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, 2020

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.)**

1 Little West 12th Street
New York, NY
(Address of principal executive offices)

10014
(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 ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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 10, 2020 there were 11,211,840 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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CAUTIONARY NOTE 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 “outlook,” “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seeks,” “approximately,” “predicts,” “intends,” “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 COVID-19 pandemic on our business and operations as well as the business or operations of our manufacturers, research partners, and other third parties with whom we conduct business or 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 (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 20, 2020. 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 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 coronavirus 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 an IND, BLA 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 the indications for which we plan to pursue are the treatment of lymphatic malformations and non-muscle invasive bladder cancer. There are no FDA-approved therapies for the treatment of lymphatic malformations. It is difficult to predict the timing and costs of clinical development for TARA-002 with respect to lymphatic malformations as well as the corresponding regulatory approval path.
- 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 no marketing capabilities and no sales organization. If we are unable to establish 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

	As of	
	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 165,904,797	$ 564,124
Restricted cash	50,000	-
Deferred offering costs	-	121,712
Prepaid expenses and other current assets	1,160,257	78,057
Total current assets	167,115,054	763,893
Non-current assets:		
Property and equipment, net	760,548	458,591
Goodwill	29,367,213	-
Other assets	1,664,442	-
Total assets	$ 198,907,257	$ 1,222,484
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,912,553	$ 715,653
Accrued expenses	1,569,348	2,634,790
Short-term debt	370,793	-
Right-of-use liability, current	34,079	-
Total current liabilities	3,886,773	3,350,443
Non-current liabilities:		
Right-of-use liability, long-term	394,721	-
Total liabilities	4,281,494	3,350,443
Commitments and Contingencies (Note 6)		
Stockholders' Equity (Deficit)		
Preferred Stock, $0.001 par value, authorized 10,000,000 shares: Series 1 Convertible Preferred Stock, 8,028 and 0 shares authorized at September 30, 2020 and December 31, 2019, respectively, 8,027 and 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively.	8	-
Common Stock, $0.001 par value, authorized 100,000,000 shares: Common Stock, 10,521,840 and 2,627,533 common shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively.	10,522	2,628
Additional Paid in Capital	232,567,265	10,651,073
Accumulated Deficit	(37,952,032)	(12,781,660)
Total Stockholders' Equity (Deficit)	194,625,763	(2,127,959)
Total Liabilities and Stockholders' Equity (Deficit)	$ 198,907,257	$ 1,222,484

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

PROTARA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating expense:				
Research & development	$ 2,796,214	$ 1,098,617	$ 8,330,727	$ 3,163,179
General & administrative	5,265,965	1,255,466	17,156,952	2,147,635
Total operating expenses	8,062,179	2,354,083	25,487,679	5,310,814
Operating loss	(8,062,179)	(2,354,083)	(25,487,679)	(5,310,814)
Other income, net				
Interest income, net	(92,094)	-	(317,307)	-
Total other income, net	(92,094)	-	(317,307)	-
Net Loss	$ (7,970,085)	$ (2,354,083)	$ (25,170,372)	$ (5,310,814)
Weighted Average Shares Outstanding, basic and diluted	6,324,295	2,564,429	5,910,849	2,560,444
Net loss per share, basic and diluted	$ (1.26)	$ (0.92)	$ (4.26)	$ (2.07)

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

PROTARA THERAPEUTICS, INC.
STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019
(unaudited)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at January 1, 2020	-	$ -	2,627,533	$ 2,628	$ 10,651,073	$ (12,781,660)	$ (2,127,959)
Issuance of Series 1 Convertible Preferred Stock, net of offering costs	3,879	4	-	-	25,318,702	-	25,318,706
Issuance of Common Stock in ArTara Private Placement, net of offering costs	-	-	284,875	285	1,867,295	-	1,867,580
Issuance of Common Stock in Proteon Private Placement, net of offering costs	-	-	1,896,888	1,897	12,411,440	-	12,413,337
Reverse business combination	-	-	1,033,907	1,033	34,531,594	-	34,532,627
Stock-based compensation - stock options	-	-	-	-	368,135	-	368,135
Stock-based compensation - restricted stock units	-	-	-	-	2,429,672	-	2,429,672
Net loss	-	-	-	-	-	(10,060,257)	(10,060,257)
Balance at March 31, 2020	3,879	$ 4	5,843,203	$ 5,843	$ 87,577,911	$ (22,841,917)	$ 64,741,841
Stock-based compensation - stock options	-	-	-	-	514,054	-	514,054
Stock-based compensation - restricted stock units	-	-	-	-	1,314,668	-	1,314,668
Net loss	-	-	-	-	-	(7,140,030)	(7,140,030)
Balance at June 30, 2020	3,879	$ 4	5,843,203	$ 5,843	$ 89,406,633	$ (29,981,947)	$ 59,430,533
Settlement of RSUs	-	-	20,870	21	(21)	-	-
Exercise of stock options	-	-	57,767	58	530,243	-	530,301
Issuance of Common Stock in public offering, net of offering costs	-	-	4,600,000	4,600	73,566,060	-	73,570,660
Issuance of Series 1 Convertible Preferred in public offering, net of offering costs	4,148	4	-	-	66,283,548	-	66,283,552
Stock-based compensation - stock options	-	-	-	-	1,473,629	-	1,473,629
Stock-based compensation - restricted stock units	-	-	-	-	1,307,173	-	1,307,173
Net loss	-	-	-	-	-	(7,970,085)	(7,970,085)
Balance at September 30, 2020	8,027	$ 8	10,521,840	$ 10,522	$ 232,567,265	$ (37,952,032)	$ 194,625,763
Balance at January 1, 2019	-	$ -	2,558,419	$ 2,558	$ 9,727,124	$ (4,952,443)	$ 4,777,239
Stock-based compensation - stock options	-	-	-	-	54,382	-	54,382
Stock-based compensation - restricted stock	-	-	-	-	22,500	-	22,500
Net loss	-	-	-	-	-	(1,528,056)	(1,528,056)
Balance at March 31, 2019	-	$ -	2,558,419	$ 2,558	$ 9,804,006	$ (6,480,499)	$ 3,326,065
Stock-based compensation - stock options	-	-	-	-	79,962	-	79,962
Stock-based compensation - restricted stock	-	-	-	-	22,500	-	22,500
Net loss	-	-	-	-	-	(1,428,675)	(1,428,675)
Balance at June 30, 2019	-	$ -	2,558,419	$ 2,558	$ 9,906,468	$ (7,909,174)	$ 1,999,852

Issuance of common stock in September capital raise	-	-	69,114	70	499,929	-	499,999
Stock-based compensation - stock options	-	-	-	-	116,640	-	116,640
Stock-based compensation - restricted stock	-	-	-	-	22,500	-	22,500
Net loss	-	-	-	-	-	(2,354,083)	(2,354,083)
Balance at September 30, 2019	-	$ -	2,627,533	$ 2,628	$ 10,545,537	$ (10,263,257)	$ 284,908

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

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

	For the Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (25,170,372)	$ (5,310,814)
Adjustments to reconcile net loss to		
Net cash used in operating activities:		
Stock based compensation	7,407,331	318,484
Amortization of operating lease right-of-use asset	60,639	-
Depreciation	71,383	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,107,236	(54,960)
Other Assets	(41,994)	-
Accounts payable	1,196,900	(152,239)
Accrued expenses	(1,236,328)	1,277,222
Right-of-use liability	(35,883)	-
Net cash used in operating activities	(16,641,088)	(3,922,307)
Cash flows from investing activities:		
Cash and restricted cash acquired in connection with the reverse merger with ArTara Therapeutics, Inc.	3,718,742	-
Purchase of property and equipment	(373,340)	(429,138)
Net cash provided by/(used in) investing activities	3,345,402	(429,138)
Cash flows from financing activities:		
Proceeds from - ArTara Private Placement, net of offering costs	1,867,580	-
Proceeds from - Proteon Private Placement, net of offering costs	12,413,337	-
Proceeds from - Series 1 Convertible Preferred Stock, net of offering costs	25,318,706	-
Proceeds from September Series 1 Convertible Preferred, net of offering costs	66,283,552	-
Proceeds from September Common Stock, net of offering costs	73,570,660	-
Repayments under short-term debt	(1,297,777)	-
Proceeds from the exercise of stock options	530,301	-
Proceeds from private placements	-	499,999
Net cash provided by financing activities	178,686,359	499,999
Net increase/(decrease) in cash and cash equivalents and restricted cash	165,390,673	(3,851,446)
Cash and cash equivalents and restricted cash - beginning of year	564,124	5,549,952
Cash and cash equivalents and restricted cash - end of year	$ 165,954,797	$ 1,698,506
Reconciliation of cash and cash equivalents and restricted cash to the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 165,904,797	$ 1,698,506
Restricted cash	50,000	-
Cash and cash equivalents and restricted cash	$ 165,954,797	$ 1,698,506
Supplemental cash flow information		
Cash paid for:		
Interest	$ 26,353	$ -
Income Taxes	$ -	$ -
Non-cash investing and financing activities:		
Deferred offering costs recognized that were previously recorded in accrued expenses	$ 121,712	$ -
Purchase of insurance agreement with notes payable	$ 1,668,570	$ -
Common stock issued in connection with the reverse merger with ArTara Therapeutics, Inc.	$ 34,532,627	$ -
Settlement of RSUs	$ 21	$ -

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 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).

On January 9, 2020, privately-held ArTara Subsidiary, Inc. ("Private ArTara") and Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc.) completed the merger and reorganization (the "Merger"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated September 23, 2019, (the "Merger Agreement") by and among Protara Therapeutics, Inc., Private ArTara and REM 1 Acquisition, Inc., a wholly owned subsidiary of Protara Therapeutics, Inc. Thereupon, Merger Sub merged with and into Private ArTara, with Private ArTara surviving as a wholly owned subsidiary of Protara Therapeutics, Inc. The Merger was structured as a reverse merger and Private ArTara was determined to be the accounting acquirer based on the terms of the Merger and other factors, and the post-merger company retained the name ArTara Therapeutics, Inc., which on May 11, 2020 was changed to Protara Therapeutics, Inc.

On January 9, 2020, in connection with and prior to the completion of the Merger, Protara Therapeutics, Inc. effected a 1-for-40 reverse stock split of its common stock (the "Protara Reverse Stock Split"), Private ArTara changed its name from "ArTara Therapeutics, Inc." to "ArTara Subsidiary, Inc.", and ArTara Therapeutics, Inc. changed its name from "Proteon Therapeutics, Inc." to "ArTara Therapeutics, Inc." All share and per share amounts presented in this quarterly report on Form 10-Q have been adjusted to reflect the Protara Reverse Stock Split and the Exchange Ratio. In addition, immediately following the closing of the Private Placements (defined below), all of the outstanding shares of Protara Therapeutics, Inc.'s Series A Preferred Stock were converted into shares of Protara Therapeutics, Inc.'s Common Stock (defined below). Shares of the Company's Common Stock commenced trading on The Nasdaq Capital Market under the new name and ticker symbol "TARA" as of market open on January 10, 2020. See Note 3 for the full discussion regarding the Merger, Exchange Ratio and recapitalization.

Liquidity, Capital Resources and Management Plans

As of September 30, 2020 and December 31, 2019, the Company's cash and cash equivalents on hand was $165,904,797 and $564,124, respectively. The Company has not generated revenues since its inception and has incurred net losses of $25,170,372 and $5,310,814 for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, the Company had working capital of $163,228,281 and stockholder's equity of $194,625,763. During the nine months ended September 30, 2020, cash flows used in operating activities were $16,641,088, consisting primarily of a net loss of $25,170,372, which includes non-cash stock-based compensation charges of $7,407,331. Since inception, the Company has met its liquidity requirements principally through the sale of its Common Stock and Series 1 Convertible Preferred Stock.

In connection with the Merger, the Company consummated the Private Placements, raising gross proceeds of $42.5 million and proceeds, net of offering costs, of $39.6 million.

On September 22, 2020, the Company entered into underwriting agreements with Cowen and Company, LLC and Guggenheim Securities, LLC, as representatives of several underwriters for separate, concurrent underwritten public offerings of the Company's Common Stock and Series 1 Convertible Preferred Stock. On September 24, 2020, gross and net proceeds from this offering were $147.6 million and $139.9 million, respectively. On October 6, 2020, the underwriters exercised their overallotment option, resulting in the receipt of gross and net proceeds of $11.6 million and $11.1 million, respectively (See Note 7).

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, as of the date of the issuance of these consolidated financial statements, are sufficient to satisfy the Company's estimated liquidity needs for at least twelve months from the date of issuance of these unaudited consolidated financial statements.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and Article 8 Section 3 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. All adjustments (consisting of normal accruals) considered necessary for a fair presentation have been included. Operating results for the nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2019 and related notes thereto included as Exhibit 99-1, within Form 8-K/A filed on March 20, 2020 with the United States Securities and Exchange Commission ("SEC").

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements, and also that affect the amount of expenses reported for each period. Actual results could differ from those which result from using such estimates. Management also utilizes various other estimates, including but not limited to income taxes, the valuation of deferred tax assets, determining the fair value of business combination considerations, determining the fair value and evaluation for impairment of goodwill and intangibles, determining the fair value of the Company's Common Stock, and the valuation of securities and assumptions underlying 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.

Cash and cash equivalents

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.

Restricted Cash

Restricted cash as of September 30, 2020 and December 31, 2019 was $50,000 and $0, respectively. As of September 30, 2020, restricted cash consists of a cash deposit of $50,000 to collateralize a letter of credit obligation.

Property and Equipment

Property and equipment is recorded at cost. Major property additions, replacements, and betterments are capitalized, while maintenance and repairs that do not extend the useful lives of an asset or add new functionality are expensed as incurred. Property and equipment not placed into service is not depreciated until such time that it is placed into service. Depreciation is recorded using the straight-line method over the respective estimated useful lives of the Company's assets.

Goodwill

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of companies acquired. Goodwill and other intangible assets acquired in a business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually. An entity has the option to first assess qualitative factors to determine whether events or circumstances lead to a conclusion that is more likely than not that the fair value of a reporting unit is greater than its carrying amount. If an entity determines that qualitative factors indicate that it is more likely than not that the fair value of the entity exceeds the carrying amount, the quantitative evaluation is not necessary. Under the quantitative impairment test, the evaluation of impairment involves comparing the current fair value of each reporting unit to its carrying value, including goodwill.

In the event the estimated fair value of the Company is less than the carrying value, the Company would recognize a goodwill impairment equal to the difference between the carrying value and its fair value, not to exceed the carrying value of goodwill.

On January 9, 2020, in connection with the Merger, the Company separately valued the assets and liabilities acquired, and then determined goodwill as the residual of the purchase price less identified net assets (See Note 3).

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding, plus the impact of common shares, if dilutive, resulting from the exercise of outstanding stock options.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	For the Three and Nine Months Ended September 30,	
	2020	**2019**
Stock options	622,339	1,151,730
Restricted stock units	407,325	-
Conversion of Series 1 Convertible Preferred Stock	8,029,039	-
Total potentially dilutive shares	9,058,703	1,151,730

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consists principally of cash amounts on deposit with financial institutions. At times, the Company's cash in banks is in excess of the Federal Deposit Insurance Corporation insurance limit. The Company has not experienced any loss as a result of these deposits.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification, or ("ASC"), Topic 718, "Compensation - Stock Compensation" ("ASC 718"). ASC 718 establishes accounting for stock-based awards exchanged for employee and consultant services. Under the provisions of ASC 718, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the employee's requisite service period (generally the vesting period of the equity grant). The fair value of the Company's stock options are estimated using the Black Scholes option-pricing model with the following assumptions: fair value of the Company's Common Stock, expected volatility, dividend rate, risk free interest rate and the expected life. The Company calculates the expected volatility using the historical volatility for a pool of peer companies over the most recent period equal to the expected term and evaluates the extent to which available information indicate that future volatility may differ from historical volatility. The expected dividend rate is zero as the Company does not expect to pay or declare any cash dividends on its Common Stock. The risk-free rates for the expected terms of the stock options are based on the U.S. Treasury yield curve in effect at the time of the grant. The Company has not experienced significant exercise activity on stock options. Due to the lack of historical information, the Company determined the expected term of its stock option awards issued using the simplified method. The simplified method assumes each vesting tranche of the award has a term equal to the midpoint between when the award vests and when the award expires. Restricted stock awards generally vest over the requisite service periods (vesting on a straight–line basis). The fair value of a stock award is equal to the fair market value of a share of the Company's Common Stock on the grant date. The Company accounts for the forfeiture of equity awards as they occur.

Fair Value Measurements

The carrying amounts of cash and cash equivalents, prepaid expenses, accounts payable and short-term debt approximate their fair values due to the short-term nature of these instruments.

ASC Topic 820 "Fair Value Measurements and Disclosures" provides the framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements).

Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants. Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

- Ø Level 1 Quoted prices in active markets for identical assets or liabilities.
- Ø Level 2 Quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly.
- Ø Level 3 Significant unobservable inputs that cannot be corroborated by market data.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Research and Development Costs

Research and development costs are expensed as incurred. These expenses include the costs of our 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.

Research and development expenses were $2,796,214 and $1,098,617 for the three months ended September 30, 2020 and 2019, and $8,330,727 and $3,163,179 for the nine months ended September 30, 2020 and 2019, respectively.

Business Combinations

For a business combination, the assets acquired and the liabilities assumed are recognized at the acquisition date, measured at their fair values as of that date. In a business combination achieved in stages, the identifiable assets and liabilities are recognized at their fair values. In a bargain purchase in which the total acquisition-date fair value of the identifiable net assets acquired exceeds the fair value of the consideration transferred plus any non-controlling interest in the acquiree, that excess in fair value is recognized as a gain.

Deferred tax liabilities and assets are recognized for the deferred tax consequences of differences between the tax bases and the recognized values of assets acquired and liabilities assumed in a business combination in accordance with ASC Topic 740-10 “Income Taxes”. See Note 3 for the Company’s accounting for the reverse merger.

Recent Accounting Pronouncements Adopted

In January 2017, the FASB issued Accounting Standards Update (“ASU”) 2017-04 (“ASU 2017-04”), Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. ASU 2017-04 simplifies the subsequent measurement of goodwill by eliminating the second step of the goodwill impairment test. The second step measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount of that goodwill. Under ASU 2017-04, a company will record an impairment charge based on the excess of a reporting unit’s carrying amount over its fair value. ASU 2017-04 will be applied prospectively and is effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. On January 1, 2020, the Company adopted ASU 2017-04. The adoption of this standard did not have a material effect on the Company’s financial position, results of operations, or cash flows.

Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were available to be issued. Other than as described in Note 1, 7 and 11, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

NOTE 3 – REVERSE MERGER WITH PROTARA AND RECAPITALIZATION

On January 9, 2020, in connection with, and prior to the completion of the Merger, Protara Therapeutics, Inc. effected the Protara Reverse Stock Split, which resulted in 557,631 pre-merger shares of Protara Therapeutics, Inc. outstanding.

Under the terms of the Merger Agreement, Protara Therapeutics, Inc. issued shares of its common stock ("Common Stock") to the Company's stockholders, at an exchange ratio of 0.190756 (the "Exchange Ratio") shares of Common Stock, after taking into account the Protara Reverse Stock Split, for each share of Private ArTara common stock outstanding immediately prior to the Merger. Protara Therapeutics, Inc. assumed all of the unvested Private ArTara restricted stock awards, which were exchanged for a number of shares of Common Stock equal to 0.190756 multiplied by the number of shares of Private ArTara common stock previously represented by such Private ArTara restricted stock awards and unvested to the same extent as such Private ArTara restricted stock awards and subject to the same restrictions as such Private ArTara restricted stock awards. The effect of the Exchange Ratio resulted in the shareholders of the Company being issued 2,627,533 shares of Protara Common Stock.

Protara Therapeutics, Inc. assumed all of the outstanding and unexercised stock options of Private ArTara, with such stock options now representing the right to purchase a number of shares of Common Stock equal to 0.190756 multiplied by the number of shares of Private ArTara common stock previously represented by such Private ArTara stock options. As a result, 219,699 shares were assumed under Private ArTara's 2017 Equity Incentive Plan. No additional awards will be made under the 2017 Equity Incentive Plan. On January 1, 2020, Protara Therapeutics, Inc. amended its Amended and Restated 2014 Equity Incentive Plan (the "2014 Equity Incentive Plan") to increase the number of shares of stock available for issuance under the 2014 Equity Incentive Plan to 1,048,300 shares and made conforming changes and updates pursuant to Section 162(m) of the Code.

Concurrently with the execution of the Merger Agreement, certain institutional investors (together, the "Investors") entered into a subscription agreement (as amended on November 19, 2019, the "Subscription Agreement") with Protara Therapeutics, Inc. and Private ArTara, pursuant to which (A) Protara Therapeutics, Inc. issued in a private placement immediately after the Merger (the "Proteon Private Placement") (i) 3,879.356 of shares of Protara Therapeutics, Inc.'s Series 1 Convertible Non-Voting Preferred Stock at a purchase price of approximately $7,011.47 per share for gross proceeds of $27,199,988 and proceeds, net of issuance costs, of $25,318,706, (ii) 1,896,888 shares of Protara Therapeutics, Inc.'s Common Stock at a purchase price of approximately $7.01 per share for gross proceeds of $13,299,974 and proceeds, net of issuance costs, of $12,413,337 and (B) Private ArTara issued in a private placement immediately prior to the Merger (the "ArTara Private Placement") 284,875 shares of Private ArTara common stock (post-Exchange Ratio basis) at a purchase price of approximately $7.01 per share (post-Exchange Ratio basis) (together with the Proteon Private Placement, the "Private Placements") for gross proceeds of $1,999,999 and proceeds, net of issuance costs, of $1,867,580. The shares issued in the Proteon Private Placement were registered for resale on a registration statement on Form S-3 filed and declared effective by the U.S. Securities and Exchange Commission (the "SEC") on January 30, 2020.

Immediately following the closing of the Proteon Private Placement, 18,954 shares of Protara Therapeutics, Inc.'s Series A Convertible Preferred Stock outstanding were converted into 476,276 shares of Protara Therapeutics, Inc.'s Common Stock. These shares, combined with the 557,631 pre-merger shares of Protara Therapeutics, Inc. outstanding after the Protara Reverse Stock Split, resulted in an aggregate of 1,033,907 shares of Common Stock issued in connection with the Merger.

Immediately after the consummation of the Merger and prior to the consummation of the Proteon Private Placement, the former stockholders and option holders of Private ArTara owned, or held rights to acquire, approximately 75.2% of the fully-diluted Common Stock of Protara, with Protara Therapeutics, Inc.'s stockholders and option holders immediately prior to the Merger owning approximately 24.8% of the fully-diluted Common Stock of Protara.

NOTE 3 – REVERSE MERGER WITH PROTARA AND RECAPITALIZATION (Continued)

Based on the terms of the Merger, the transaction was treated as a reverse merger of Protara Therapeutics, Inc. by Private ArTara. The Merger was accounted for using acquisition accounting under ASC Topic 805 “Business Combinations”. Under acquisition accounting, the assets and liabilities (including executory contracts, commitments and other obligations) of Protara Therapeutics, Inc. as of the effective time of the Merger were recorded at their respective fair values and added to those of Private ArTara. Any excess of purchase price consideration over the fair values of the identifiable net assets is recorded as goodwill.

The following details the preliminary allocation of the purchase price consideration:

Cash	$ 3,668,742
Restricted cash	50,000
Prepaid expenses and other current assets	1,739,270
Goodwill	29,367,213
Accrued expenses	(292,598)
Total purchase price consideration	$ 34,532,627

The total fair value of the net assets of Protara Therapeutics Inc. was determined by the Company to be $34,532,627 based on the consideration transferred. The total consideration was based on the enterprise value of Protara Therapeutics Inc. as of January 9, 2020, based upon the number of common shares deemed outstanding, multiplied by the closing stock price on January 9, 2020.

Of the amount of goodwill acquired in the reverse merger, no portion is deductible for tax purposes.

The primary reasons for the reverse merger: the increased access to sources of capital and a broader range of investors to support the clinical development of the Company’s product candidates, the potential to provide current stockholders with greater liquidity by owning stock in a public company, the potential for a more cost-effective means to access capital and the registration of Protara Common Stock issued to Private ArTara’s stockholders. In addition, Protara assumed the existing 2014 Equity Incentive Plan (the “2014 Plan”), and all outstanding stock options thereunder. In addition, no additional shares may be issued under the 2017 Equity Incentive Plan (See Note 8).

The following presents the unaudited pro forma combined financial information as if the reverse merger had occurred as of January 1, 2019. Since the merger was consummated on January 9, 2020, the results of the merger are fully incorporated into the condensed consolidated financial information for the three months ended September 30, 2020.

	For the Three Months Ended September 30,	For the Nine Months Ended September 30,	
	2019	2020	2019
Net loss	$ (3,890,083)	$ (24,945,372)	$ (18,692,814)
Pro forma loss per common share, basic and diluted	$ (0.67)	$ (4.22)	$ (3.24)
Pro forma weighted average number of common shares outstanding, basic and diluted	5,780,199	5,910,849	5,776,114

The pro forma combined results of operations are not necessarily indicative of the results of operations that actually would have occurred had the reverse merger been completed as of January 1, 2019, nor are they necessarily indicative of future consolidated results.

NOTE 4 – ACCRUED EXPENSES

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

	As of	
	September 30, 2020	December 31, 2019
Legal fees	$ 356,422	$ 1,572,554
Research and development	152,071	1,050,500
Bonus	715,500	-
Other	345,355	11,736
Total	$ 1,569,348	$ 2,634,790

NOTE 5 – SHORT-TERM DEBT

Financing Agreement

On February 19, 2020, the Company entered into a nine month financing agreement with AFCO Credit Corporation for its directors and officers ("D&O") liability insurance in the amount of $2,224,760. The Company made a down payment of $556,190, leaving a principal balance of $1,668,570. The financing bears interest at a rate of 4.25% per annum, and will be repaid in monthly installments of $189,161, which includes both principal and interest. As of September 30, 2020, the balance under this debt was $370,793.

NOTE 6 – COMMITMENTS AND CONTINGENCIES

Lease Agreements

The Company has entered into operating leases for office and laboratory space. On January 1, 2019 ("Effective Date"), the Company adopted ASC Topic 842, Leases ("ASC 842"), which increases transparency and comparability by recognizing a lessee's rights and obligations resulting from leases by recording them on the balance sheet as lease assets and lease liabilities. The new guidance requires the recognition of the right-of-use ("ROU") assets and related operating lease liabilities on the balance sheet. The Company adopted the new guidance using the modified retrospective approach on January 1, 2019.

The adoption of ASC 842 on January 1, 2019 did not result in the recognition of ROU assets as the Company did not have any leases at that time with a term of twelve months or more. However, on January 9, 2020, subsequent to the Merger and Private Placements, it became reasonably certain that the Company would maintain its quarter-to-quarter lease with its contract development and manufacturing organization for its manufacturing space for an expected term of approximately eight years, therefore resulting in the recognition of an ROU asset and related operating lease liability.

On July 1, 2020, the Company began a quarter-to-quarter lease of a development laboratory space for an expected term of approximately eight years with a contract development and manufacturing organization, therefore resulting in the recognition of an additional ROU asset and related operating lease liability.

For contracts entered into on or after the Effective Date, at the inception of a contract, the Company will assess whether the contract is, or contains, a lease. The Company's assessment is based on: (i) whether the contract involves the use of a distinct identified asset, (ii) whether the Company obtained the right to substantially all the economic benefit from the use of the asset throughout the period, and (iii) whether the Company has the right to direct the use of the asset. Leases entered into prior to January 1, 2019, which were accounted for under ASC 840, Leases, were not reassessed for classification.

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Lease Agreements (Continued)

For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments. The Company generally uses its incremental borrowing rate as the discount rate for leases, unless an interest rate is implicitly stated in the lease. The present value of the lease payments is calculated using the incremental borrowing rate for operating leases, which was determined using a rate of interest that we would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term. The lease term for the Company's lease includes the noncancellable period of the lease plus any additional periods covered by either a Company option to extend the lease that the Company is reasonably certain to exercise, or an option to extend the lease controlled by the lessor. ROU assets, once recorded, are reviewed for impairment.

Lease expense for operating leases consists of the lease payments plus any initial direct costs and is recognized on a straight-line basis over the lease term.

Balance sheet information related to our leases is presented below:

		As of		
Operating leases:	**Balance Sheet Location**	**September 30, 2020**	**January 9, 2020**	**December 31, 2019**
Right-of-use assets	Other assets	$ 404,044	$ 403,161	$ -
Right-of-use liability, current	Right-of-use liability, current	34,079	9,195	-
Right-of-use lease liability, long-term	Right-of-use lease liability, long-term	394,721	393,966	-

The following provides details of the Company's lease expense:

Lease cost	**For the Three Months Ended September 30, 2020**	**For the Nine Months Ended September 30, 2020**
Operating lease cost	$ 21,147	$ 60,639
Short-term lease cost	2,793	151,332
Total	$ 23,940	$ 211,971

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Lease Agreements (Continued)

Other information related to leases is presented below:

	As of September 30, 2020
Other information	
Weighted-average discount rate – operating lease	12.00%
Weighted-average remaining lease term – operating lease (in months)	91

On January 9, 2020, subsequent to the Merger and Private Placements, it became reasonably certain that the Company would maintain its quarter-to-quarter lease for its manufacturing space for a term of approximately eight years and on July 1, 2020, its quarter-to-quarter lease for its development lab began for a term of approximately eight years.

As of September 30, 2020, the expected annual minimum lease payments of our operating lease liabilities and other short-term leases were as follows:

For Years Ending December 31,	Operating lease
2020 (excluding the nine months ended September 30, 2020)	$ 82,911
2021	145,176
2022	84,402
2023	86,088
2024	87,810
Thereafter	297,618
Total future minimum lease payments, undiscounted	784,005
Less: Imputed interest for leases in excess of one year	230,345
Present value of future minimum lease payments	$ 553,660
Present value of future minimum lease payments for our operating lease liabilities	$ 428,800
Present value of future minimum lease payments, short-term leases	$ 124,860

Employment Agreements

Executive Employment Agreements

In connection with the consummation of the Merger, Jesse Shefferman, the Company's Chief Executive Officer, had his base salary increased from $365,000 to $510,000 and Jacqueline Zummo, the Company's Head of Operations and Medical Affairs, had her base salary increased from $305,000 to $325,000. The Company also entered into an employment agreement with Blaine Davis to become the Company's Chief Financial Officer on January 31, 2020, effective as of February 11, 2020, for a base salary of $385,000, and with Julio Casoy to become the Company's Chief Medical Officer, on February 6, 2020, for a base salary of $400,000. During the nine months ended September 30, 2020, Mr. Shefferman, Dr. Zummo and Dr. Casoy received bonus payments of $259,688, $95,313 and $115,500, respectively, which were included in research and development expenses of $210,813 and in general and administrative expenses of $259,688, in the three months ended March 31, 2020.

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Employment Agreements (Continued)

Temporary Employment Agreement

On December 6, 2018, the Company entered into a temporary employment agreement (the "Temporary Employment Agreement") with an individual who assisted with certain corporate development activities. Pursuant to the Temporary Employment Agreement, the individual was entitled to receive an annual base salary of $90,000. In addition, the individual would be entitled to a performance-based success fee which would be adjusted based on amounts of funding achieved and timing of when such funding was received. On January 9, 2020, the Company's capital raise triggered a performance-based compensation obligation and accordingly this individual was paid $462,500, which was included in general and administrative expenses within the Company's unaudited condensed consolidated statements of operations for the nine months ended September 30, 2020.

Departure of Executive

The Company and Dr. Casoy entered into a Separation Agreement and Release (the "Separation Agreement"), effective August 3, 2020, whereupon, Dr. Casoy would no longer be employed by the Company as Chief Medical Officer. Pursuant to the Separation Agreement, in consideration for a general release of all claims against the Company and certain representations, warranties, covenants and agreements, Dr. Casoy received (i) his base salary for a period of nine months paid in a lump sum, (ii) a one-time lump sum payment equal to nine months of his bonus at target, (iii) reimbursement of all business expenses for which he was entitled, (iv) reimbursement of COBRA premium costs for nine months, or until he has secured other employment, whichever comes first and (v) pro-rata vesting of his outstanding equity award given that he was not employed through the one-year anniversary of the applicable grant date of such outstanding equity award (See Note 8).

Product License and Clinical Services Agreements

Alan L. Buchman and Choline License Agreement

On September 27, 2017, the Company entered into a license agreement (the "Choline License Agreement") with Alan L. Buchman ("Dr. Buchman"). Pursuant to the Choline License Agreement, the Company received from Dr. Buchman the license rights in and to the "Licensed Orphan Designations", the "Licensed IND", "Existing Study Data" and the "Licensed Know-How" for one or more of the licensed indications. In consideration for the rights and licenses granted, Dr. Buchman received a payment of $50,000 on October 2, 2017, and license payments of $50,000 and $50,000 on December 12, 2018 and January 8, 2019, respectively, upon the Company meeting the criteria for certain meetings to be held with the Federal Drug Administration (the "FDA"). Pursuant to the Choline License Agreement, effective October 2017, the Company incurred a fixed obligation to Dr. Buchman of $400,000 (the "Choline License Fee"). Upon the Company receiving $5,000,000 in cumulative funding (as defined), Dr. Buchman would be entitled to receive payment of the Choline License Fee as a lump sum if the funds are received by April 15, 2019 and the Choline License Fee shall be increased to a one-time payment of $600,000 if the funds are received by October 15, 2019. On October 2, 2019, the Company made a payment of $50,000 to Dr. Buchman. On January 22, 2020, in connection with the closing of the Merger and concurrent financing, Dr. Buchman was paid $550,000 which was included in accrued expenses as of December 31, 2019.

During the three months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $0, respectively, and during the nine months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $200,000, respectively, for expenditures to Dr. Buchman in connection with obligations under the Choline License Agreement.

The Feinstein Institute for Medical Research

On December 22, 2017, the Company entered into an agreement (the "Feinstein Agreement") with The Feinstein Institute for Medical Research (the "Feinstein Institute"), a not-for-profit corporation with 50 research labs and 2,500 clinical research studies. Pursuant to the Feinstein Agreement, the Company acquired an exclusive license relating to treatment of fatty liver diseases in humans for which Choline may be an effective therapeutic. In consideration for the rights and license granted, the Feinstein Institute would receive a royalty of one percent (1%) of the first one hundred million dollars ($100,000,000) of net sales of IV Choline Chloride and a royalty of one and one-half percent (1.5%) of all net sales thereafter. In addition, the Company would pay the Feinstein Institute twelve and one-half percent (12.5%) of net proceeds resulting from agreements entered within 2 years from the effective date, and seven and one-half percent (7.5%) of net proceeds resulting from agreements entered into thereafter. Pursuant to the Feinstein Agreement additional payments would be due to the Feinstein Institute for license maintenance payments and for meeting milestone events. On January 9, 2020, the Company's raising of over $5,000,000 triggered a financing milestone obligation and accordingly the Feinstein Institute was paid $100,000. Pursuant to the Feinstein Agreement, upon the achievement of certain future new drug application milestones, the Company would be obligated to remit an aggregate of $275,000.

During the three months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $0, respectively, and during the nine months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $100,000 and $0, respectively, in connection with the Feinstein Agreement.

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Product License and Clinical Services Agreements (Continued)

The University of Iowa

On November 28, 2018, the Company entered into a sponsored research and license agreement (the "Iowa Agreement") with the University of Iowa. Pursuant to the Iowa Agreement, the University of Iowa, which is engaged in clinical research to improve the diagnosis and treatment of lymphangioma using a pharmaceutical product (OK-432), would assist the Company in collecting case reports, forms, source data, and safety data available to the University of Iowa in support of the development of the Company's proprietary *Streptococcus Pyogenes* investigational product, TARA-002 for the LMs indication. During the term of the services, the Company would pay the University of Iowa thirty thousand dollars ($30,000) per year to fund the project, plus additional amounts upon the realization of certain milestones. More specifically, upon forty-five (45) days of an approval of the TARA-002 by the FDA, the Company would pay up to $1,750,000 to the University of Iowa for meeting their milestones. Furthermore, the Company would pay the University of Iowa royalties of up to 1.75% for net sales ranging from $0 - $25,000,000, 2.25% for net sales ranging from $25,000,000+ to $50,000,000, and 2.50% for net sales of $50,000,000+. Pursuant to the Iowa Agreement, the University of Iowa would be entitled to additional payments for annual net sales payments as per the following milestones. For annual net sales of product up to $25,000,000; $62,500; for annual net sales of product of up to $50,000,000; $62,500; and for annual net sales of product of up to $100,000,000; $125,000.

During the three months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $7,500 and $7,500, respectively, and during the nine months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $22,500 and $22,500, respectively, in connection with the Iowa Agreement.

Chugai Pharmaceutical Co., LTD

On June 17, 2019, the Company entered into an agreement (the "Chugai Pharmaceutical Agreement") with Chugai Pharmaceutical Co., LTD ("Chugai"), a drug manufacturing firm with offices and operations in Japan. Pursuant to the Chugai Pharmaceutical Agreement, Chugai would help the Company in its goals to develop and commercialize a therapeutic product (the "New Product") which is comparable to the Chugai existing therapeutic product (the "Existing Product"). In addition, the Company would be entitled to the use of Chugai materials and technical support as necessary. On July 14, 2020, the Company and Chugai entered into an amendment (the "Chugai Amendment") to the Chugai Pharmaceutical Agreement. The Chugai Amendment is effective as of June 30, 2020. The Chugai Amendment extended the date through which Chugai will exclusively provide the Existing Product and materials to the Company from June 30, 2020 to June 30, 2021, extended the date through which Chugai will not provide materials or technical support to any third party for the purpose of development and commercialization in a given area from the fifth anniversary to the eleventh anniversary of the original effective date and provides that, in addition to the designated fee provided upon the initial indication approval in the Chugai Pharmaceutical Agreement, the Company will pay Chugai a designated fee for each additional indication approval. The Company is obligated to Chugai for certain payments upon the completion of agreed upon milestones. As of December 31, 2019, Chugai fulfilled a performance obligation upon which the Company recorded an obligation of $500,000, which the Company paid on July 27, 2020.

During the three months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $500,000, respectively, and during the nine months ended September 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $500,000, respectively, in connection with the Chugai Agreement, as amended.

Johns Hopkins University

In February 2002, Proteon entered into an agreement to license certain intellectual property in connection with vonapanitase with Johns Hopkins University. The agreement calls for payments to be made by the Company upon the commencement of vonapanitase related product sales, in the form of a royalty of 2.5% on net sales of the product. As of September 30, 2020, the Company has not commenced vonapanitase product sales and therefore has recognized no royalties on product sales.

Litigation

From time to time, Protara may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

Between November 15 and December 23, 2019, four lawsuits were filed in federal court against Proteon, ArTara, Merger Sub and the individual members of the Proteon Board (captioned Patrick Plumley v. Proteon Therapeutics, Inc., et al., Case No. 1:19-cv-02143-UNA (D. Del. filed 11/15/19)); Jeffrey Teow v. Proteon Therapeutics, Inc., et al., Case No. 1:19-cv-06745 (E.D.N.Y., filed 11/30/19); Neil Lanteigne v. Proteon Therapeutics, et al., Case No. 1:19-cv-12436 (D. Mass., filed 12/03/19); Stephen Wagner v. Proteon Therapeutics, Inc., et al., Case No. 1:19-cv-02343 (D. Del., filed 12/23/19). The Plumley complaint was brought as a purported class action lawsuit. All four lawsuits alleged that the definitive proxy statement in the preliminary registration statement on Form S-4 filed by Proteon on November 7, 2019 with the SEC in connection with the proposed Merger (the "Proxy Statement") omitted material information with respect to the transactions contemplated by the Merger Agreement, rendering it false and misleading in violation of Sections 14(a) (and Rule 14a-9 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiffs in each of the four lawsuits sought, among other things, injunctive relief, rescission, declaratory relief and unspecified monetary damages. On December 31, 2019, Proteon filed an amendment to the Proxy Statement on Form 8-K, which contained certain supplemental disclosures intended to moot the plaintiffs' disclosure claims. On January 9, 2020, Proteon held a special meeting of its stockholders, at which the Company's stockholders approved the Merger. On January 27, 2020, plaintiff in the Lanteigne action voluntarily dismissed his case. On February 3, 2020, plaintiff in the Plumley action voluntarily dismissed his case. On February 7, 2020, plaintiff in the Teow action voluntarily dismissed his case. On February 10, 2020, plaintiff in the Wagner action dismissed his case. Thereafter, in connection with the supplemental disclosures that were filed by the Company to moot plaintiffs' claims in these actions, counsel for plaintiffs demanded an award of attorney's fees, which the parties resolved in July 2020.

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Other

The Company is involved in various claims and legal actions arising in the ordinary course of business. 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, 2020 and December 31, 2019, the Company has 100,000,000 shares of Common Stock authorized for issuance, $0.001 par value per share, of which 10,521,840 and 2,627,533 shares were issued and outstanding, respectively.

The holders of the Company's Common Stock are entitled to one vote per share.

Authorized Series 1 Convertible Preferred Stock

In connection with the Preferred Offering (defined below) on September 22, 2020, the Company filed a Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Preferred Stock of the Company (the "Amendment") with the State of Delaware to increase the authorized number of shares of the Company's Series 1 Convertible Preferred Stock that may be issued from 3,880 to 8,028. The Amendment was approved by a committee of the Company's Board of Directors and the requisite holders of outstanding shares of Series 1 Convertible Preferred Stock. No approval of the holders of the Company's Common Stock was required to effectuate the Amendment.

As of September 30, 2020 and December 31, 2019, 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, $0.001 par value per share, and 8,027 and 0 shares were issued and outstanding, respectively.

Description of Series 1 Convertible Preferred Stock

Each share of Series 1 Convertible Preferred Stock is convertible into 1,000 shares of Common Stock, at a conversion price initially equal to approximately $7.01 per common share, subject to adjustment for any stock splits, stock dividends and similar events, at any time at the option of the holder, provided that any conversion of Series 1 Convertible Preferred Stock by a holder into shares of Common Stock would be prohibited if, as a result of such conversion, the holder, together with its affiliates and any other person or entity whose beneficial ownership of the Common Stock would be aggregated with such holder's for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, would beneficially own more than 9.99% of the total number of shares Common Stock issued and outstanding after giving effect to such conversion. Upon written notice to the Company, the holder may from time to time increase or decrease such limitation to any other percentage not in excess of 19.99% specified in such notice. Each share of Series 1 Convertible Preferred Stock is entitled to a preference of $10.00 per share upon liquidation of the Company, and thereafter will share ratably in any distributions or payments on an as-converted basis with the holders of Common Stock. In addition, upon the occurrence of certain transactions that involve the merger or consolidation of the Company, an exchange or tender offer, a sale of all or substantially all of the assets of the Company or a reclassification of its Common Stock, each share of Series 1 Convertible Preferred Stock will be convertible into the kind and amount of securities, cash and/or other property that the holder of a number of shares of Common Stock issuable upon conversion of one share of Series 1 Convertible Preferred Stock would receive in connection with such transaction. The Company's Series 1 Convertible Preferred Stock are non-voting.

The terms of the Series 1 Convertible Preferred Stock provide that, in the event of a fundamental transaction (as such term is described in the certificate of designation of preferences, rights and limitations of series 1 convertible non-voting preferred stock), each share of Series 1 Convertible Preferred Stock outstanding shall thereafter be convertible into the kind and amount of securities, cash and/or other property which a holder of the number of shares of Common Stock of the Company issuable upon conversion of one share of Series 1 Convertible Preferred Stock immediately prior to such fundamental transaction would have been entitled to receive pursuant to such fundamental transaction, provided that, if the value of the aggregate of such securities, cash and/or other property the which the holder of one share of Series 1 Convertible Preferred Stock would be entitled to upon conversion thereof would be less than the stated value, then each outstanding share of Series 1 Convertible Preferred Stock shall instead be convertible into such kind of securities, cash and/or other property with an aggregate value equal to the stated value.

NOTE 7 – STOCKHOLDERS' EQUITY (Continued)

Underwritten Public Offering

On September 24, 2020, pursuant to an underwriting agreement (dated September 22, 2020), the Company issued and sold in an underwritten public offering (the "Common Offering") an aggregate of 4,600,000 shares of its Common Stock at an offering price of $16.87 per share, for gross and net proceeds of approximately $77.6 million and $73.6 million, respectively. The underwriters were granted an option to purchase up to 690,000 additional shares of Common Stock at the public offering price, less the underwriting discount. This option was exercisable for a period of 30 days. On October 6, 2020, the underwriters exercised their overallotment option in full, purchasing an additional 690,000 shares, resulting in the receipt of gross and net proceeds of $11.6 million and $11.1 million, respectively.

On September 24, 2020, pursuant to an underwriting agreement (dated September 22, 2020), the Company issued and sold in an underwritten public offering (the "Preferred Offering") an aggregate of 4,148 shares of its Series 1 Convertible Preferred Stock at an offering price of $16,873.54 per share, for gross and net proceeds of approximately $70.0 million and $66.3 million, respectively.

The Common Offering and the Preferred Offering were made pursuant to the Company's registration statement on Form S-3, declared effective by the Securities and Exchange Commission on May 26, 2020 (Registration No. 333-238273).

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, 2020, 507,350 shares remain available to be issued under the 2020 Inducement Plan.

2017 Equity Incentive Plan

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

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

2014 Equity Incentive Plan

On October 3, 2014, the stockholders approved the 2014 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. Pursuant to a special meeting of the Proteon stockholders held on January 9, 2020, the number of shares available for issuance under the Amended 2014 Plan increased by 900,002 shares from 148,298 shares to 1,048,300 shares on January 1, 2020. As of September 30, 2020, 232,850 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.

NOTE 8 – STOCK-BASED COMPENSATION (Continued)

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. As of September 30, 2020, the authorized number of shares under the 2014 ESPP is 18,012 and the number of shares available for issuance is 13,340. During the nine months ended September 30, 2020 and 2019, no shares were issued under the 2014 ESPP.

Restricted Stock Units

Awards to Directors

The following RSUs were granted pursuant to the Amended 2014 Plan. Settlement for the RSUs is deferred until the earliest to occur of (i) the director's termination of service, (ii) death, (iii) disability and (iv) a change in control of the Company. In the event of a change in control of the Company, the RSUs will vest in full.

On January 10, 2020, the Board of Directors granted an aggregate of 254,000 RSUs to directors of the Company. These RSUs vest 12.5% on the date of grant and in twenty-one equal monthly installments thereafter. The grant date fair value of these RSUs was $7,620,000.

On January 10, 2020, the Board of Directors granted an aggregate of 62,000 RSUs to directors of the Company. These RSUs vest 50% on the one year anniversary of the grant date and the remainder vest in 12 equal monthly installments thereafter. The grant date fair value of these RSUs was $1,860,000.

Awards to Others

On January 10, 2020, the Board of Directors granted an aggregate of 91,000 RSUs to officers of the Company. These RSUs vest in four equal installments beginning on the first anniversary of the date of grant. The grant date fair value of these RSUs was $2,730,000.

On January 10, 2020, the Board of Directors granted an aggregate of 14,825 RSUs to employees of the Company. These RSUs vest in four equal annual installments beginning on the first anniversary of the date of grant. The grant date fair value of these RSUs was $444,750.

On January 10, 2020, the Board of Directors granted 50,000 RSUs to the Chief Executive Officer of the Company. These RSUs vest in four equal annual installments beginning on the first anniversary of the date of grant. The grant date fair value of these RSUs was $1,500,000.

On July 1, 2020, the Compensation Committee of the Company granted 7,500 RSUs to a new hire of the Company under the 2014 Equity Incentive Plan. These RSUs will vest 25% on the one, two, three and four year anniversary of the date of grant. The grant date fair value of these RSUs was $211,500.

Following is a summary of restricted stock unit activities for the nine months ended September 30, 2020:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested 1/1/2020	-	$ -
Granted	479,325	29.97
Forfeited	(56,375)	30.00
Vested	(119,896)	30.00
Non-vested 9/30/2020	303,054	$ 29.96

NOTE 8 – STOCK-BASED COMPENSATION (Continued)

Restricted Stock Units (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, 2020, the unamortized value of RSUs was $7,604,720. As of September 30, 2020, the weighted average remaining amortization period was 1.96 years. As of September 30, 2020 and 2019, 104,271 and 0 RSUs, respectively, have vested that have not yet been settled into shares of the Company's Common Stock.

On July 10, 2020, the Company issued 5,245 shares of Common Stock from the settlement of RSUs.

On July 29, 2020, the Company issued 9,938 shares of Common Stock from the settlement of RSUs.

On August 8, 2020, the Company issued 5,687 shares of Common Stock from the settlement of RSUs.

Restricted Stock Units Modification

On July 23, 2020, in connection with Dr. Casoy's separation, the Company agreed to accelerate the vesting of 5,687 RSUs. The Company recorded a charge of $151,843 during the three months ended September 30, 2020 to research and development expense within the Company's condensed consolidated statements of operations in connection with the modification of this award (See Note 6).

Stock Option Grants

During the first quarter of 2020, the Board of Directors granted stock options to purchase an aggregate of 205,250 shares of the Company's Common Stock. These options had an exercise price ranging from $30.00 to $37.30. The options expire ten years from their respective dates of grant and vest 25% on the one year anniversary of the grant date and the remainder of the underlying shares vest in thirty-six equal monthly installments thereafter. The grant date fair value of these options was $5,453,691.

During the second quarter of 2020, the Board of Directors granted stock options to purchase an aggregate of 113,450 shares of the Company's Common Stock. These options had an exercise price ranging from $24.02 to $51.12. The options expire ten years from their respective dates of grant. Options representing the purchase of 59,450 shares of the Company's Common Stock vest 25% on the one year anniversary of the date of grant and the remainder of the underlying shares vest in thirty-six equal monthly installments thereafter. Options representing the purchase of 54,000 shares of the Company's Common Stock vest monthly over one year. The grant date fair value of these options was $2,547,829.

During the third quarter of 2020, the Board of Directors granted stock options to purchase an aggregate of 194,700 shares of the Company's Common Stock. These options had an exercise price ranging from $20.51 to $28.20. The options expire ten years from their respective dates of grant. Options representing the purchase of 168,450 shares of the Company's Common Stock vest 25% on the one year anniversary of the date of grant and the remainder of the underlying shares vest in thirty-six equal monthly installments thereafter. Options representing the purchase of 8,250 shares of the Company's Common Stock vest monthly over one year. Options representing the purchase of 18,000 shares of the Company's Common Stock vest monthly over three years. The grant date fair value of these options was $3,922,772.

Stock Option Modifications

Effective July 20, 2020, Scott Braunstein, M.D. notified the Company of his resignation from the Company's Board of Directors. In connection with Dr. Braunstein's resignation, the Compensation Committee approved the accelerated vesting of all stock options issued to Dr. Braunstein prior to the Merger, and to extend the post-termination exercise period of vested options to 12 months from the date of resignation. Due to the modification of Dr. Braunstein's options, the Company recorded the incremental value of $500,563 during the three months ended September 30, 2020 to general and administrative expense within the Company's condensed consolidated statements of operations.

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,	
	2020	**2019**
Stock price	$ 20.51 - $ 51.12	$ 6.81 - $8.65
Exercise price	$ 20.51 - $ 51.12	$ 9.18
Dividend yield	0%	0%
Expected volatility	95% - 101%	97%
Risk-free interest rate	0.28% - 1.69%	1.71% - 2.37%
Expected life (in years)	5.27 - 6.08	5.58 - 6.02

Following is a summary of stock option activities for the nine months ended September 30, 2020:

	Options	**Weighted Average Grant Date Fair Value**	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (years)**	**Aggregate Intrinsic Value**
Outstanding 1/1/2020	219,592	$ 7.29	$ 9.18	9.72	$ -
Granted	513,400	23.23	30.01	-	-
Exercised	(57,767)	6.72	9.18		
Forfeited	(52,886)	14.08	18.91	-	-
Outstanding 9/30/2020	622,339	$ 20.93	$ 25.53	9.25	$ 1,049,496
Exercisable as of 9/30/2020	86,583	$ 9.70	$ 13.24	8.31	$ 552,391

The weighted average grant date fair value of the options granted during the nine months ended September 30, 2019 was $6.71. 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, 2020, the unamortized value of stock options was $10,151,722. As of September 30, 2020, the weighted average remaining amortization period was 3.12 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,	
	2020	**2019**	**2020**	**2019**
Restricted stock	$ -	$ 22,500	$ -	$ 67,500
RSUs	1,307,173	-	5,051,513	-
Stock options	1,473,629	116,640	2,355,818	250,984
Total	$ 2,780,802	$ 139,140	$ 7,407,331	$ 318,484

Stock-based compensation expense was reflected within the statements of operations as:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Research and development	$ 158,040	$ 81,645	$ 568,678	$ 175,197
General and administrative	2,622,762	57,495	6,838,653	143,287
Total	$ 2,780,802	$ 139,140	$ 7,407,331	$ 318,484

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 and nine months ended September 30, 2020, the Company recorded expense of $33,553 and $41,509, respectively, under the 401(k) Plan.

NOTE 10 – COVID-19

The ultimate impact of the current COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, its research and development activities, healthcare systems or the global economy as a whole. However, the effects could have a material impact on the Company's operations, liquidity and capital resources and the Company will continue to monitor the COVID-19 situation closely.

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

Severe and/or long-term disruptions in the Company's operations will negatively impact its business, operating results and financial condition in other ways, as well. Specifically, the Company anticipates that the stress of COVID-19 on healthcare systems around the globe will 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 11 – SUBSEQUENT EVENTS

On November 2, 2020, employees and new hires of the Company were granted options to purchase an aggregate of 10,200 shares of the Company's Common Stock with an exercise price of $17.84. These stock options expire ten years from the date of grant and vest 25% on the one year anniversary of the vesting commencement date and the remainder of the underlying shares shall vest in thirty-six equal monthly installments thereafter.

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. 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, 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 is approved in Japan and Taiwan for the treatment of lymphatic malformations ("LMs") and multiple oncologic indications. We are initially developing TARA-002 in the U.S. for the treatment of LMs. In addition, we are also developing TARA-002 in the U.S. for the treatment of non-muscle invasive bladder cancer ("NMIBC"). In July 2020, the U.S. Food and Drug Administration ("FDA"), granted Rare Pediatric Disease designation ("RPD") for TARA-002 for the treatment of LMs.

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. ("Chugai Pharmaceutical")). Following a recent pre-Investigational New Drug ("IND") engagement with the Office of Tissues and Advanced Therapies division of the Center for Biologics Evaluation and Research ("CBER"), the FDA agreed that we have successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432. In addition, we continue to be on track to conduct three large-scale batch runs to confirm comparability. Good Manufacturing Practice ("GMP") scale up is currently in process and we will initiate GMP comparability runs with an expected completion date in mid-2021. In addition, we have requested a meeting with the FDA Division of Vaccines and Related Products Applications to discuss the regulatory path for TARA-002 in LMs. We also reached alignment with the FDA on a proposed clinical development plan to evaluate TARA-002 in patients with NMIBC. Subject to the successful completion of select non-clinical studies as well as acceptance of an IND filing, we plan to commence NMIBC clinical trials with TARA-002 in 2021.

Our third program, Intravenous ("IV") Choline Chloride, is an investigational, Phase 3-ready, phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition ("PN") who have intestinal failure associated liver disease ("IFALD"). IV Choline Chloride has been granted Orphan Drug Designation ("ODD") and Fast Track designation ("FTD") by the FDA for this indication.

Our fourth program, vonapanitase, is a recombinant human elastase. 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.

We 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 any significant revenues prior to 2022, 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.

COVID-19

The ultimate impact of the current COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our research and development activities, healthcare systems or the global economy as a whole. However, the effects could have a material impact on our operations, liquidity and capital resources and we will continue to monitor the COVID-19 situation closely.

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 social distancing 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 will negatively impact our business, operating results and financial condition in other ways, as well. 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 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 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.

Merger

As further described in Note 3 of the financial statements included in Part I, Item I of this quarterly report on Form 10-Q, on January 9, 2020, privately-held ArTara Subsidiary, Inc. ("Private ArTara") and Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc.) completed the merger and reorganization (the "Merger"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated September 23, 2019, (the "Merger Agreement") by and among Protara Therapeutics, Inc., Private ArTara and REM 1 Acquisition, Inc., a wholly owned subsidiary of Protara Therapeutics, Inc. ("Merger Sub"). Thereupon, Merger Sub merged with and into Private ArTara, with Private ArTara surviving as a wholly owned subsidiary of Protara Therapeutics, Inc. The Merger was structured as a reverse merger and Private ArTara was determined to be the accounting acquirer based on the terms of the Merger and other factors, and the post-merger company retained the name ArTara Therapeutics, Inc. which, on May 11, 2020, was changed to Protara Therapeutics, Inc.

On January 9, 2020, in connection with, and prior to the completion of, the Merger, Protara Therapeutics, Inc. effected a 1-for-40 reverse stock split of its common stock ("Protara Reverse Stock Split") Private ArTara changed its name from "ArTara Therapeutics, Inc." to "ArTara Subsidiary, Inc.", and Protara Therapeutics, Inc. changed its name from "Proteon Therapeutics, Inc." to "ArTara Therapeutics, Inc." All share and per share amounts presented in this quarterly report on Form 10-Q have been adjusted to reflect the Protara Reverse Stock Split. In addition, immediately following the closing of the Private Placements (described below), all of the outstanding shares of Protara Therapeutic, Inc.'s Series A Preferred Stock were converted into shares of Protara Therapeutics, Inc.'s Common Stock. Shares of our Common Stock commenced trading on The Nasdaq Capital Market under the new name and ticker symbol "TARA" as of market open on January 10, 2020.

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 ("CROs"), contract development and manufacturing organizations ("CDMOs"), the cost of acquiring, developing and manufacturing clinical trial materials, 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 as well as 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 and restricted cash and interest expenditures 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 the Annual Report of Private ArTara for the year ended December 31, 2019 as Exhibit 99.1 within the Form 8-K/A, as filed with the SEC on March 20, 2020.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Period-to-Period Change
	2020	2019	
Operating expenses:			
Research and development	$ 2,796,214	$ 1,098,617	$ 1,697,597
General and administrative	5,265,965	1,255,466	4,010,499
Total operating expenses	8,062,179	2,354,083	5,708,096
Operating loss	(8,062,179)	(2,354,083)	(5,708,096)
Other income, net:			
Interest income, net	(92,094)	-	(92,094)
Total other income, net	(92,094)	-	(92,094)
Net Loss	$ (7,970,085)	$ (2,354,083)	$ (5,616,002)

Research and Development Expenses. During the three months ended September 30, 2020, our research and development expenses were $2.8 million which represented an increase of $1.7 million as compared to the three months ended September 30, 2019. This increase was primarily due to an increase of $0.7 million in consulting and studies related to TARA-002, an increase of $0.4 million related to the manufacturing and testing of TARA-002 and an increase of $0.6 million in headcount cost due to the hiring of additional employees.

General and Administrative Expenses. During the three months ended September 30, 2020, our general and administrative expenses were $5.3 million which represented an increase of $4.0 million as compared to the three months ended September 30, 2019. The increase was primarily due to an increase of $2.6 million in stock-based compensation, an increase of $0.6 million in insurance and an increase of $0.7 million in headcount cost due to the hiring of additional employees.

Interest Income, Net. During the three months ended September 30, 2020, interest income, net was $0.1 million higher as compared to the three months ended September 30, 2019. The increase was primarily due to the Company earning interest on the funds received in the Private Placements (as defined below).

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,		Period-to-Period Change
	2020	2019	
Operating expenses:			
Research and development	$ 8,330,727	$ 3,163,179	$ 5,167,548
General and administrative	17,156,952	2,147,635	15,009,317
Total operating expenses	25,487,679	5,310,814	20,176,865
Operating loss	(25,487,679)	(5,310,814)	(20,176,865)
Other income, net:			
Interest income, net	(317,307)	-	(317,307)
Total other income, net	(317,307)	-	(317,307)
Net Loss	$ (25,170,372)	$ (5,310,814)	$ (19,859,558)

Research and Development Expenses. During the nine months ended September 30, 2020, our research and development expenses were $8.3 million which represented an increase of $5.2 million as compared to the nine months ended September 30, 2019. This increase was primarily due to an increase of $0.8 million related to the manufacturing and testing of TARA-002, an increase of $1.2 million in consulting and studies related to TARA-002, and increase of $1.3 million for product development, manufacturing and stability studies, an increase of $0.5 million in data management for TARA-002, an increase of $1.2 million in headcount cost due to bonuses earned upon the merger, and the hiring of additional employees and an increase of $0.3 million in stock-based compensation.

General and Administrative Expenses. During the nine months ended September 30, 2020, our general and administrative expenses were $17.2 million which represented an increase of $15.0 million as compared to the nine months ended September 30, 2019. The increase was primarily due to an increase of $6.8 million in stock-based compensation, an increase of $2.3 million in professional fees in conjunction with being a public company, an increase of $0.5 million in professional fees directly related to the merger, an increase of $1.9 million in insurance, an increase of $0.9 million in recruiting fees and an increase of $1.7 million in headcount cost due to the hiring of additional employees.

Interest Income, Net. During the nine months ended September 30, 2020, interest income, net was $0.3 million higher as compared to the nine months ended September 30, 2019. The increase was primarily due to the Company earning interest on the funds received in the Private Placements.

Liquidity and Capital Resources

Overview

As of September 30, 2020 and December 31, 2019, our cash on hand was $165,904,797 and $564,124, respectively. We have not generated revenues since our inception and have incurred net losses of $25,170,372 and $5,310,814 for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had working capital of $163,228,281 and stockholder's equity of $194,625,763. During the nine months ended September 30, 2020, cash flows used in operating activities were $16,641,088, consisting primarily of a net loss of $25,170,372, which includes non-cash stock-based compensation charges of $7,407,331. Since inception, we have met our liquidity requirements principally through the sale of our equity in private placements.

In connection with the Merger, we consummated the Private Placements, raising gross proceeds of $42.5 million and proceeds, net of offering costs, of $39.6 million.

Concurrently with the execution of the Merger Agreement, certain institutional investors (together, the "Investors") entered into a subscription agreement (as amended on November 19, 2019, the "Subscription Agreement") with Protara Therapeutics, Inc. and Private ArTara, pursuant to which (A) Protara Therapeutics, Inc. issued, in a private placement immediately after the Merger (the "Proteon Private Placement"), (i) 3,879.356 of shares of Protara Therapeutics, Inc.'s Series 1 Convertible Non-Voting Preferred Stock ("Series 1 Preferred Stock") at a purchase price of approximately $7,011.47 per share for gross proceeds of $27,199,988 and proceeds, net of issuance costs, of $25,318,706, (ii) 1,896,888 shares of Protara Therapeutics, Inc.'s Common Stock at a purchase price of approximately $7.01 per share for gross proceeds of $13,299,974 and proceeds, net of issuance costs, of $12,413,337 and (B) Private ArTara issued, in a private placement immediately prior to the Merger (the "ArTara Private Placement"), 284,875 shares of Private ArTara common stock (post-Exchange Ratio (as defined in the Merger Agreement) basis) at a purchase price of approximately $7.01 per share (post-Exchange Ratio basis) (together with the Proteon Private Placement, the "Private Placements") for gross proceeds of $1,999,999 and proceeds, net of issuance costs, of $1,867,580. The shares issued in the Proteon Private Placement were registered for resale on a registration statement on Form S-3 filed and declared effective by the U.S. Securities and Exchange Commission (the "SEC") on February 10, 2020.

In connection with the Preferred Offering on September 22, 2020, we filed a Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock of the Company (the "Amendment") with the Secretary of State of the State of Delaware to increase the authorized number of shares of our Series 1 Convertible Preferred Stock that may be issued from 3,880 to 8,028.

On September 24, 2020, pursuant to an underwriting agreement, dated September 22, 2020, we issued and sold in an underwritten public offering (the "Common Offering") an aggregate of 4,600,000 shares of our common stock at an offering price of $16.87 per share, for gross and net proceeds of approximately $77.6 million and $73.6 million, respectively. The underwriters were granted an option to purchase up to 690,000 additional shares of common stock at the public offering price, less the underwriting discount. This option was exercisable for a period of 30 days. On October 6, 2020, the underwriters exercised their overallotment option in full, purchasing an additional 690,000 shares, resulting in the receipt of gross and net proceeds of $11.6 million and $11.1 million, respectively.

On September 24, 2020, pursuant to an underwriting agreement, dated September 22, 2020, we issued and sold in an underwritten public offering (the "Preferred Offering") an aggregate of 4,148 shares of our Series 1 Preferred Stock at an offering price of $16,873.54 per share, for gross and net proceeds of approximately $70.0 million and $66.3 million, respectively.

The Common Offering and the Preferred Offering were made pursuant to the our registration statement on Form S-3, declared effective by the Securities and Exchange Commission on May 26, 2020 (Registration No. 333-238273).

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,		
	2020	**2019**	**Period-to-Period Change**
Net cash used in operating activities	$ (16,641,088)	$ (3,922,307)	$ (12,718,781)
Net cash provided by/(used in) investing activities	3,345,402	(429,138)	3,774,540
Net cash provided by financing activities	178,686,359	499,999	178,186,360
Net increase/(decrease) in cash and cash equivalents, and restricted cash	$ 165,390,673	$ (3,851,446)	169,242,119

Comparison of the Nine Months Ended September 30, 2020 and 2019

Net cash used in operating activities was $16.6 million for the nine months ended September 30, 2020 compared to $3.9 million for the nine months ended September 30, 2019. The increase of $12.7 million in cash used in operating activities was primarily driven by an increased net loss of $19.9 million and a decrease in accrued expenses of $2.5 million, off-set by an increase of $7.1 million of stock-based compensation, an increase of $1.3 million in accounts payable and a decrease of $1.2 million in prepaid expenses and other current assets.

Net cash provided by investing activities was $3.3 million for the nine months ended September 30, 2020 compared to net cash used in investing activities of $0.4 million in the nine months ended September 30, 2019. The increase of $3.8 million was primarily due to the cash and restricted cash acquired in connection with the Merger with Protara Therapeutics, Inc. of $3.7 million.

Net cash provided by financing activities was $178.7 million for the nine months ended September 30, 2020 compared to $0.5 million for the nine months ended September 30, 2019. The increase of $178.2 million was primarily due to proceeds, net of offering costs, from the Common Offering of $73.6 million, the Preferred Offering of $66.3 million, the ArTara Private Placement of $1.9 million, the Proteon Private Placement of $12.4 million, and the issuance of Series 1 Preferred Stock of $25.3 million, offset by repayments of short-term debt of $1.3 million.

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 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, 2020, 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. 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, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

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

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, 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, with respect to the entity that operationally survived the Merger, 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. 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 the Company 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 the company 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 the Company could also cause you to lose all or part of your investment.

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

In December 2019, a novel coronavirus disease ("COVID-19") was reported and in January 2020, the World Health Organization (the "WHO") declared it a Public Health Emergency of International Concern. On February 28, 2020, the WHO raised its assessment of the COVID-19 threat from high to very high at a global level due to the continued increase in the number of cases and affected countries, and on March 11, 2020, the WHO characterized COVID-19 as a pandemic. As COVID-19 continues to spread 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 nonclinical 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 coronavirus 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- continues to evolve. The extent to which the COVID-19 coronavirus 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 (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 self 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 to confirm the comparability of TARA-002 and OK-432;
- 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 (“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 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 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 an IND, 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 submitted an investigational new drug application (IND), conducted any clinical trials, or submitted a BLA or new drug application (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, one indication for which we plan to pursue is the treatment of lymphatic malformations. There are no FDA-approved therapies for the treatment of lymphatic malformations. It is difficult to predict the timing and costs of clinical development for TARA-002 with respect to lymphatic malformations as well as the corresponding regulatory approval path.

To date, there are no FDA-approved therapies for the treatment of lymphatic malformations. 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. In addition, the previous clinical trials conducted on OK-432 for LMs in the United States included a control arm in which treatment was initially delayed. It is unclear whether this trial design could support FDA approval or whether a placebo-control or other randomization will be required by the FDA. 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.

The regulatory path to approval of TARA-002 is dependent on FDA acceptance of prior clinical data from OK-432.

The proposed regulatory strategy for the TARA-002 program is a combination of demonstrating comparability to a product that is not FDA approved and relying upon existing data. By demonstrating that TARA-002 is, in fact, OK-432, we believe that the large volume of data published on OK-432 including the data generated by the University of Iowa led study in LMs will then apply to TARA-002. This strategy will rely on some components of a biosimilar pathway, with a significant difference being that the same genetically distinct strain and proprietary manufacturing processes will be used to produce TARA-002 as OK-432. If comparability is fully demonstrated and accepted by regulatory authorities, we will attempt to rely on existing OK-432 safety and efficacy data to submit the BLA. There is no example to date of a biologic product that was approved utilizing this regulatory approach that we are aware of.

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, 2020. However, if a drug candidate receives Rare Pediatric Disease Designation before October 1, 2020, it is eligible to receive a voucher if it is approved before October 1, 2022.

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 surgery for the treatment of lymphatic malformations;
- 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 their 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.

Our regulatory strategy for TARA-002 requires that we demonstrate that TARA-002 is the same biologic substance as OK-432, which is currently manufactured in Japan and marketed in Japan and Taiwan by Chugai. The FDA has agreed that we have successfully demonstrated initial manufacturing comparability between TARA-002 and OK-432; we are on track to conduct three large-scale batch runs to confirm comparability. Good Manufacturing Practice (GMP) scale up is currently in process and the Company will initiate GMP comparability runs with an expected completion date in mid-2021. There can be no assurances that our contract manufacturer will be able to produce a sufficiently comparable product or that the FDA will find such substances comparable or permit us to use any of the data from prior clinical trials as part of the BLA filing for TARA-002.

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 FDA based on the prevalence of the disease. There are no approved pharmacotherapies currently available for the treatment of LMs and the current standard of care is a high-risk surgical procedure. There are a handful 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 and earlier experiments in LMs utilizing other compounds utilizing these mechanisms have not produced conclusive evidence of safety or efficacy. 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, or 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 expect 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 expect to rely on third-party contract research organizations (CROs) to conduct and oversee our TARA-002 and IV Choline Chloride clinical trials and other aspects of product development. We also expect to 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 (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 (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 noncompliance 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.

We currently have no marketing capabilities and no sales organization. If we are unable to establish 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 no 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, including for convenience after June 30, 2021, following which such rights become nonexclusive.

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 not exclusive following June 17, 2030 or following any termination of the agreement by either party, which includes a termination by Chugai for convenience, which it has the right to do upon 90 days' notice after June 30, 2021. 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 (OPDP) 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 noncompliance 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 noncompliance 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. 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.

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

The current presidential administration and certain members of the majority of the U.S. Congress have sought to repeal all or part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "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, such that the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code was eliminated beginning in 2019. In addition, litigation may result in the repeal or replacement of prevent some or all of the Affordable Care Act legislation from taking effect. For example, on December 14, 2018, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the tax reform legislation, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers, and the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, on June 24 , 2020, President Trump signed four (4) executive orders designed to lower drug costs, including measures to increase drug importation from abroad; finalize the rulemaking process on modifying the anti-kickback law safe harbor on discounts for plans, pharmacies and pharmaceutical benefit managers; require the Medicare program to purchase certain drug products at the same price available in other countries; and require federally qualified health centers to pass discounts on the cost of insulin and epipens to patients. While these and other measures may require additional authorization to become effective, we expect that additional state and federal healthcare reform measures will be adopted in the future, 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.

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 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 new federal Right-to-Try legislation; and state law equivalents of many of the above federal laws.

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 recently enacted 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 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 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 CMO 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 CMOs 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 CMO 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 the company’s 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, shareholders 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 newly public company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that ArTara Subsidiary Inc. did not incur as a private company, 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, 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 have a public float of less than $250 million and therefore 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.

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 the Company's business. As a result, capital appreciation, if any, of your shares of the Company will be your sole source of gain, if any, for the foreseeable future.

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.

Our ability to use our net operating loss carry-forwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2019, for U.S. federal and state income tax reporting purposes, Private ArTara had approximately $11.4 million of unused net operating losses ("NOLs") available for carry forward to future years. The 2019 and 2018 federal and New York City NOLs may be carried forward indefinitely, but utilization will be subject to an annual deduction limitation of 80% of taxable income. These 2019 and 2018 losses will not be allowed to be carried back. The 2019 state NOLs may be carried forward through the year 2039 and may be applied against future taxable income. The 2017 federal and New York City NOLs will begin to expire during the year ended December 31, 2037.

Furthermore, as of December 31, 2019, for U.S. federal and state income tax reporting purposes, Proteon had approximately $41.7 million of unused NOLs available to carry forward to future years. The pre-2018 federal net operating loss carryforwards expire at various dates through 2037. Federal net operating loss carryforwards generated in 2018 and forward will have an unlimited carryforward period as part of the Tax Cuts and Jobs Act. The indefinite lived net operating loss carryforwards as of December 31, 2019 are approximately $30.6 million. As of December 31, 2019, Proteon had state net operating loss carryforwards of approximately $37.2 million to offset future state taxable income, which will expire at various dates through 2039. As of December 31, 2019, Proteon has tax credit carryforwards of approximately $3.6 million to offset future federal and state income taxes, which will expire at various dates through 2039.

Because United States tax laws limit the time during which NOL carry forwards may be applied against future taxable income, we may be unable to take full advantage of our NOLs for federal income tax purposes when we do generate taxable income. Further, net operating loss carryforwards of both Private ArTara and Proteon entities will be limited since there was a more than 50% ownership change for each entity.

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 do not know when we will be able to use our office facilities located there. Our contract manufacturer's and suppliers' facilities are located in multiple locations where there are similar stay-at-home orders in place for the current crisis 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.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. 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. In addition, since the Company sponsors clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in the company to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products and product candidates could be delayed.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of the Company 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 the Company. 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.

The certificate of incorporation of the Company provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between the Company 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.

The certificate of incorporation of the Company 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 the Company 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 the principal business of the Company, 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. As a private company, ArTara Subsidiary was not required to test its internal controls within a specified period. 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.

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 noncompliance 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 the Company has 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 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

Use of Proceeds from Unregistered Securities

None.

Purchase of Equity Securities

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.

SIGNATURES

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

PROTARA THERAPEUTICS, INC.

Date: November 12, 2020

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

Date: November 12, 2020

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

EXHIBIT INDEX

Exhibit No.	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company'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 Company (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).
10.1*#	Amendment to Agreement, by and between Chugai Pharmaceutical Co., Ltd. and the Registrant, dated as of July 14, 2020 and effective as of June 30, 2020.
10.2†	Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2020).
10.3†^	Separation Agreement and Release, dated as of July 23, 2020, by and between the Registrant and Julio Casoy (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2020).
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*	Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Balance Sheets as of September 30, 2020 (unaudited) and the Consolidated Balance Sheets as of December 31, 2019; (ii) the Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2020 and 2019; and (iii) the Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2020 and 2019; and (iv) the notes to the Condensed Consolidated Financial Statements (unaudited).

* Exhibits filed herewith.
** Exhibits furnished herewith.
# Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.
† Indicates management contract or compensatory plan or arrangement.
^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY […*…], HAS BEEN OMITTED BECAUSE PROTARA THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO PROTARA THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.**

CONFIDENTIAL EXECUTION COPY

Amendment to the Agreement dated June 17th, 2019

This Amendment to the Agreement dated June 17th, 2019 (this "**Amendment** "), dated and effective as of June 30, 2020 (the "**Amendment Effective Date**"), is entered into by and between CHUGAI PHARMACEUTICAL CO., LTD., a company organized and existing under the laws of Japan, having its principal office at 1-1 Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo 103-8324, Japan ("**Chugai**") and PROTARA THERAPEUTICS, INC., a corporation organized under the laws of the state of Delaware, U.S.A., having its principal office at 1 Little West 12th Street, New York, NY 10014 ("**Protara**") (collectively, the "**Parties,**" or each, individually, a "**Party**").

WHEREAS, Chugai and ARTARA THERAPEUTICS, INC. have entered into the Agreement effective as of June 17th, 2019 with respect to development and commercialization of therapeutic products in the United States and certain other countries around the world ("**Agreement**");

WHEREAS, any and all rights and obligations of ARTARA THERAPEUTICS INC. under or arising out of the Agreement on and after June 30, 2020 have been assigned, delegated and transferred to its Affiliate, Protara, in accordance with Article 11 of the Agreement;

WHEREAS, the Parties wish to amend certain terms and conditions of the Agreement; NOW, THEREFORE, the Parties hereby agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms used in this Amendment shall have the meanings set forth in the Agreement except otherwise defined in this Amendment.

2. Amendment.

2.1 The term of abbreviated definition "ArTara" in the Agreement shall be replaced with the term "Protara" and the one "ArTara Territory" shall be replaced with the term "Protara Territory".

2.2 Section 2.1(a) of the Agreement shall be replaced in its entirety with the following:

> "(a) Chugai shall provide Protara with access to the Chugai Materials and provide technical support (*Q&A sessions between the Parties regarding the Chugai Materials*) during the Chugai Service Period , to the extent requested by Protara and deemed reasonably necessary by Chugai for Protara's use in the development and commercialization of the New Product. During the Chugai Service Period, Chugai shall not provide Existing Product or Chugai Materials to any Third Parties other than for medical, compassionate use and/or non-commercial research purposes. Further, during the period from the Effective Date until *the eleventh anniversary of the Effective Date* ("***Restricted Period***") , Chugai shall not provide Chugai Materials or the technical support to any Third Party for the purpose of the development and commercialization in the Protara Territory of a therapeutic product comparable to the Existing Product. *The Restricted Period shall be automatically extended to the fifteenth anniversary of the Effective Date so long as Chugai does not exercise the Opt-Out Option in accordance with Section 2.6, and further, if any of the Additional Indication Approval is made during the Restricted Period (including extension thereof), the Restricted Period shall be further extended until the […***…] anniversary of the Effective Date; provided, however, that in any event the Restricted Period shall terminate automatically when this Agreement is terminated by Chugai due to a material breach or default by Protara in accordance with Section 8.4(a), insolvency, etc. of Protara in accordance with Section 8.4(b) or Change of Control in accordance with Section 8.4(c), or when Protara determines to cease all the development and commercialization of the New Product in the Protara Territory;*

*In the event the Opt-Out Option is exercised, and the New Product receives Additional Indication Approval by the […***…] anniversary of the Effective Date ([…***…]), the Restricted Period of a total of […***…] years from the Effective Date will be granted. In the event the Opt-Out Option is exercised, and the New Product fails to receive Additional Indication Approval by the […***…] anniversary of the Effective Date ([…***…]), then the Restricted Period will end at such date ([…***…]);"*

2.3 the following provisions shall be added as Section 2.1(f) of the Agreement:

"(f) If comparability between Existing Product and New Product is established and accepted by FDA, Chugai will designate Protara as custodian of the sample of the OK-432 cell line currently catalogued at the ATCC library facility in the US."

2.4 Section 4.1 of the Agreement shall be replaced in its entirety with the following:

"4.1 Protara will *initially* pay Chugai a total of […***…] US Dollars (US$[…***…]) as consideration for Chugai's performance under this Agreement. Payment shall be made in two (2) one-time payments in the amounts of (a) […***…] US Dollars (US$[…***…]) and (b) […***…] US Dollars (US$[…***…]). *In addition to the foregoing, Protara will pay Chugai […***…] US Dollars (US$[…***…]) per each FDA approval for an additional indication of the New Product ("**Additional Indication Approval**") as part of consideration for Chugai's performance under this Agreement. For the avoidance of doubt, such Additional Indication Approval shall include the initial FDA approval for any new indication, which, in the case of oncology, shall be differentiated by tumor type, but exclude supplemental approvals for usage and/or dose and administration in the same indication. For the purpose of this Section, usage shall mean the application scope in the same indication such as i) sex, ii) age, iii) genotype, iv) gene mutation, v) treatment guideline or algorithm including lines of therapy such as first-line/second-line."*

2.5 Section 4.2(a) of the Agreement shall be replaced in its entirety with the following:

> "(a) Invoices. Chugai will issue to Protara invoices of (i) US$[…***…] in July 2020 and (ii) US$[…***…] upon the FDA approval of the *first indication for* the New Product. *Further, Chugai will issue to Protara invoice(s) of US$[…***…] upon each Additional Indication Approval that may be made during the Restricted Period."*

2.6 The first sentence of Section 8.1 of the Agreement shall be replaced in its entirety with the following:

> "8. 1 Term. This Agreement is effective as of the Effective Date and shall remain in full force and effect until it naturally expires, for no cause, on the first anniversary of the date of the *initial* FDA's approval of the New Product (the "**Term**")"

2.7 The following provisions shall be added to as the last sentence of Section 8.6 of the Agreement:

> *"It is agreed that, to the extent applicable, the third and fourth sentences of Section 2.1(a), whole provisions of Section 2.5(a) and Section 4 will survive the expiration and termination of this Agreement, unless the Restricted Period is terminated in accordance with Section 2.1, and that, once this Agreement is expired or terminated, thereafter, interval of Protara s report obligation under Section 2.5(a) may be reduced to once a year."*

2.8 Definition of the "Chugai Service Period" set forth in SCHEDULE 1 of the Agreement shall be replaced in its entirety with the following:

> "**Chugai Service Period**" means the period of time from the Effective Date until […***…] as the period during which Chugai shall provide Protara with the Chugai Materials and technical support. *The Chugai Service Period shall not be extended unless otherwise agreed by the Parties in writing*.

2.9 SCHEDULE 3 of the Agreement shall be replaced in its entirety with the attachment to this Amendment.

3 Term. This Amendment shall become effective as of the Amendment Effective Date and shall continue in full force until the termination of the Agreement. Other terms and conditions of the Agreement shall remain unchanged and effective.

4. Miscellaneous. This Amendment and all related Schedules, constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. This Amendment and all related documents, and all matters arising out of or relating to this Amendment, are governed by, and construed in accordance with, the laws of Japan, without regard to the conflict of laws provisions thereof to the extent such principles or rules would require or permit the application of the laws of any jurisdiction other than those of Japan. The Parties confirm that ARTARA THERAPEUTICS INC. shall have no rights under the Agreement on and after […***…].

IN WITNESS WHEREOF, the Parties have executed this Amendment effective as of the Amendment Effective Date.

Chugai Pharmaceutical Co., Ltd.

By /s/ Tetsuya Yamaguchi
Name: Tetsuya Yamaguchi
Title: SVP, General Manager of Corporate Planning Dept.

Protara Therapeutics, Inc.

By /s/ Jesse Shefferman
Name: Jesse Shefferman
Title: CEO

Attachment

SCHEDULE 3

DEVELOPMENT PLAN as of May 2020

[…***…]

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, 2020 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 12, 2020

/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, 2020 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 12, 2020

/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, 2020, 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 12, 2020

By: /s/ Jesse Shefferman

Jesse Shefferman
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2020

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 Company and will be retained by the Company 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 Company specifically incorporates it by reference.