication and has also been granted Fast Track Designation for the treatment of IFALD. Following a positive end of Phase 2 meeting with the FDA, we received feedback on the design of the studies necessary to complete the registration package for IV Choline Chloride for the treatment of IFALD, including a Phase 1 pharmacokinetic trial and a Phase 3 clinical trial. Prior to initiating these clinical trials, we are undertaking a prevalence study to enhance understanding of the PN patient population and we plan to use this information to determine the next steps for the development program. On September 13, 2021, we reported results of the retrospective part of the prevalence study, which supported the significant unmet medical need in patients dependent on PN who have IFALD. We are currently undertaking the prospective part of the study, which is a multi-center, cross-sectional observational study that will assess the prevalence of choline deficiency, as well as cholestasis and steatosis, in approximately 300 patients dependent on PN.

Our fourth program, vonapanitase, is a recombinant human elastase. We are reviewing the research, preclinical, and clinical data of vonapanitase and have not yet determined whether to pursue further development of this product candidate in the future.

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. TARA-002 is in later stage development for LMs and has not yet been approved for use for treatment of LMs, NMIBC or any other indications. We do not expect to generate revenues in the near-term, if ever. 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.

Since inception, we have incurred significant operating losses. As of September 30, 2021, we had an accumulated deficit of approximately $83.8 million. We expect to continue to incur significant expenses and increasing 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, 2021, we had approximately $138.4 million in cash, cash equivalents, and marketable debt securities.

COVID-19

The ultimate impact of the current COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We have experienced delays, but may experience additional future delays that impact our business, our research and development activities, healthcare systems and the global economy as a whole. We will continue to monitor the COVID-19 situation closely should the effects have a material impact on our operations, liquidity and capital resources.

In response to public health directives and orders, we have implemented work-from-home policies for our employees and temporarily modified our operations to comply with applicable safety recommendations. Similar health directives and orders are affecting third parties with whom we do business, including the third parties that we have contracted with to conduct studies for TARA-002. The effects of the orders and our related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Severe and/or long-term disruptions in our operations as a result of COVID-19, including in response to related public health directives and orders will negatively impact our business, operating results and financial condition. Specifically, we anticipate that the stress of COVID-19 on healthcare systems around the globe will negatively impact our ability to conduct clinical trials in the near-term due primarily to the lack of resources at clinical trial sites and the resulting inability to enroll patients in the trials. We also anticipate that the global impact of COVID-19 will negatively impact our ability to conduct non-clinical studies due primarily to laboratory closures and limited availability of personnel. In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

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 employee-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 employee-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, patent review, 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.

Interest Income, Net

Interest income, net, consists of interest income earned on our cash, cash equivalents, restricted cash, and marketable debt securities, net of interest expense related to our short-term debt.

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. On an ongoing basis, we evaluate estimates, which include estimates related to clinical trial accruals, stock-based compensation expense, and reported amounts of revenues and expenses during the reported period. 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 policies are accounting for research and development expenses and stock-based compensation. 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 on March 11, 2021.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Period-to-Period Change
	2021	2020	
Operating expenses:			
Research and development	$ 4,093	$ 2,796	$ 1,297
General and administrative	6,737	5,266	1,471
Total operating expenses	10,830	8,062	2,768
Operating loss	(10,830)	(8,062)	(2,768)
Other income, net:			
Interest income, net	(53)	(92)	39
Total other income, net	(53)	(92)	39
Net Loss	$ (10,777)	$ (7,970)	$ (2,807)

Research and Development Expenses. During the three months ended September 30, 2021, our research and development expenses were approximately $4.1 million which represented an increase of approximately $1.3 million as compared to the three months ended September 30, 2020. This increase was primarily due to an increase of $0.8 million of non-clinical, clinical and regulatory expenses associated with TARA-002, an increase in stock-based compensation of $0.2 million, and an increase of $0.2 million in compensation, benefits and other employee-related expenses.

General and Administrative Expenses. During the three months ended September 30, 2021, our general and administrative expenses were approximately $6.7 million which represented an increase of approximately $1.5 million as compared to the three months ended September 30, 2020. The increase is principally due to an increase of $0.6 million in compensation, benefits and other employee-related expenses, an increase of $0.5 million in expenses for development of commercial capabilities, and an increase of $0.3 million in expenses associated with the opening of our new corporate office in New York, NY.

Interest Income, Net. During the three months ended September 30, 2021, interest income, net was approximately $0.05 million which represented a decrease of approximately $0.04 million as compared to the three months ended September 30, 2020.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine Months Ended September 30,		Period-to-Period
	2021	**2020**	**Change**
Operating expenses:			
Research and development	$ 17,020	$ 8,330	$ 8,690
General and administrative	20,182	17,157	3,025
Total operating expenses	37,202	25,487	11,715
Operating loss	(37,202)	(25,487)	(11,715)
Other income, net:			
Interest income, net	(178)	(317)	139
Total other income, net	(178)	(317)	139
Net Loss	$ (37,024)	$ (25,170)	$ (11,854)

Research and Development Expenses. During the nine months ended September 30, 2021, our research and development expenses were approximately $17.0 million which represented an increase of approximately $8.7 million as compared to the nine months ended September 30, 2020. This increase was primarily due to an increase of $5.1 million for manufacturing activities associated with TARA-002, an increase of $2.5 million of non-clinical, clinical and regulatory expenses associated with TARA-002, and an increase of $1.2 million in compensation, benefits and other employee-related expenses.

General and Administrative Expenses. During the nine months ended September 30, 2021, our general and administrative expenses were approximately $20.2 million which represented an increase of approximately $3.0 million as compared to the nine months ended September 30, 2020. The increase is primarily due to an increase of $1.8 million in compensation, benefits and other employee-related expenses, an increase of $1.0 million in expenses for development of commercial capabilities, an increase of $0.5 million in expenses associated with the opening of our new corporate office in New York, NY, and an increase of $0.5 million in stock-based compensation. This was partially off-set by a decrease of $0.6 million in legal fees, as we incurred significant one-time expenses in the first quarter of 2020 upon the closing of the reverse merger.

Interest Income, Net. During the nine months ended September 30, 2021, interest income, net was approximately $0.2 million which represented a decrease of approximately $0.1 million as compared to the nine months ended September 30, 2020.

Liquidity and Capital Resources

Overview

As of September 30, 2021 and December 31, 2020, the Company's cash, cash equivalents, and marketable debt securities were $138.4 million and $168.6 million, respectively. We have not generated revenues since our inception and have incurred net losses of approximately $10.8 million and $8.0 million for the three months ended September 30, 2021 and 2020, respectively, and $37.0 million and $25.2 million for the nine months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021, cash flows used in operating activities were approximately $27.6 million, consisting primarily of a net loss of approximately $37.0 million which includes non-cash stock-based compensation charges of approximately $8.5 million. Since inception, we have met our liquidity requirements principally through the sale of our common stock and Series 1 Convertible Preferred Stock.

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 these condensed consolidated financial statements, are sufficient to satisfy our estimated liquidity needs for at least twelve months from the issuance of these condensed consolidated financial statements.

As a result of economic conditions, general global economic uncertainty, political change, global pandemics, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development activities. Specifically, the COVID-19 pandemic has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 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, 2021 and 2020 (in thousands):

	Nine Months Ended September 30,		Period-to-Period
	2021	2020	Change
Net cash used in operating activities	$ (27,595)	$ (16,641)	$ (10,954)
Net cash (used in)/provided by investing activities	(100,083)	3,346	(103,429)
Net cash (used in)/provided by financing activities	(228)	178,686	(178,914)
Net (decrease)/increase in cash and cash equivalents, and restricted cash	$ (127,906)	$ 165,391	$ (293,297)

Comparison of the Nine Months Ended September 30, 2021 and 2020

Net cash used in operating activities was $27.6 million for the nine months ended September 30, 2021 compared to $16.6 million for the nine months ended September 30, 2020. The increase of $11.0 million in cash used in operating activities was primarily driven by an increased net loss of $11.9 million, which was partially offset by a $3.0 million increase in non-cash items including stock-based compensation, right-of-use asset, and amortization of premium on bonds. There was a decrease in working capital of $2.1 million, primarily related to changes in prepaid expenses and other current assets, accounts payable, and accrued expenses resulted from the timing of payments to our service providers.

Net cash used in investing activities was $100.1 million for the nine months ended September 30, 2021 compared to net cash provided by investing activities of $3.3 million in the nine months ended September 30, 2020. The change of $103.4 million resulted primarily from the proceeds from maturity of marketable debt securities, available-for-sale of $2.6 million and proceeds from redemption of marketable debt securities, available-for-sale of $13.8 million. This was offset by the purchases of marketable debt securities, available-for-sale of $116.0 million during the nine months ended September 30, 2021.

Net cash used in financing activities was $0.2 million for the nine months ended September 30, 2021 compared to net cash provided by financing activities of $178.7 million for the nine months ended September 30, 2020. The net cash used in financing of $0.2 million for the nine months ended September 30, 2021 was for the repurchase of shares in connection with the settlement of restricted stock units. The net cash provided by financing activities for the nine months ended September 30, 2020 consisted primarily of the proceeds, net of offering costs, from both private placements of $39.6 million in connection with the reverse merger in January 2020 and $139.9 million in connection with an underwritten public offering in September 2020.

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, 2021, our management, with the participation of our principal executive officer 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 officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2021, 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

During the three months ended September 30, 2021, there were no changes in our internal control over financial reporting, 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

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Financial Condition

We have a very limited operating history and have never generated any revenues.

We are an early-stage biopharmaceutical company with a very limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations have been limited to organizing and staffing the company, business planning, raising capital, developing our pipeline assets (TARA-002 and IV Choline Chloride), identifying product candidates, and other research and development. Although our employees have made regulatory submissions and conducted successful clinical trials in the past across many therapeutic areas while employed at other companies, we have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, nor have we ever generated any revenue from product sales or otherwise. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and cannot estimate with precision the extent of our future losses. We expect to incur increasing levels of operating losses for the foreseeable future as we execute on the plan to continue research and development activities, including the ongoing and planned clinical development of our product candidates, potentially acquire new products and/or product candidates, seek regulatory approvals of and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, and incur the additional costs of operating as a public company. We expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

To become and remain profitable, we must develop or acquire and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval, manufacturing, marketing and selling any product candidate for which we obtain marketing approval, and satisfying post-marketing requirements, if any. We may never succeed in these activities and, even if we succeed in obtaining approval for and commercializing one or more products, we may never generate revenues that are significant enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Furthermore, because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of us and could impair our ability to raise capital, maintain our research and development efforts, expand the business or continue operations. A decline in the value of us could also cause you to lose all or part of your investment.

The COVID-19 pandemic could adversely impact our business, including our clinical development plans.

As the COVID-19 pandemic and measures imposed to contain this pandemic continue in the United States and around the world, we may experience disruptions that could severely impact our business, including:

- interruption of key manufacturing, research and clinical development activities, due to limitations on work and travel imposed or recommended by federal or state governments, employers and others;
- delays or difficulties in clinical trial site operations, including difficulties in recruiting clinical site investigators and clinical site staff and difficulties in enrolling patients;
- interruption of key business activities, due to illness and/or quarantine of key individuals and delays associated with recruiting, hiring and training new temporary or permanent replacements for such key individuals, both internally and at our third party service providers;
- delays in research and clinical trial sites receiving the supplies and materials needed to conduct preclinical studies and clinical trials, due to work stoppages, travel and shipping interruptions or restrictions or other reasons;
- delays or difficulties conducting non-clinical studies due to limitations in employee resources or laboratory closures;
- difficulties in raising additional capital needed to pursue the development of our programs due to the slowing of our economy and near-term and/or long-term negative effects of the pandemic on the financial, banking and capital markets;
- changes in local regulations as part of a response to the COVID-19 pandemic outbreak which may require us to change the ways in which research, including clinical development, is conducted, which may result in unexpected costs; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources, travel restrictions or forced furlough of government employees.

The global outbreak of COVID-19 continues to evolve. The extent to which the COVID-19 pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus. The duration and extent of the impact from the COVID-19 pandemic depend on future developments that cannot be accurately predicted at this time, such as the severity and transmission rate of the virus, the extent and effectiveness of containment actions and the impact of these and other factors on our operations, employees, partners and vendors. If we are not able to respond to and manage the impact of such events effectively, our business will be harmed.

In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access additional capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

To the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this “Risk Factors” section.

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

We will require substantial additional funds to conduct the costly and time-consuming clinical efficacy trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of TARA-002 and IV Choline Chloride in new indications or uses. Our future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders’ ownership interests or inhibit our ability to achieve our business objectives. As a result of economic conditions, general global economic uncertainty, political change, and other factors, including uncertainty associated with the COVID-19 pandemic, 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. Specifically, the COVID-19 pandemic has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity.

If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interests of our common stockholders will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Clinical drug development is very expensive, time-consuming and uncertain.

Clinical development for our product candidates is very expensive, time-consuming, difficult to design and implement, and the outcomes are inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved many do not cover their costs of development. In addition, we, any partner with which we may in the future collaborate, the FDA, an institutional review board, or IRB, or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time.

Risks Related to Drug/Biologics Development

Our business depends on the successful clinical development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride.

The success of our business, including our ability to finance our operations and generate revenue in the future, primarily depends on the successful development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride. The clinical and commercial success of TARA-002 and IV Choline Chloride depends on a number of factors, including the following:

- timely and successful completion of required clinical trials not yet initiated, which may be significantly slower or costlier than we currently anticipate and/or produce results that do not achieve the endpoints of the trials;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional studies beyond those planned to support the approval and commercialization of TARA-002 and IV Choline Chloride;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with their contractual obligations and with all regulatory requirements applicable to TARA-002 and IV Choline Chloride;
- ability for the Vaccines Division to align with the OTAT Division and confirm GMP-scale comparability of TARA-002 and OK-432 for LMs;
- ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of TARA-002 and IV Choline Chloride, to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- a continued acceptable safety profile during clinical development and following approval of TARA-002 and IV Choline Chloride;
- ability to obtain favorable labeling for TARA-002 and IV Choline Chloride through regulators that allows for successful commercialization, given the drugs may be marketed only to the extent approved by these regulatory authorities (unlike with most other industries);
- ability to successfully commercialize TARA-002 and IV Choline Chloride in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, insurers and payors, and patients of the quality, benefits, safety and efficacy of TARA-002 and IV Choline Chloride, if either is approved, including relative to alternative and competing treatments;
- existence of a regulatory environment conducive to the success of TARA-002 and IV Choline Chloride;
- ability to price TARA-002 and IV Choline Chloride to recover our development costs and generate a satisfactory profit margin; and
- our ability and our partners' ability to establish and enforce intellectual property rights in and to TARA-002 and IV Choline Chloride.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize TARA-002 and IV Choline Chloride. Even if regulatory approvals are obtained, we may never be able to successfully commercialize TARA-002 and IV Choline Chloride. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of TARA-002 and IV Choline Chloride to continue our business.

The COVID-19 pandemic is impacting our business and the business of the third-parties with which we contract for key services related to our clinical development plans. If the crisis persists, it is likely to have a significant delay in our development timelines and result in additional and unexpected costs. Presently, we anticipate that the stress of the COVID-19 pandemic on healthcare systems around the globe will negatively impact our ability to conduct clinical trials in the near-term due primarily to the lack of resources at clinical trial sites and the resulting inability to enroll patients in these trials. In addition, it is possible that the stress of the COVID-19 pandemic on regulatory agencies may make it more difficult to collaborate with, and receive guidance from, such agencies, which could delay our development timelines and negatively impact our business.

We have never made a BLA or NDA submission or conducted a clinical trial and may be unable to successfully do so for TARA-002 or IV Choline Chloride.

The conduct of a clinical trials is a long, expensive, complicated and highly regulated process. Although our employees have made regulatory submissions and conducted successful clinical trials in the past across many therapeutic areas while employed at other companies, we, as a company, have not conducted any clinical trials, or submitted a biological license application, or BLA, or new drug application, or NDA, and as a result may require more time and incur greater costs than we anticipate. Failure to commence or complete, or delays in, our planned regulatory submissions or clinical trials would prevent us from, or delay us, in obtaining regulatory approval of and commercializing TARA-002 and IV Choline Chloride, which would adversely impact our financial performance, as well as subject us to significant contract liabilities.

TARA-002 is an immunopotentiator, and one indication for which we plan to pursue is the treatment of LMs. There are no FDA-approved therapies for the treatment of LMs. It is difficult to predict the timing and costs of clinical development for TARA-002 with respect to LMs.

To date, there are no FDA-approved therapies for the treatment of LMs. The regulatory approval process for novel product candidates such as TARA-002 can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches. We may be delayed in reaching agreement with FDA on the design of a pediatric LMs trial to support approval of TARA-002. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring TARA-002 to market could decrease our ability to generate sufficient revenue to maintain our business.

Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Unforeseen side effects from TARA-002 or IV Choline Chloride could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining U.S. or foreign regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process for IV Choline Chloride for the treatment of IFALD.

The FDA has granted fast track designation to IV Choline Chloride for the treatment of IFALD. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. Even though we have received fast track designation for IV Choline Chloride for the treatment of IFALD, we may not experience a faster development process, review or approval. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Although the FDA has granted Rare Pediatric Disease Designation for TARA-002 for the treatment of LMs, a BLA for TARA-002, if approved, may not meet the eligibility criteria for a priority review voucher.

Rare Pediatric Disease Designation has been granted for TARA-002 for the treatment of LMs. In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

For the purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2024. However, if a drug candidate received Rare Pediatric Disease Designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026.

However, TARA-002 for the treatment of LMs may not be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that a BLA will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease Designation does not lead to faster development or regulatory review of the product, or increase the likelihood that it will receive marketing approval. We may or may not realize any benefit from receiving a voucher.

Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of both TARA-002 and IV Choline Chloride, if approved, will depend significantly on the broad adoption and use of them by physicians and patients for approved indications, and neither may be commercially successful even though the product is shown to be safe and effective. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat the indication for which a product is approved;
- the effectiveness of the product compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- in the case of TARA-002, overcoming physician or patient biases toward alternative treatments for LMs;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration;
- patient satisfaction with the results, administration and overall treatment experience;

- limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final FDA-approved labeling for the applicable product;
- any FDA requirement to undertake a risk evaluation and mitigation strategy;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts;
- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

If either TARA-002 or IV Choline Chloride is approved for use but fails to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Any adverse developments that occur in patients undergoing treatment with OK-432 / Picibanil or in patients participating in clinical trials conducted by third parties may affect our ability to obtain regulatory approval or commercialize TARA-002.

Chugai Pharmaceutical Co., Ltd., over which we have no control, has the rights to commercialize TARA-002 and it is currently marketed in Japan and Taiwan, under the name Picibanil, for various indications. In addition, clinical trials using Picibanil are currently ongoing in various countries around the world. If serious adverse events occur with patients using Picibanil or during any clinical trials of Picibanil conducted by third parties, the FDA may delay, limit or deny approval of TARA-002 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for TARA-002 and a new and serious safety issue is identified in connection with use of Picibanil or in clinical trials of Picibanil conducted by third parties, the FDA may withdraw the approval of the product or otherwise restrict our ability to market and sell TARA-002. In addition, treating physicians may be less willing to administer TARA-002 due to concerns over such adverse events, which would limit our ability to commercialize TARA-002.

We may in the future conduct clinical trials for our product candidates outside the United States, and the FDA and applicable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside of the United States. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusion. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate the potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. For example, we are reviewing the research and preclinical and clinical data of vonapanitase and have not yet determined whether to pursue further development of this product candidate in the future.

If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

Our or our third party's clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during their development, which could prevent or delay marketing approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of the product candidate.

Before obtaining marketing approvals for the commercial sale of any product candidate, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidate is both safe and effective for use in the applicable indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and are associated with side effects or have characteristics that are unexpected. Based on the safety profile seen in clinical testing, we may need to abandon development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more tolerable from a risk-benefit perspective. The FDA or an IRB may also require that we suspend, discontinue, or limit clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for the product candidate. Many pharmaceutical candidates that initially showed promise in early stage testing and which were efficacious have later been found to cause side effects that prevented further development of the drug candidate and, in extreme cases, the side effects were not seen until after the drug was marketed, causing regulators to remove the drug from the market post-approval.

Other Risks Related to Our Business

Our product candidates, if approved, will face significant competition and their failure to compete effectively may prevent them from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, less effective patent terms, and a strong emphasis on developing newer, fast-to-market proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing, including TARA-002 and IV Choline Chloride. We will face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, more international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than we have. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts.

With respect to our lead product candidate, TARA-002, for the treatment of LMs and NMIBC, the active ingredient in TARA-002 is a genetically distinct strain of *Streptococcus pyogenes* (group A, type 3) Su strain. TARA-002 is produced through a proprietary manufacturing process. We anticipate that, if approved by the FDA, TARA-002 will be protected by 12 years of biologic exclusivity. In addition, TARA-002 is likely to have seven years of concurrent Orphan Drug Designation exclusivity for the treatment of LMs if deemed comparable to OK-432 by the Vaccines Division based on the prevalence of the disease. There are no approved pharmacotherapies currently available for the treatment of LMs and the current treatment options include a high-risk surgical procedure and off-label use of sclerosants. There are a number of drug development companies and academic researchers exploring oral formulations of various agents including macrolides, phosphodiesterase inhibitors, and calcineurin/mTOR inhibitors. These are in early development. TARA-002, if approved for the treatment of NMIBC, would be subject to competition from existing treatment methods of surgery, chemotherapy and immunomodulatory therapy.

There are no treatments currently available for IFALD. With respect to IV Choline Chloride for the treatment of IFALD, IV Choline Chloride is the only sterile injectable form of choline chloride that can be combined with parenteral nutrition. Further, if approved, IV Choline Chloride will be protected by Orphan Drug Designation exclusivity for seven years.

TARA-002 and any future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Reconciliation Act of 2010, or collectively, the Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes are intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We rely and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates.

We rely and expect to continue to rely on third-party contract research organizations, or CROs, to conduct and oversee our TARA-002 and IV Choline Chloride clinical trials and other aspects of product development. We also rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and good clinical practice, or GCP, requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties will play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We will rely heavily on these parties for the execution of our clinical trials and preclinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with GCP and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal non-compliance from an audit or inspection, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials comply with applicable GCP and GLP requirements. In addition, our clinical trials generally must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

Interim, topline and preliminary data from our clinical trials may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary, interim, or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, preliminary, interim, and topline data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure.

We currently have limited marketing capabilities and no sales organization. If we are unable to grow our sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the United States, Canada, the European Union, Latin America and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products, and business development activities involving external alliances, from prior employment at other companies, we, as a company, have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products.

We have only received the exclusive rights to the materials required to commercialize TARA-002 in territories other than Japan and Taiwan until June 17, 2030, or an earlier date if Chugai terminates the agreement with us for any number of reasons, following which such rights become non-exclusive.

Pursuant to an agreement with Chugai Pharmaceutical Co., Ltd. dated June 17, 2019, as amended on July 14, 2020 (effective June 30, 2020), Chugai agreed to provide us with exclusive access to the starting material necessary to manufacture TARA-002 as well as technical support necessary for us to develop and commercialize TARA-002 anywhere in the world other than Japan and Taiwan. However, this agreement does not prevent Chugai from providing such materials and support to any third party for medical, compassionate use and/or non-commercial research purposes and this agreement is exclusive through June 17, 2030 or following any termination of the agreement by either party. Once our rights to the materials and technology necessary to manufacture, develop and commercialize TARA-002 are not exclusive, third parties, including those with greater expertise and greater resources, could obtain such materials and technology and develop a competing therapy, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our product candidates.

The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our biopharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country and frequently are revised.

Even after we achieve U.S. regulatory approval for a product candidate, if any, we will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We also will be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates.

These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with cGMP requirements and with the FDA's GCP requirements and GLP requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that it conducts post-approval, as well as continued compliance with the FDA's laws governing commercialization of the approved product, including but not limited to the FDA's Office of Prescription Drug Promotion, regulation of promotional activities, fraud and abuse, product sampling, scientific speaker engagements and activities, formulary interactions as well as interactions with healthcare practitioners. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar or more onerous (i.e., prohibition on direct-to-consumer advertising that does not exist in the United States) restrictions and requirements imposed by laws and government regulators in those countries.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the manufacturing, processing, distribution or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians or the public, withdrawal of the product from the market, or suspension of manufacturing.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the sale, marketing or manufacturing of the product, amend, suspend or withdraw product approvals or revoke necessary licenses;
- mandate modifications to promotional and other product-specific materials or require us to provide corrective information to healthcare practitioners or in our advertising;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, penalties for non-compliance and, in extreme cases, require an independent compliance monitor to oversee our activities;
- issue warning letters, bring enforcement actions, initiate surprise inspections, issue show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- place restrictions on the kind of promotional activities that can be done;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change, and new or additional statutes or government regulations may be enacted, including at the state and local levels, which can differ by geography and could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulations that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to commercialize our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability or similar causes of action as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding that we comply with applicable laws on promotional activity. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or potentially even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others, and under some circumstances even government agencies. If we cannot successfully defend our self against product liability or similar claims, we will incur substantial liabilities, reputational harm and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- significant delay in product launch;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

We intend to obtain product liability insurance coverage for our clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive and narrow, and, in the future, we may not be able to maintain adequate insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability or other similar legal actions. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which we wish to launch. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could decrease our cash and harm our business, financial condition, operating results and future prospects.

Our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with whom we may collaborate may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, anti-kickback and Medicare/Medicaid rules, or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against us and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, debarments, contractual damages, imprisonment, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of our operations, any of which could adversely affect our ability to operate our business and our operating results.

We may be subject to risks related to off-label use of our product candidates.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress and the public. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Although physicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities.

Even if we obtain regulatory approval for our product candidates, the FDA or comparable foreign regulatory authorities may require labeling changes or impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In the United States, engaging in impermissible promotion of our product candidates for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to significant civil, criminal and/or administrative penalties and fines and agreements, such as a corporate integrity agreement, that materially restrict the manner in which we promote or distribute our product candidates. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect on our business, financial condition and operating results and even result in having an independent compliance monitor assigned to audit our ongoing operations for a lengthy period of time.

If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for TARA-002 or IV Choline Chloride following regulatory approval, their commercial success may be hindered severely.

If TARA-002 and IV Choline Chloride only becomes available by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse most or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and private third-party payors is often critical to new product acceptance. Coverage decisions may depend on clinical and economic standards that disfavor new drug products when more established or lower-cost therapeutic alternatives are already available or subsequently become available, or may be affected by the budgets and demands on the various entities responsible for providing health insurance to patients who will use TARA-002 and IV Choline Chloride. Even if we obtain coverage for our products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use a product unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies and there may be time limitations on when a new drug may even apply for formulary inclusion. Also, third-party payors may refuse to include products in their formularies or otherwise restrict patient access to such products when a less costly generic equivalent or other treatment alternative is available in the discretion of the formulary.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require us to provide scientific, clinical and health economics support for the use of our products compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what time frame.

Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare reform measures could hinder or prevent the commercial success of our product candidates.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any future product candidates we may develop. For example, the Trump administration and certain members of the U.S. Congress sought to repeal all or part of the Affordable Care Act and implement a replacement program. For example, the so-called "individual mandate" was repealed as part of tax reform legislation adopted in December 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, such that the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, which is commonly referred to as the "individual mandate," was eliminated beginning in 2019. Additionally, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing President Trump's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new Presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

There are also calls to place additional restrictions on or to ban all direct-to-consumer advertising of pharmaceuticals, which would limit our ability to market our product candidates. The United States is in a minority of jurisdictions that allow this kind of advertising and its removal could limit the potential reach of a marketing campaign. Further, it is possible that additional government action is taken in response to the COVID-19 pandemic.

We may also be subject to stricter healthcare laws, regulation and enforcement, and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse, privacy, transparency, and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct business. The healthcare laws and regulations that may affect our ability to operate include but are not limited to: the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act; the Prescription Drug Marketing Act (for sampling of drug product among other things); the federal physician sunshine requirements under the Affordable Care Act; the Foreign Corrupt Practices Act as it applies to activities outside of the United States; the federal Right-to-Try legislation; and similar state laws of such federal laws, which may be broader in scope.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business and result in reputational damage. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, imprisonment, additional oversight and reporting obligations, or the curtailment or restructuring of our operations, and injunctions, any of which could adversely affect our ability to operate our business and financial results.

We intend to in-license and acquire product candidates and may engage in other strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management.

Our strategy is to in-license and acquire product candidates and we may engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results and prospects. We have no current plan, commitment or obligation to enter into any transaction described above, and we are not engaged in discussions related to additional partnerships.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We intend to in-license, acquire, develop and market additional products and product candidates. Because our internal research and development capabilities are limited, we may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.

We expect to rely upon the efforts of third parties for the successful development and commercialization of our current and future product candidates. The clinical and commercial success of our product candidates may depend upon maintaining successful relationships with third-party partners which are subject to a number of significant risks, including the following:

- our partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner;
- reduced control over delivery and manufacturing schedules;
- price increases and product reliability;
- manufacturing deviations from internal or regulatory specifications;
- quality incidents;

- the failure of partners to perform their obligations for technical, market or other reasons;
- misappropriation of our current or future product candidates; and
- other risks in potentially meeting our current and future product commercialization schedule or satisfying the requirements of our end-users.

We cannot assure you that we will be able to establish or maintain third-party relationships in order to successfully develop and commercialize our product candidates.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, which may include sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Additionally, we have not entered into a long-term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop our product candidates is dependent, and our ability to supply our products commercially will depend, in part, on our ability to obtain the analytical profile indexes, or APIs, and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates.

We do not have direct control over whether our contract suppliers and manufacturers will maintain current pricing terms, be willing to continue supplying us with API and finished products or maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMPs for production of both APIs and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidate successfully, and we may be held liable for injuries sustained as a result.

In order to conduct larger or late-stage clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our drug substances and product candidates in larger quantities, more cost-effectively and, in certain cases, at higher yields than they currently achieve. If our third-party contractors are unable to scale up the manufacture of any of our product candidates successfully in sufficient quality and quantity and at commercially reasonable prices, or are shut down or put on clinical hold by government regulators, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to transfer the processes successfully on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third-party manufacturer's or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries.

In addition, we cannot be certain that any prolonged, intensified or worsened effect from the COVID-19 pandemic would not impact our supply chain.

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If our CDMO encounters such difficulties, the ability to provide supply of TARA-002 for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of TARA-002, if approved, could be delayed or stopped.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We are completely dependent on CDMOs to fulfill our clinical and commercial supply of TARA-002. The process of manufacturing biologics is complex, highly regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely harm our business. Moreover, if the FDA determines that our manufacturer is not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for TARA-002 or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Scaling up a biologic manufacturing process is a difficult and uncertain task, and any CDMO we contract may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely meet product demand.

We expect our stock price to be highly volatile.

The market price of our shares could be subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to:

- our ability to obtain timely regulatory approvals for TARA-002, IV Choline Chloride or future product candidates, and delays or failures to obtain such approvals;
- failure of TARA-002 or IV Choline Chloride, if approved, to achieve commercial success;
- issues in manufacturing TARA-002, IV Choline Chloride or future product candidates;
- the results of current and any future clinical trials of TARA-002 or IV Choline Chloride;
- failure of other of our product candidates, if approved, to achieve commercial success;
- the entry into, or termination of, or breach by partners of key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any dilutive equity financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and
- the loss of key employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our shares.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. In addition, such securities litigation often has ensued after a reverse merger or other merger and acquisition activity. Such litigation if brought could impact negatively our business.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

As a public company, we have incurred, and will continue to incur, significant legal, accounting and other expenses, including costs associated with public company reporting and other SEC requirements. We have also incurred, and will continue to incur, costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq.

We expect the rules and regulations applicable to public companies will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. Our executive officers and other personnel will need to continue to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it expensive for us to operate our business.

We are able to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

We qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for our investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive due to our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $100 million and we have a public float of less than $700 million.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

In addition, the United States is currently experiencing a decrease in unemployment rates and an increasingly competitive labor market, which may result in difficulties in hiring or retaining sufficient qualified personnel to maintain and grow our business. We are uncertain as to the employment environment in the future, or how that environment will impact our workforce, including our ability to retain qualified management and other key personnel.

We do not anticipate paying any dividends in the foreseeable future.

The current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of your shares of us will be your sole source of gain, if any, for the foreseeable future.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states and localities will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

We may be adversely affected by natural disasters, pandemics and other catastrophic events and by man-made problems such as terrorism that could disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate office is located in New York, New York. If a disaster, power outage, computer hacking, or other event occurred that prevented us from using all or a significant portion of an office, that damaged critical infrastructure, such as enterprise financial systems, IT systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. As an example, New York City has been significantly impacted by the COVID-19 pandemic and, due to safety considerations for our employees and government restrictions, we have been unable to use our facilities located there for an extended period of time. Our contract manufacturer's and suppliers' facilities are located in multiple locations where there have been similar working restrictions in place for the COVID-19 pandemic and where other natural disasters or similar events, such as tornadoes, fires, explosions or large-scale accidents or power outages, or IT threats, pandemic, acts of terrorism and other geo-political unrest, could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of TARA-002 or IV Choline Chloride, our business, financial condition, operating results and prospects would suffer.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding voting stock from merging or combining with us. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Certain stockholders have the ability to control or significantly influence certain matters submitted to our stockholders for approval.

Certain stockholders have consent rights over certain significant matters of our business. These include decisions to effect a merger or other similar transaction, changes to our principal business, and the sale or other transfer of TARA-002 or other assets with an aggregate value of more than $2,500,000. As a result, these stockholders, have significant influence over certain matters that require approval by our stockholders.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; harm to our reputation; and other adverse effects on our business or prospects.

In the ordinary course of business, we collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share (collectively, "Process" or "Processing") personal information and other sensitive and confidential information, including information we collect about patients in connection with clinical trials, or, as necessary to operate our business, for legal and marketing purposes, and for other business-related purposes.

Accordingly, we are, or may become, subject to numerous federal, state, local and international data privacy and security laws, regulations, guidance and industry standards as well as external and internal privacy and security policies, contracts and other obligations that apply to the Processing of personal data by us and on our behalf, or collectively, Data Protection Requirements. The number and scope of Data Protection Requirements are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other. If we fail, or are perceived to have failed, to address or comply with Data Protection Requirements, this could result in government enforcement actions against us that could include investigations, fines, penalties, audits and inspections, additional reporting requirements and/or oversight, temporary or permanent bans on all or some Processing of personal data, orders to destroy or not use personal data, and imprisonment of company officials. Further, individuals or other relevant stakeholders could bring a variety of claims against us for our actual or perceived failure to comply with the Data Protection Requirements. Any of these events could have a material adverse effect on our reputation, business, or financial condition, and could lead to a loss of actual or prospective customers, collaborators or partners; interrupt or stop clinical trials; result in an inability to Process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; or require us to revise or restructure our operations, or each, a Material Adverse Impact.

We are, or may become, subject to U.S. privacy laws. For example, in the United States, there are a broad variety of data protection laws and regulations that may apply to our activities such as state data breach notification laws, state personal data privacy laws (for example, the California Consumer Privacy Act of 2018, or CCPA), state health information privacy laws, and federal and state consumer protection laws. A range of enforcement agencies exist at both the state and federal levels that can enforce these laws and regulations. For example, the CCPA requires covered businesses that process personal information of California residents to disclose their data collection, use and sharing practices. Further, the CCPA provides California residents with new data privacy rights (including the ability to opt out of certain disclosures of personal data), imposes new operational requirements for covered businesses, provides for civil penalties for violations (up to $7,500 per violation).as well as a private right of action for data breaches and statutory damages (that is expected to increase data breach class action litigation and result in significant exposure to costly legal judgements and settlements). Aspects of the CCPA and its interpretation and enforcement remain uncertain. Further, the new California Privacy Rights Act, or CPRA, which was passed in November 2020, substantially expands the CCPA's requirements effective January 1, 2023.The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how it is interpreted. The enactment of the CCPA has prompted similar legislative developments in other states, which could create the potential for a patchwork of overlapping but different state laws. The federal government is also considering comprehensive privacy legislation. We may be subject to additional U.S. privacy regulations in the future, including the Virginia Consumer Data Protection Act, or VCDPA, and the Colorado Privacy Act, both of which become effective in 2023.

There are also an increasing number of laws, regulations and industry standards concerning privacy, data protection and information security in various international jurisdictions. For example, in May 2018, the European Union's, or EU, General Data Protection Regulation (EU) 2016/679, or GDPR, came into effect across the European Economic Area, or EEA. Also, notwithstanding the United Kingdom's, or UK withdrawal from the EU, by operation of the so-called "UK GDPR," the GDPR continues to apply in substantially equivalent form in the context of the UK, UK establishments and UK-focused Processing operations. European data protection laws provide robust regulatory enforcement and greater penalties for non-compliance than previous data protection laws, including, for example, under the GDPR, fines of up to €20 million or 4% of global annual revenue of any non-compliant organization for the preceding financial year, whichever is higher.

Collectively, European data protection laws (including the GDPR) are wide-ranging in scope and impose numerous, significant and complex compliance burdens in relation to the Processing of personal data, such as: limiting permitted Processing of personal data to only that which is necessary for specified, explicit and legitimate purposes; requiring the establishment of a legal basis for Processing personal data; broadening the definition of personal data to possibly include 'pseudonymized' or key-coded data; creating obligations for controllers and processors to appoint data protection officers in certain circumstances; increasing transparency obligations to data subjects; introducing the obligation to carry out data protection impact assessments in certain circumstances; establishing limitations on the collection and retention of personal data through 'data minimization' and 'storage limitation' principles; introducing obligations to honor increased rights for data subjects; formalizing a heightened and codified standard of data subject consent; establishing obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data; introducing the obligation to provide notice of certain significant personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or EU in certain circumstances. In particular, the Processing of "special category personal data" (such as personal data related to health and genetic information), which could be relevant to our operations in the context of our conduct of clinical trials, imposes heightened compliance burdens under European data protection laws and is a topic of active interest among relevant regulators.

Recent developments in Europe have created uncertainty regarding how to lawfully transfer data from Europe to the United States and, as a result, we could have difficulty transferring personal data, including patient data, internationally. The GDPR includes restrictions on cross-border data transfers. On July 15, 2020, the Court of Justice of the European Union, or CJEU, invalidated the primary compliance mechanism on which many companies relied for such transfers, namely, the EU-US Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, or SCCs, can lawfully be used for personal data transfers from Europe to the United States or most other countries. The European Commission recently updated the SCCs. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA. The SCCs, however, require parties that rely upon that legal mechanism to comply with additional obligations such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the SCCs will remain a valid mechanism for personal data transfers out of the EEA. We may be required to incur significant costs and increase our foreign data processing capabilities in an effort to comply with these requirements, and there is no assurance they will be successful.

In addition to European restrictions on cross-border personal data transfers, other jurisdictions have enacted or are considering similar cross-border personal data transfer laws and local personal data residency laws, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border personal data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. Inability to import personal data to the United States may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense.

These laws exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and may require us to modify our Processing practices at substantial costs and expenses in an effort to comply. Given the breadth and evolving nature of Data Protection Requirements, preparing for and complying with these requirements is rigorous, time-intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that Process personal data on our behalf.

We may publish privacy policies and other documentation regarding our Processing of personal data and/or other confidential, proprietary or sensitive information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, third-party collaborators, service providers, contractors or consultants fail to comply with our policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business or have other Material Adverse Impacts.

Risks Related to Intellectual Property Rights

We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates will depend, in part, on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents around the world.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of our patents effectively, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over-the-counter pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target.

Competitors in the field of immunology and oncology therapeutics have created a substantial amount of prior art, including scientific publications, posters, presentations, patents and patent applications and other public disclosures including on the Internet. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the United States, and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting, or are otherwise precluded from effectively protecting, our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use and if we and our agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, we may not be allowed to retrieve this and maintain the exclusivity we previously enjoyed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and even in launching an identical version of our product notwithstanding we have a valid patent in that country. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement on infringing activities is inadequate or where we have no patents. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, and the judicial and government systems are often corrupt, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our global patents at risk of being invalidated or interpreted narrowly and our global patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate or infringement actions brought against us, and the damages or other remedies awarded, if any, may not be commercially meaningful when we are the plaintiff. When we are the defendant we may be required to post large bonds to stay in the market while we defend ourselves from an infringement action.

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patent holder’s patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. In these situations, the royalty the court requires to be paid by the license holder receiving the compulsory license is not calculated at fair market value and can be inconsequential, thereby disaffecting the patent holder’s business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the Unites States. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals For example, in Brazil, pharmaceutical patents require initial approval of the Brazilian health agency (ANVISA). Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay a prosecution fee. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We have entered into in-license arrangements with respect to certain of our product candidates. These license agreements impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot assure that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S.- and foreign-issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies notwithstanding patents we may possess. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to our technology. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or the like. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act or other countries' laws similar to the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us is ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party significant damages for having violated the other party's patents.

Because we rely on certain third-party licensors and partners and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition or operating results.

We may be subject to claims that our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

General Risk Factors

If our information technology systems or data is or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, and a loss of customers or sales.

In the ordinary course of our business, we may Process (as defined above) proprietary, confidential and sensitive information, including personal data (including, key-coded data, health information and other special categories of personal data), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties, or collectively, Sensitive Information.

We may use third-party service providers and subprocessors to help us operate our business and engage in Processing the Sensitive Information on our behalf. We may also share Sensitive Information with our partners or other third parties in conjunction with our business. If we, our service providers, partners or other relevant third parties have experienced, or in the future experience, any security incident(s) that result in, any data loss; deletion or destruction; unauthorized access to; loss, unauthorized acquisition, disclosure, or exposure of, Sensitive Information, or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, or any, a Security Breach, it may result in a Material Adverse Impact (as defined above), including the diversion of funds to address the breach, and interruptions, delays, or outages in our operations and development programs. In the first quarter of 2020, our email server was compromised in a cyber-attack. We quickly isolated the incident and have, since, implemented additional risk prevention measures.

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. In addition to traditional computer "hackers"; threat actors; software bugs; malicious code (such as viruses and worms); employee error, theft or misuse; denial-of-service attacks (such as credential stuffing); advanced persistent threat intrusions; natural disasters; terrorism; war; telecommunication and electrical failures; ransomware attacks, sophisticated nation-state and nation-state supported actors are threats to our information technology assets and data. For example, the loss of access to (e.g., via a denial of service attack) or loss of clinical trial data (e.g., via a ransomware attack) that we may have collected from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our systems and networks or the systems and networks of third parties that support us and our services. We may also be the subject of server malfunction, software or hardware failures, loss of data or other computer assets, and other similar issues. Due to the COVID-19 pandemic, a significant portion of our workforce works remotely, increasing the risk to our information technology assets and data.

We may be required to expend additional, significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against Security Breaches and to mitigate, detect, and remediate actual and potential vulnerabilities. Applicable Data Protection Requirements (as defined above) may require us to implement specific security measures or use industry-standard or reasonable measures to protect against Security Breaches. Even if we were to take and have taken security measures designed to protect against Security Breaches, there can be no assurance that such security measures or those of our service providers, partners and other third parties will be effective in protecting against all Security Breaches and Material Adverse Impacts that may arise from such Security Breaches.

Actual or perceived Security Breaches or vulnerabilities, and concerns regarding data privacy, security or Processing may cause some of our actual or prospective customers, collaborators, partners and/or clinical trial participants to stop using our products or services or working with us. This discontinuance, or failure to meet the expectations of such third parties, could result in material harm to our operations, financial performance or reputation and affect our ability to grow and operate our business.

Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of Sensitive Information, including preventing us from conducting clinical trials, tests or research and development activities and preventing us from managing the administrative aspects of our business.

Applicable Data Protection Requirements may require us to notify relevant stakeholders of Security Breaches, including affected individuals, partners, collaborators, customers, regulators, law enforcement agencies, credit reporting agencies and others. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to Material Adverse Impacts. There can be no assurance that any limitations or exclusions of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with Data Protection Requirements related to information security or Security Breaches.

We cannot be sure that our insurance coverage, if any, will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or Material Adverse Impacts arising out of our Processing operations, privacy and security practices, or Security Breaches we may experience. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co-insurance requirements), could have a Material Adverse Impact.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

None.

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 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	Second Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 of Current Report on Form 8-K, filed 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).
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 4, 2021

By: /s/ Jesse Shefferman

Jesse Shefferman
Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2021

By: /s/ Blaine Davis

Blaine Davis
Chief Financial Officer
(Principal Financial and Accounting 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, 2021 of Protara Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

/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, Blaine Davis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2021 of Protara Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

/s/ Blaine Davis
Blaine Davis
Chief Financial Officer
(Principal Financial and Accounting 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, 2021, 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, Blaine Davis, 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 4, 2021

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

Date: November 4, 2021

By: /s/ Blaine Davis
Blaine Davis
Chief Financial Officer
(Principal Financial and Accounting Officer)

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