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 June 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 ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting company ☒

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

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 Par Value per share	TARA	The Nasdaq Capital Market

As of July 31, 2020 there were 5,858,386 shares of the registrant's common stock, par value $0.001 per share, outstanding.

TABLE OF CONTENTS

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.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

PROTARA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of	
	June 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 29,970,617	$ 564,124
Restricted cash	50,000	-
Deferred offering costs	-	121,712
Prepaid expenses and other current assets	2,828,556	78,057
Total current assets	32,849,173	763,893
Non-current assets:		
Property and equipment, net	655,495	458,591
Right-of-use asset	384,081	-
Goodwill	29,367,213	-
Total assets	$ 63,255,962	$ 1,222,484
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 915,206	$ 715,653
Accrued expenses	1,575,068	2,634,790
Short-term debt	926,983	-
Right-of-use liability, current	29,287	-
Total current liabilities	3,446,544	3,350,443
Non-current liabilities:		
Right-of-use liability, long-term	378,885	-
Total liabilities	3,825,429	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, 3,880 and 0 shares authorized at June 30, 2020 and December 31, 2019, respectively, 3,879 and 0 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively.	4	-
Common Stock, $0.001 par value, authorized 100,000,000 shares:		
Common Stock, 5,843,203 and 2,627,533 common shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively.	5,843	2,628
Additional Paid in Capital	89,406,633	10,651,073
Accumulated Deficit	(29,981,947)	(12,781,660)
Total Stockholders' Equity (Deficit)	59,430,533	(2,127,959)
Total Liabilities and Stockholders' Equity (Deficit)	$ 63,255,962	$ 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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expense:				
Research & development	$ 2,469,720	$ 986,716	$ 5,534,513	$ 2,064,562
General & administrative	4,796,155	441,959	11,890,987	892,169
Total operating expenses	7,265,875	1,428,675	17,425,500	2,956,731
Operating loss	(7,265,875)	(1,428,675)	(17,425,500)	(2,956,731)
Other (income) expense, net				
Interest (income) expense, net	(125,845)	-	(225,213)	-
Total other (income) expense, net	(125,845)	-	(225,213)	-
Net Loss	$ (7,140,030)	$ (1,428,675)	$ (17,200,287)	$ (2,956,731)
Weighted Average Shares Outstanding, basic and diluted	5,843,203	2,558,419	5,701,855	2,558,419
Net loss per share, basic and diluted	$ (1.22)	$ (0.56)	$ (3.02)	$ (1.16)

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 THREE AND SIX MONTHS ENDED JUNE 30, 2020 AND 2019
(unaudited)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(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
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

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 Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (17,200,287)	$ (2,956,731)
Adjustments to reconcile net loss to Net cash used in operating activities:		
Stock based compensation	4,626,529	179,344
Amortization of operating lease right-of-use asset	39,492	-
Depreciation	44,291	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	657,341	(25,681)
Accounts payable	199,553	(79,248)
Accrued expenses	(1,230,608)	172,569
Right-of-use liability	(15,401)	-
Net cash used in operating activities	(12,879,090)	(2,709,747)
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	(241,195)	(103,738)
Net cash provided by/(used in) investing activities	3,477,547	(103,738)
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	-
Repayments under short-term debt	(741,587)	-
Net cash provided by financing activities	38,858,036	-
Net increase/(decrease) in cash and cash equivalents and restricted cash	29,456,493	(2,813,485)
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	$ 30,020,617	$ 2,736,467
Supplemental cash flow information		
Cash paid for:		
Interest	$ 15,059	$ -
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	$ -

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 focused on identifying and advancing transformative therapies for people with rare and specialty diseases. Protara's portfolio includes its lead program, TARA-002, an investigational cell based therapy being developed for the treatment of lymphatic malformations (LMs). In addition to LMs, the Company is also evaluating the potential of TARA-002 in oncologic indications. The second 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, or the 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 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. 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 June 30, 2020 and December 31, 2019, the Company's cash and cash equivalents on hand was $29,970,617 and $564,124, respectively. The Company has not generated revenues since its inception and has incurred net losses of $17,200,287 and $2,956,731 for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, the Company had working capital of $29,402,629 and stockholder's equity of $59,430,533. During the six months ended June 30, 2020, cash flows used in operating activities were $12,879,090, consisting primarily of a net loss of $17,200,287, which includes non-cash stock-based compensation charges of $4,626,529. Since inception, the Company has met its liquidity requirements principally through the sale of its Common Stock and Series 1 Convertible Preferred Stock in private placements.

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.

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 six months ended June 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 June 30, 2020 and December 31, 2019 was $50,000 and $0, respectively. As of June 30, 2020, restricted cash consists of a cash deposit of $50,000 to collateralize a letter of credit obligation.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 two step quantitative evaluation is not necessary. Under the two-step 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 Six Months Ended June 30,	
	2020	2019
Stock options	518,292	207,194
Restricted stock units	477,070	-
Conversion of Series 1 Convertible Preferred Stock	3,880,169	-
Total potentially dilutive shares	4,875,531	207,194

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 ("FDIC") 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 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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- 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.
- Level 3 Significant unobservable inputs that cannot be corroborated by market data.

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 $2,469,720 and $986,716 for the three months ended June 30, 2020 and 2019, and $5,534,513 and $2,064,562 for the six months ended June 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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Recent Accounting Pronouncements Adopted

In January 2017, the FASB issued 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 this ASU. 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 6, 8 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 a 1-for-40 reverse stock split of its common stock (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 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).

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

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 June 30, 2020.

	For the Three Months Ended June 30,	For the Six Months Ended June 30,	
	2019	2020	2019
Net loss	$ (6,743,675)	$ (16,975,287)	$ (14,802,731)
Pro forma loss per common share, basic and diluted	$ (1.17)	$ (2.91)	$ (2.56)
Pro forma weighted average number of common shares outstanding, basic and diluted	5,774,089	5,843,203	5,774,089

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 consolidated financial statements are:

	As of	
	June 30, 2020	December 31, 2019
Legal fees	$ 199,884	$ 1,572,554
Research and development	534,751	1,050,500
Bonus	541,325	-
Other	299,108	11,736
Total	$ 1,575,068	$ 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 June 30, 2020 the balance under this debt was $926,983.

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 reverse 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 a term of approximately eight years, therefore resulting in the recognition of an 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, 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:

	Balance Sheet Location	June 30, 2020	January 9, 2020	December 31, 2019
Operating leases:				
Right-of-use assets	Right-of-use assets	$ 384,081	$ 403,161	$ -
Right-of-use liability, current	Right-of-use liability, current	29,287	9,195	-
Right-of-use lease liability, long-term	Right-of-use lease liability, long-term	378,885	393,966	-

On March 1, 2020, the Company entered into new month-to-month lease agreements for three additional office spaces at monthly rents of $4,890, $1,270 and $7,200. On June 30, 2020, the Company terminated the lease agreements for these office spaces and entered into a new three-month agreement for a smaller office space at a monthly rent of $810.

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

	For the Three Months Ended June 30, 2020	For the Six Months Ended June 30, 2020
Lease cost		
Operating lease cost	$ 19,746	$ 39,492
Short-term lease cost	89,279	148,539
Total	$ 109,025	$ 188,031

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Lease Agreements (Continued)

Other information related to leases is presented below:

	As of June 30, 2020
Other information	
Weighted-average discount rate – operating leases	12.00%
Weighted-average remaining lease term – operating lease (in months)	93

The Company's future minimum lease payments consists solely of its quarter-to-quarter obligation for its manufacturing space. On January 9, 2020, subsequent to the reverse 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.

As of June 30, 2020, the expected annual minimum lease payments of our operating lease liability was as follows:

For Years Ending December 31,	Operating lease
2020 (excluding the six months ended June 30, 2020)	$ 38,346
2021	77,460
2022	79,008
2023	80,586
2024	82,200
Thereafter	278,613
Total future minimum lease payments, undiscounted	636,213
Less: Imputed interest	228,041
Present value of future minimum lease payments	$ 408,172

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 (See Note 11). During the six months ended June 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 such period.

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 six months ended June 30, 2020.

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 June 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $200,000, respectively, and during the six months ended June 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.

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Product License and Clinical Services Agreements (Continued)

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

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. 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 June 30, 2020 and 2019, the Company recorded Research and Development expense of $7,500 and $7,500, respectively, and during the six months ended June 30, 2020 and 2019, the Company recorded Research and Development expense of $15,000 and $15,000, respectively, in connection with the Iowa Agreement.

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

Product License and Clinical Services Agreements (Continued)

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 June 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $0, respectively, and during the six months ended June 30, 2020 and 2019, the Company recorded Research and Development expense of $0 and $0, 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 June 30, 2020 the Company has not commenced vonapanitase product sales and therefore has recognized no royalties on product sales.

NOTE 6 – COMMITMENTS AND CONTINGENCIES (Continued)

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 recently resolved.

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 Stock

As of June 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 5,843,203 and 2,627,533 shares were issued and outstanding, respectively. As of June 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 3,880 shares of Series 1 Convertible Preferred Stock are authorized for issuance, $0.001 par value per share, and 3,879 and 0 shares were issued and outstanding, respectively.

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

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 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 June 30, 2020, 560,550 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 ("Board") 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 reverse 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 Equity Incentive Plan (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 June 30, 2020, 317,114 shares remain available to be issued under the 2014 Equity Incentive 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 June 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 six months ended June 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 Company's 2014 Equity Incentive 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 year anniversary of the 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 year anniversary of the 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 CEO of the Company. These RSUs vest in four equal annual installments beginning on the first year anniversary of the date of grant. The grant date fair value of these RSUs was $1,500,000.

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

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested 1/1/2020	-	$ -
Granted	471,825	30.00
Vested	(84,668)	30.00
Non-vested 6/30/2020	387,157	$ 30.00

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 June 30, 2020 the unamortized value of RSUs was $10,414,800. As of June 30, 2020, the weighted average remaining amortization period was 2.22 years. As of June 30, 2020 and 2019, 89,913 and 0 RSUs, respectively, have vested that have not yet been settled into shares of the Company's Common Stock.

NOTE 8 – STOCK BASED COMPENSATION (Continued)

Stock Options

On January 10, 2020, the Board of Directors approved the grant of two options under the 2014 Equity Incentive Plan for the purchase of an aggregate 222,500 shares of the Company's Common Stock to Mr. Shefferman. The first option, granted on January 10, 2020, is for the purchase of 111,250 shares of the Company's Common Stock and has an exercise price of $30 per share. This option expires ten years from the date of grant and vests 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 this option was $2,662,135.

The second option, which was granted on July 10, 2020, is for the purchase of 111,250 shares of the Company's Common Stock. The option has an exercise price of $27.42 per share. This option will expire ten years from the date of grant and will 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.

On February 4, 2020, pursuant to the hiring of the Company's CFO, the Board of Directors approved the grant of a stock option under the 2014 Equity Incentive Plan to purchase 94,000 shares of the Company's Common Stock with an exercise price of $37.30 per share. This option will expire ten years from the date of grant and will 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. Mr. Davis will be eligible for future equity awards under such plan on an annual basis. The grant date fair value of this option was $2,791,556.

On February 26, 2020, the Compensation Committee of the Company pre-approved the grants of stock options under the Inducement Plan to new hires of the Company. On April 1, 2020, these employees were granted options to purchase an aggregate of 51,650 shares of the Company's Common Stock with an exercise price of $24.25 per share. These options will expire ten years from the date of grant and will each vest 25% between March 9, 2021 and March 23, 2021 (depending on the specific grant) and the remainder of the underlying shares shall vest in thirty-six equal monthly installments thereafter. The grant date fair value of these options was $954,053.

On April 27, 2020, the Compensation Committee of the Company approved the grant of stock options under the 2020 Inducement Plan to new hires of the Company. On May 1, 2020, these employees were granted options to purchase an aggregate of 4,100 shares of the Company's Common Stock with an exercise price of $24.02 per share. These options expire ten years from the date of grant and vests 25% between April 20, 2021 and April 27, 2021 (depending on the specific grant) and the remainder of the underlying shares shall vest in thirty-six equal monthly installments thereafter. The grant date fair value of these options was $75,019.

On May 19, 2020, the Compensation Committee of the Company approved the grant of a stock option under the 2020 Inducement Plan to a new hire of the Company. On June 1, 2020, this employee was granted an option to purchase 3,700 shares of the Company's Common Stock with an exercise price of $51.12 per share. This option expires ten years from the date of grant and vests 25% on May 11, 2021 and the remainder of the underlying shares shall vest in thirty-six equal monthly installments thereafter. The grant date fair value of this option was $144,025.

On June 9, 2020, the Company issued to directors of the Company stock options to purchase an aggregate of 54,000 shares of the Company's common stock. These stock options has an exercise price of $35.00, expire 10 years from the date of grant, and vest monthly over 12 months. The grant date fair value of these options was $1,374,732.

NOTE 8 – STOCK BASED COMPENSATION (Continued)

Stock Options (Continued)

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

	For the Six Months Ended June 30,	
	2020	2019
Stock price	$ 24.02 - $ 51.12	$ 8.65
Exercise price	$ 24.02 - $ 51.12	$ 9.18
Dividend yield	0%	0%
Expected volatility	95% - 101%	97%
Risk-Free interest rate	0.40% - 1.69%	2.37%
Expected life (in years)	5.27 - 6.08	6.02

Following is a summary of stock option activities for the six months ended June 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	318,700	25.11	32.24	-	-
Forfeited	(20,000)	18.47	24.25	-	-
Outstanding 6/30/2020	518,292	$ 17.57	$ 22.78	9.16	$ 4,604,778
Exercisable as of 6/30/2020	94,220	$ 6.75	$ 9.18	8.41	$ 1,897,591

The weighted average grant date fair value of the options granted during the six months ended June 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 June 30, 2020 the unamortized value of stock options was $7,751,851. As of June 30, 2020, the weighted average remaining amortization period was 2.92 years.

NOTE 8 – STOCK BASED COMPENSATION (Continued)

Summary of Stock Based Compensation Expense

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Restricted stock	$ -	$ 22,500	$ -	$ 45,000
RSUs	1,314,668	-	3,744,340	-
Stock options	514,054	79,962	882,189	134,344
Total	$ 1,828,722	$ 102,462	$ 4,626,529	$ 179,344

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 201,872	$ 52,479	$ 410,637	$ 93,552
General and administrative	1,626,850	49,983	4,215,892	85,792
Total	$ 1,828,722	$ 102,462	$ 4,626,529	$ 179,344

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 plan was implemented in June of 2020. For the three and six months ended June 30, 2020, the Company recorded expense of $7,956 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 party that the Company has contracted with to conduct comparability studies for TARA-002. The effects of the orders and the Company's related adjustments in its business is 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

Issuance of Stock Options

On June 30, 2020, the Compensation Committee of the Company approved the grant of stock options under the 2020 Inducement Plan to new hires of the Company. On July 1, 2020, these employees were granted options to purchase an aggregate of 25,700 shares of the Company's Common Stock with an exercise price of $28.20 per share. These options expire ten years from the date of grant and vests 25% on June 29, 2021 and the remainder of the underlying shares shall vest in thirty-six equal monthly installments thereafter.

Issuance of RSUs

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.

Settlement of RSUs

On July 9, 2020, the Company issued 5,245 shares of common stock from the settlement of RSUs.

NOTE 11 – SUBSEQUENT EVENTS (Continued)

Departure of Executive

On July 23, 2020, effective July 31, 2020, the Company and Dr. Casoy entered into a Separation Agreement and Release (the "Separation Agreement"), whereupon Dr. Casoy will no longer be employed by the Company as Chief Medical Officer, effective August 3, 2020. Pursuant to the Separation Agreement, in consideration of a general release of all claims against the Company and certain representations, warranties, covenants and agreements, Dr. Casoy is entitled to receive (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 is 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.

Resignation of Director

On July 20, 2020, Scott Braunstein, M.D. notified the Company of his resignation from the Company's Board of Directors, effective immediately. 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.

Appointment of Director

On July 23, 2020, the Company's Board of Directors appointed Barry Flannelly, Pharm.D, MBA as a director to fill the vacancy created by Dr. Braunstein's resignation, to serve in such capacity until the Company's 2023 annual meeting of stockholders.

On July 23, 2020, the Company issued to Dr. Flannelly a stock option to purchase 18,000 shares of the Company's common stock. This stock option has an exercise price of $26.70 per share, expires 10 years from the date of grant, and will vest in equal monthly installments following the date of grant over a three year period.

On July 23, 2020, the Company issued to Dr. Flannelly a stock option to purchase 8,250 shares of the Company's common stock. This stock option has an exercise price of $26.70 per share, expires 10 years from the date of grant, and will vest in equal monthly installments following the date of grant over a one year period, and in any event will be fully vested on the date of the Company's 2021 annual meeting of stockholders.

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 focused on identifying and advancing transformative therapies for people with rare and specialty diseases. We prioritize creativity, diverse perspectives, integrity and tenacity to expedite our goal of bringing life-changing therapies to people with limited treatment options.

Our lead program, TARA-002 is an investigational cell based therapy currently being developed for the treatment of lymphatic malformations (LMs). In addition to LMs, the Company is also evaluating the potential of TARA-002 in oncologic indications. TARA-002 was developed from the same master cell bank of genetically distinct group *A Streptococcus pyogenes* as OK-432 (marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd. (Chugai Pharmaceutical)). We have engaged the U.S. Food and Drug Administration (FDA) to determine the requirements for a biologics license application (BLA) submission for the treatment of LMs, including agreement on requirements to demonstrate the comparability of the two products. Through this engagement with the FDA, we are evaluating whether OK-432's more than 25-year safety database in LMs, as well as the efficacy and safety database from the clinical trials conducted in the US and led by the University of Iowa are sufficient for a BLA submission for TARA-002. Based on the guidance from the FDA, we may be required to conduct additional clinical trials as necessary. TARA-002 has been granted Rare Pediatric Disease designation (RPD) by the FDA for the LMs indication.

Our second 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 third 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. The lead program, TARA-002, is in later stage development and has not yet been approved for use for treatment of LMs or any other indications. The Company does not expect to generate any significant revenues prior to 2022, if ever. To finance the Company's current strategic plans, including the conduct of ongoing and future clinical trials and further research and development costs, the Company 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 party that we have contracted with to conduct comparability studies for TARA-002. The effects of the orders and our related adjustments in our business is 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, or the 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 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, or CROs, contract development and manufacturing organizations, or 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) Expense, Net

Interest (income) expense, 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 June 30, 2020 and 2019

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

	Three Months Ended June 30,		Period-to-Period Change
	2020	2019	
Operating expenses:			
Research and development	$ 2,469,720	$ 986,716	$ 1,483,004
General and administrative	4,796,155	441,959	4,354,196
Total operating expenses	7,265,875	1,428,675	5,837,200
Operating loss	(7,265,875)	(1,428,675)	(5,837,200)
Other income:			
Interest (income) expense, net	(125,845)	-	(125,845)
Total other (income) expense	(125,845)	-	(125,845)
Net Loss	$ (7,140,030)	$ (1,428,675)	$ (5,711,355)

Research and Development Expenses. During the three months ended June 30, 2020, our research and development expenses were $2.5 million which represented an increase of $1.5 million as compared to the three months ended June 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 $0.5 million related to the manufacturing and testing of TARA-002, an increase of $0.2 million in headcount cost due to the hiring of additional employees and an increase of $0.1 million in stock-based compensation.

General and Administrative Expenses. During the three months ended June 30, 2020, our general and administrative expenses were $4.8 million which represented an increase of $4.4 million as compared to the three months ended June 30, 2019. The increase was primarily due to an increase of $1.6 million in stock-based compensation, an increase of $1.0 million in professional fees in conjunction with being a public company, an increase of $0.6 million in insurance, an increase of $0.5 million in headcount cost due to the hiring of additional employees and an increase of $0.3 million in recruiting fees.

Interest (Income) Expense, Net. During the three months ended June 30, 2020, interest (income) expense was $0.1 million higher as compared to the three months ended June 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 Six Months Ended June 30, 2020 and 2019

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

	Six Months Ended June 30,		Period-to-Period Change
	2020	2019	
Operating expenses:			
Research and development	$ 5,534,513	$ 2,064,562	$ 3,469,951
General and administrative	11,890,987	892,169	10,998,818
Total operating expenses	17,425,500	2,956,731	14,468,769
Operating loss	(17,425,500)	(2,956,731)	(14,468,769)
Other income:			
Interest (income) expense, net	(225,213)	-	(225,213)
Total other (income) expense	(225,213)	-	(225,213)
Net Loss	$ (17,200,287)	$ (2,956,731)	$ (14,243,556)

Research and Development Expenses. During the six months ended June 30, 2020, our research and development expenses were $5.5 million which represented an increase of $3.5 million as compared to the six months ended June 30, 2019. This increase was primarily due to an increase of $1.3 million related to the manufacturing and testing of TARA-002, an increase of $1.0 million in consulting and studies related to TARA-002, an increase of $0.5 million in data management for TARA-002 an increase of $0.5 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 six months ended June 30, 2020, our general and administrative expenses were $11.9 million which represented an increase of $11.0 million as compared to the six months ended June 30, 2019. The increase was primarily due to an increase of $4.2 million in stock-based compensation, an increase of $2.3 million in professional fees in conjunction with being a public company, an increase of $0.6 million in professional fees directly related to the merger, an increase of $1.2 million in insurance, an increase of $0.9 million in recruiting fees and an increase of $1.0 million in headcount cost due to the hiring of additional employees.

Interest (Income) Expense, Net. During the six months ended June 30, 2020, interest (income) expense was $0.2 million higher as compared to the six months ended June 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 June 30, 2020 and December 31, 2019, our cash on hand was $29,970,617 and $564,124, respectively. We have not generated revenues since our inception and have incurred net losses of $17,200,287 and $2,956,731 for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had working capital of $29,402,629 and stockholder's equity of $59,430,533. During the six months ended June 30, 2020, cash flows used in operating activities were $12,879,090, consisting primarily of a net loss of $17,200,287, which includes non-cash stock-based compensation charges of $4,626,529. 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 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 January 30, 2020.

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.

The Company currently has an effective shelf registration statement on Form S-3 ("2020 Shelf Registration Statement") on file with the Securities and Exchange Commission ("SEC"), which expires in May 2023. The 2020 Shelf Registration Statement currently permits the offering, issuance and sale by the Company of up to an aggregate in offering price of $150.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination. No securities have been sold under the 2020 Shelf Registration Statement.

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:

	Six Months Ended June 30,	
	2020	**2019**
Net cash used in operating activities	$ (12,879,090)	$ (2,709,747)
Net cash provided by/(used in) investing activities	3,477,547	(103,738)
Net cash provided by financing activities	38,858,036	-
Net increase/(decrease) in cash and cash equivalents, and restricted cash	$ 29,456,493	$ (2,813,485)

Comparison of the Six Months Ended June 30, 2020 and 2019

Net cash used in operating activities was $12.9 million for the six months ended June 30, 2020 compared to $2.7 million for the six months ended June 30, 2019. The increase of $10.2 million in cash used in operating activities was primarily driven by an increased net loss of $14.2 million and change in accrued expenses of $1.4 million, off-set by a change of $4.4 million of stock-based compensation and a change of $0.7 million in prepaid expenses and other current assets.

Net cash provided by investing activities was $3.5 million for the six months ended June 30, 2020 compared to net cash used in investing activities of $0.1 million in the six months ended June 30, 2019. The increase of $3.6 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 was $38.9 million for the six months ended June 30, 2020 compared to $0 for the six months ended June 30, 2019. The increase of $38.9 million was primarily due to proceeds, net of offering costs, from the ArTara Private Placement of $1.9 million, proceeds from the Proteon Private Placement, net of offering costs of $12.4 million, proceeds from the issuance of Series 1 Convertible Preferred Stock, net of offering costs of $25.3 million, offset by repayments of short-term debt of $0.7 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 June 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 June 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

During the three months ended June 30, 2020, the Company hired a Senior Manager of Finance, implemented additional review and validation procedures for the tracking of contractual obligations and the monthly and quarterly financial accounting close process, implemented enhanced controls and procedures for accounts payable and implemented an online stock plan administration platform. Other than as described herein, there were no other 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, 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, 2019, 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 recently resolved.

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 expenditures 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; and

- 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;

- 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 rapidly 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 depends 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 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 stock holders 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, the Company, 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 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 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 subjecting us to significant contract liabilities.

TARA-002 is an immunopotentiator, the first indication for which we plan to pursue is the treatment of lymphatic malformations, an indication for which there are no FDA-approved therapies. This makes it difficult to predict the timing and costs of clinical development for TARA-002, as well as the regulatory approval path.

To date, there are no FDA-approved therapies for the treatment of lymphatic malformations and the standard of care is surgery. 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 clinical trials conducted on TARA-002 in the United States to date, 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 in LMs 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 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 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 first that we can 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. In order to demonstrate comparability, we plan to conduct studies using batches of OK-432 from Japan and batches of TARA-002 manufactured in the United States by our contract manufacturer. If we can demonstrate comparability, through our engagement with the FDA, we will seek the FDA's agreement to use OK-432's safety and efficacy data from clinical trials previously conducted by third parties for our BLA filing. 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. Further, due to the COVID-19 pandemic and the associated government-imposed stay-at-home orders, a third-party lab with which we have contracted for some of the initial comparability testing had to stop studies prior to its completion. When the stay-at-home orders are lifted, we anticipate that this third-party will be able to initiate new testing but we cannot predict when that will occur or how long of a delay the stoppage will cause for our development timelines 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, 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 if deemed comparable to OK-432 by the FDA or 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.

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 does 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 contracts 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.

We 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 will also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new rules implemented by the SEC and Nasdaq.

These rules and regulations are expected to 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 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, including stay-at-home orders, 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. As an example, due to the COVID-19 pandemic and the associated government-imposed stay-at-home orders, the third-party contract manufacturer with which we have contracted for the initial comparability study had to stop the study prior to its completion. We do not know when they will be able to return to work or initiate a new study. 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, Awe 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 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.

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.

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

The following disclosure is provided in accordance with and in satisfaction of the requirement of Item 5.02 *"Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers"* of Form 8-K:

As previously announced in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 24, 2020, Julio Casoy, M.D. will no longer be employed by the Company as Chief Medical Officer effective August 3, 2020, or the Separation Date. In connection with Dr. Casoy's departure, the Company and Dr. Casoy have entered into a Separation Agreement and Release, or the Separation Agreement, effective July 31, 2020, pursuant to which Dr. Casoy will receive severance benefits from the Company. Pursuant to the Separation Agreement, in consideration of a general release of all claims against the Company and certain representations, warranties, covenants and agreements, Dr. Casoy is entitled to receive (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 is 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.

The foregoing description of the Separation Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Separation Agreement, a copy of which is attached as Exhibit 10.2 hereto and is incorporated herein by reference.

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: July 31, 2020

By: /s/ Jesse Shefferman

Jesse Shefferman
Chief Executive Officer
(Principal Executive Officer)

Date: July 31, 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 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	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	Fifth Amended and Restated Investors' Rights Agreement, dated as of June 22, 2017 by and among the Registrant and the stockholders party thereto (incorporated by reference to Exhibit 4.18 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 23, 2017).
4.3	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*†	Restated Non-Employee Director Compensation Policy.
10.2*†^	Separation Agreement and Release, dated as of July 23, 2020, by and between the Registrant and Julio Casoy.
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 June 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 six months ended June 30, 2020 and 2019; and (iii) the Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2020 and 2019; and (iv) the notes to the Condensed Consolidated Financial Statements (unaudited).

* Exhibits filed herewith
** Exhibits furnished herewith.
† 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.

Exhibit 10.1

PROTARA THERAPEUTICS, INC.

AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Protara Therapeutics, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy is effective as of July 23, 2020 (the "***Effective Date***") and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board. This policy supersedes any prior agreement that provides for compensation terms as of the Effective Date.

Cash Compensation

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

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

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

2. Annual Committee Chair Service Retainer:
   a. Chairman of the Audit Committee: $15,000
   b. Chairman of the Compensation Committee: $12,000
   c. Chairman of the Nominating and Corporate Governance Committee: $9,000
   d. Chairman of the Scientific Advisory Committee: $50,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $6,000
   c. Member of the Nominating and Corporate Governance Committee: $5,000
   d. Member of the Scientific Advisory Committee: $25,000

Equity Compensation

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

1. Initial Grant: On the date of the Eligible Director's initial election to the Board, for each Eligible Director who is first elected to the Board following the Effective Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 18,000 shares (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's continuous service as a member of the Board through each such vesting date and will vest in full upon a Change of Control (as defined in the Plan).

2. Annual Grant: On the date of each Company annual stockholder meeting held on or after the Effective Date, for each Eligible Director who continues to serve as a non-employee member of the Board (or who is first elected to the Board at such annual stockholder meeting), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 9,000 shares (the "***Annual Grant***"). In addition, each Eligible Director who is first elected to the Board following the Effective Date and other than at an annual stockholder meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted an Annual Grant, pro-rated for the number of months remaining until the next annual stockholder meeting. The shares subject to the Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will, in any case, be fully vested on the date of the Company's next annual stockholder meeting, subject to the Eligible Director's continuous service as a member of the Board through such vesting date and will vest in full upon a Change of Control.

SEPARATION AGREEMENT AND RELEASE

This Separation Agreement and Release ("Agreement") is made by and between Julio Casoy ("Employee") and Protara Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party").

RECITALS

WHEREAS, Employee was employed by the Company;

WHEREAS, Employee signed an Executive Employment Agreement with the Company effective February 13, 2020 (the "Executive Employment Agreement");

WHEREAS, Employee signed an Employee Confidential Information and Inventions Assignment Agreement with the Company on July 21, 2020 (the "Confidentiality Agreement"), attached as Exhibit A;

WHEREAS, on April 29, 2019, the Company granted Employee the option to purchase 38,151 shares of the Company's common stock (the "2019 Option Grant"), subject to the terms and conditions of the Company's 2017 Equity Incentive Plan and the Stock Option Agreement (collectively the "ISO Stock Agreements");

WHEREAS, on January 10, 2020, the Company and Employee have entered into a Restricted Stock Unit Award Agreement and Restricted Stock Unit Award Grant Notice, granting Employee 45,500 shares of the Company's common stock subject to the terms and conditions of the Company's Amended and Restated 2014 Equity Incentive Plan, the Restricted Stock Unit Award Agreement, and Restricted Stock Unit Award Grant Notice (collectively the "RSU Stock Agreements"), and further subject to the Company's option to repurchase the restricted stock, as set forth in the Restricted Stock Unit Award Agreement (the "Repurchase Option");

WHEREAS, Employee separated from employment with the Company effective August 3, 2020 (the "Separation Date"); and

WHEREAS, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that the Employee may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Employee's employment with or separation from the Company;

NOW, THEREFORE, in consideration of the mutual promises made herein, the Company and Employee hereby agree as follows:

COVENANTS

1. Consideration. In consideration of Employee's execution of this Agreement and Employee's fulfillment of all of its terms and conditions, and provided that Employee does not revoke the Agreement under the Acknowledgement of Waiver of Claims under ADEA Section below, the Company agrees as follows:

a. Payment. The Company agrees to pay Employee a lump sum approximately equivalent to nine (9) months of Employee's base salary, for a total of Three Hundred Thousand Dollars ($300,000), less applicable withholding. This payment will be made to Employee within ten (10) business days after the Effective Date of this Agreement.

b. 2020 Bonus Payout. The Company agrees to pay Employee a lump sum approximately equivalent to nine (9) months of Employee's annual bonus target of Thirty Five Percent (35%) of Employee's base salary, for a total of One Hundred Forty Thousand Dollars ($140,000), less applicable withholding. This payment will be made to Employee within ten
(10) business days after the Effective Date of this Agreement.

c. Pro-Rata Vesting of RSU. Notwithstanding that Employee was not employed through the one-year anniversary of the Grant Date (as defined in the Restricted Stock Unit Award Grant Notice, the Company agrees to calculate the number of shares subject to the Repurchase Option on a pro-rata basis beginning on the Grant Date.

d. COBRA. The Company shall reimburse Employee for the payments Employee makes for COBRA coverage for a period of nine (9) months, or until Employee has secured other employment, whichever occurs first, provided Employee timely elects and pays for COBRA coverage. COBRA reimbursements shall be made by the Company to Employee consistent with the Company's normal expense reimbursement policy, provided that Employee submits documentation to the Company substantiating Employee's payments for COBRA coverage.

e. General. Employee acknowledges that without this Agreement, Employee is otherwise not entitled to the consideration listed in this Section 1.

2. Stock.

a. The Parties agree that for purposes of determining the number of shares of the Company's common stock that Employee is entitled to purchase from the Company under the 2019 Option Grant, pursuant to the exercise of outstanding options, Employee will be considered to have vested only up to the Separation Date. Employee acknowledges that as of the Separation Date, Employee will have vested in 13,515 options and no more. The exercise of Employee's vested options and shares shall continue to be governed by the terms and conditions of the Company's ISO Stock Agreements.

b. The Parties agree that for purposes of determining the number of shares of the Company's common stock that have been released from the Company's Repurchase Option under the RSU Stock Agreements, and in consideration of Section 1(c) above, Employee shall be considered to have vested in, and the Company's Repurchase Option shall be considered to have been terminated as to 5,687 shares awarded to Employee pursuant to the Restricted Stock Unit Award Agreement. The Repurchase Option shall continue to exist with respect to the remaining 39,813 shares awarded to Employee pursuant to the Restricted Stock Unit Award Agreement. All shares, including those no longer subject to the Repurchase Option, shall continue to be subject to all other terms of the RSU Stock Agreements.

3. Benefits. Employee's health insurance benefits shall cease on the last day of the month in which the Separation Date occurs, subject to Employee's right to continue Employee's health insurance under COBRA or comparable state law, if applicable. Employee's participation in all benefits and incidents of employment, including, but not limited to, vesting in stock options, and the accrual of bonuses, vacation, and paid time off, ceased as of the Separation Date.

4. Payment of Salary and Receipt of All Benefits. Employee acknowledges and represents that, other than the consideration set forth in this Agreement, the Company and its agents have paid or provided all salary, wages, bonuses, accrued vacation/paid time off, notice periods, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, stock, stock options, vesting, and any and all other benefits and compensation due to Employee.

5. Release of Claims. Employee agrees that the foregoing consideration represents settlement in full of all outstanding obligations owed to Employee by the Company, ArTara Therapeutics, Inc., ArTara Subsidiary, Inc., and their current and former respective officers, directors, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, professional employer organization or co-employer, insurers, trustees, divisions, and subsidiaries, and predecessor and successor corporations and assigns (collectively, the "Releasees"). Employee, on Employee's own behalf and on behalf of Employee's respective heirs, family members, executors, agents, and assigns, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, demand, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Employee may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the Effective Date of this Agreement, including, without limitation:

a. any and all claims relating to or arising from Employee's employment relationship with the Company and the termination of that relationship;

b. any and all claims relating to, or arising from, Employee's right to purchase, or actual purchase of shares of stock of the Company, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;

c. any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

d. any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; the Uniformed Services Employment and Reemployment Rights Act; the New York State Human Rights Law, the New York Executive Law, the New York Civil Practice Law and Rules, the New York Judiciary Law, the New York Corrections Law, the New York Labor Law, the New York Civil Rights Law, the New York Administrative Code, the New York City Administrative Code, the New York City Human Rights Law; the New York Hours of Labor Law; the New York Wage Payment Law; the New York Minimum Wage Act; the New York Whistleblower Law; and the New York Off-Duty Conduct Lawful Activities Discrimination Law;

e. any and all claims for violation of the federal or any state constitution;

f. any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

g. any claim for any loss, cost, damage, or expense arising out of any dispute over the nonwithholding or other tax treatment of any of the proceeds received by Employee as a result of this Agreement; and

h. any and all claims for attorneys' fees and costs.

Employee agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not extend to any obligations incurred under this Agreement. This release does not release claims that cannot be released as a matter of law, including any Protected Activity (as defined below). This release does not extend to any right Employee may have to unemployment compensation benefits or workers' compensation benefits. Employee represents that Employee has made no assignment or transfer of any right, claim, complaint, charge, duty, obligation, demand, cause of action, or other matter waived or released by this Section. This release does not extend to any indemnification rights Employee has under any applicable insurance policy, contract, state law or by-law.

6. Acknowledgment of Waiver of Claims under ADEA. Employee acknowledges that Employee is waiving and releasing any rights Employee may have under the Age Discrimination in Employment Act of 1967 ("ADEA") against the Releasees, and that this waiver and release is knowing and voluntary. Employee agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the Effective Date of this Agreement. Employee acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Employee was already entitled. Employee further acknowledges that Employee has been advised by this writing that: (a) Employee should consult with an attorney prior to executing this Agreement; (b) Employee has twenty-one (21) days within which to consider this Agreement; (c) Employee has seven (7) days following Employee's execution of this Agreement to revoke this Agreement; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Employee from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Employee signs this Agreement and returns it to the Company in less than the 21-day period identified above, Employee hereby acknowledges that Employee has freely and voluntarily chosen to waive the time period allotted for considering this Agreement. Employee acknowledges and understands that revocation must be accomplished by a written notification to the undersigned Company representative that is received prior to the Effective Date. The Parties agree that changes, whether material or immaterial, do not restart the running of the 21-day period.

7. No Pending or Future Lawsuits. Employee represents that Employee has no lawsuits, claims, or actions pending in Employee's name, or on behalf of any other person or entity, against the Company or any of the other Releasees. Employee also represents that Employee does not intend to bring any claims on Employee's own behalf or on behalf of any other person or entity against the Company or any of the other Releasees.

8. No Right to Employment. Employee understands and agrees that, as a condition of this Agreement, Employee shall not be entitled to any employment with the Company, and Employee hereby waives any right, or alleged right, of employment or re-employment with the Company.

9. Confidentiality. Employee agrees to maintain in complete confidence the existence of this Agreement, the contents and terms of this Agreement, and the consideration for this Agreement (hereinafter collectively referred to as "Separation Information"). Except as required by law, court order or regulation, Employee may disclose Separation Information only to Employee's immediate family members, the Court in any proceedings to enforce the terms of this Agreement, Employee's counsel, and Employee's accountant and any professional tax advisor to the extent that they need to know the Separation Information in order to provide advice on tax treatment or to prepare tax returns, and must prevent disclosure of any Separation Information to all other third parties. Employee agrees that Employee will not publicize, directly or indirectly, any Separation Information. Employee acknowledges and agrees that Employee does not possess any claim or allegation, either asserted or otherwise, involving harassment or discrimination, that may be subject to or covered under N.Y. C.P.L.R. § 5003-b and N.Y. General Obligations Law § 5-336.

10. Trade Secrets and Confidential Information/Company Property. Employee reaffirms and agrees to observe and abide by the terms of the Confidentiality Agreement, specifically including the provisions therein regarding nondisclosure of the Company's trade secrets and confidential and proprietary information, noncompetition, and nonsolicitation of Company employees. Employee agrees that the above reaffirmation and agreement with the Confidentiality Agreement shall constitute a new and separately enforceable agreement to abide by the terms of the Confidentiality Agreement, entered and effective as of the Effective Date. Employee acknowledges and agrees that Employee did not disclose any prior inventions on Exhibit A to the Confidentiality Agreement. Employee specifically acknowledges and agrees that any violation of the restrictive covenants in the Confidentiality Agreement shall constitute a material breach of this Agreement. Employee's signature below constitutes Employee's certification under penalty of perjury that Employee has returned all documents and other items provided to Employee by the Company, developed or obtained by Employee in connection with Employee's employment with the Company, or otherwise belonging to the Company, including, but not limited to, all passwords to any software or other programs or data that Employee used in performing services for the Company.

11. No Third Party Cooperation. Employee agrees that Employee will not knowingly encourage, counsel, or assist any attorneys or their clients in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints by any third party against any of the Releasees, unless under a subpoena or other court order to do so or as related directly to the ADEA waiver in this Agreement. Employee agrees both to immediately notify the Company upon receipt of any such subpoena or court order, and to furnish, within three (3) business days of its receipt, a copy of such subpoena or other court order. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints against any of the Releasees, Employee shall state no more than that Employee cannot provide counsel or assistance.

12. Cooperation with the Company. Employee agrees that upon reasonable request that Employee will assist and cooperate with the Company in connection with the defense or prosecution of any claim that may be made against or by the Company or any Releasees, or in connection with any ongoing or future investigation or dispute or claim of any kind involving the Company, including meeting with the Company's counsel, any proceeding before any arbitral, administrative, judicial, legislative, or other body or agency, including testifying in any proceeding to the extent such claims, investigations or proceedings relate to services performed or required to be performed by Employee, pertinent knowledge possessed by Employee, or any act or omission by Employee. Employee further agrees upon reasonable request to perform all acts and execute and deliver any documents that may be reasonably necessary to carry out the provisions of this paragraph.

13. Nondisparagement. Employee agrees to refrain from any disparagement, defamation, libel, or slander of any of the Releasees, and agrees to refrain from any tortious interference with the contracts and relationships of any of the Releasees, including, but not limited to, anonymous or named reviews, tweets, posts, or other comments published on the Internet. Employee affirms that Employee has not disparaged the Company from the Separation Date through the date Employee signs this Agreement. Employee furthers agrees that, by no later than the Effective Date, Employee shall delete or otherwise remove any and all disparaging public comments or statements that Employee made prior to the Effective Date about or relating to the Company, including, but not limited to, comments in online forums or on websites (including, but not limited to, Facebook, Glassdoor, Yelp, and LinkedIn). Employee shall direct any inquiries by potential future employers to the Company's human resources department, which shall use its best efforts to provide only the Employee's last position and dates of employment. Employee's violation of this provision shall be a material breach of this Agreement. Nothing herein shall prevent Employee from providing truthful testimony in response to a court order or subpoena.

14. Breach. In addition to the rights provided in the "Attorneys' Fees" section below, Employee acknowledges and agrees that any material breach of this Agreement, unless such breach constitutes a legal action by Employee challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, or of any provision of the Confidentiality Agreement shall entitle the Company immediately to cease providing the consideration provided to Employee under this Agreement, recover the net amounts paid to Employee under this Agreement, and to obtain damages, except as provided by law, provided, however, that the Company shall not recover One Hundred Dollars ($100.00) of the consideration already paid pursuant to this Agreement and such amount shall serve as full and complete consideration for the promises and obligations assumed by Employee under this Agreement and the Confidentiality Agreement.

15. No Admission of Liability. Employee understands and acknowledges that this Agreement constitutes a compromise and settlement of any and all actual or potential disputed claims by Employee. No action taken by the Company hereto, either previously or in connection with this Agreement, shall be deemed or construed to be (a) an admission of the truth or falsity of any actual or potential claims or (b) an acknowledgment or admission by the Company of any fault or liability whatsoever to Employee or to any third party.

16. Costs. The Parties shall each bear their own costs, attorneys' fees, and other fees incurred in connection with the preparation of this Agreement.

17. ARBITRATION. THE PARTIES AGREE THAT ANY AND ALL DISPUTES ARISING OUT OF THE TERMS OF THIS AGREEMENT, THEIR INTERPRETATION, AND ANY OF THE MATTERS HEREIN RELEASED, SHALL BE SUBJECT TO ARBITRATION IN NEW YORK COUNTY, BEFORE THE JUDICIAL ARBITRATION AND MEDIATION SERVICE ("JAMS") UNDER ITS COMPREHENSIVE ARBITRATION RULES ("JAMS RULES") AND NEW YORK LAW. THE COMPANY SHALL BE RESPONSIBLE FOR PAYMENT OF ALL JAMS FEES, INCLUDING, BUT NOT LIMITED TO, THE FEES OF THE ARBITRATOR. THE ARBITRATOR MAY GRANT INJUNCTIONS AND OTHER RELIEF IN SUCH DISPUTES. THE ARBITRATOR SHALL ADMINISTER AND CONDUCT ANY ARBITRATION IN ACCORDANCE WITH NEW YORK LAW, AND THE ARBITRATOR SHALL APPLY SUBSTANTIVE AND PROCEDURAL NEW YORK LAW TO ANY DISPUTE OR CLAIM, WITHOUT REFERENCE TO ANY CONFLICT-OF-LAW PROVISIONS OF ANY JURISDICTION. TO THE EXTENT THAT THE JAMS RULES CONFLICT WITH NEW YORK LAW, NEW YORK LAW SHALL TAKE PRECEDENCE. THE DECISION OF THE ARBITRATOR SHALL BE FINAL, CONCLUSIVE, AND BINDING ON THE PARTIES TO THE ARBITRATION. THE PARTIES AGREE THAT THE PREVAILING PARTY IN ANY ARBITRATION SHALL BE ENTITLED TO INJUNCTIVE RELIEF IN ANY COURT OF COMPETENT JURISDICTION TO ENFORCE THE ARBITRATION AWARD. EACH PARTY SHALL SEPARATELY PAY FOR ITS RESPECTIVE COUNSEL FEES AND EXPENSES; PROVIDED, HOWEVER, THAT THE ARBITRATOR SHALL AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, EXCEPT AS PROHIBITED BY LAW. THE PARTIES AGREE THAT PUNITIVE DAMAGES SHALL BE UNAVAILABLE IN ARBITRATION. THE PARTIES HEREBY AGREE TO WAIVE THEIR RIGHT TO HAVE ANY DISPUTE BETWEEN THEM RESOLVED IN A COURT OF LAW BY A JUDGE OR JURY. NOTWITHSTANDING THE FOREGOING, THIS SECTION WILL NOT PREVENT EITHER PARTY FROM SEEKING INJUNCTIVE RELIEF (OR ANY OTHER PROVISIONAL REMEDY) FROM ANY COURT HAVING JURISDICTION OVER THE PARTIES AND THE SUBJECT MATTER OF THEIR DISPUTE RELATING TO THIS AGREEMENT AND THE AGREEMENTS INCORPORATED HEREIN BY REFERENCE. SHOULD ANY PART OF THE ARBITRATION AGREEMENT CONTAINED IN THIS PARAGRAPH CONFLICT WITH ANY OTHER ARBITRATION AGREEMENT BETWEEN THE PARTIES, THE PARTIES AGREE THAT THIS ARBITRATION AGREEMENT SHALL GOVERN.

18. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Employee represents and warrants that Employee has the capacity to act on Employee's own behalf and on behalf of all who might claim through Employee to bind them to the terms and conditions of this Agreement. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

19. Protected Activity. Employee understands that nothing in this Agreement shall in any way limit or prohibit Employee from engaging for a lawful purpose in any Protected Activity, provided, however, that Employee agrees not to seek or accept any monetary award from such a proceeding (except with respect to proceedings before the Securities and Exchange Commission). For purposes of this Agreement, "Protected Activity" shall mean filing a charge, complaint, or report with, or otherwise communicating with, cooperating with or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission, the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, and the National Labor Relations Board ("Government Agencies"), or discussing the terms and conditions of Employee's employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act. Employee understands that in connection with such Protected Activity, Employee is permitted to disclose documents or other information to Government Agencies as permitted by law, and without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Employee agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company confidential information under the Confidentiality Agreement to any parties other than the relevant Government Agencies. Employee further understands that "Protected Activity" does not include the disclosure of any Company attorney- client privileged communications, and that any such disclosure without the Company's written consent shall constitute a material breach of this Agreement. In addition, pursuant to the Defend Trade Secrets Act of 2016, Employee is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if (and only if) such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

20. Waiver of Statutory Information Rights. Employee hereby waives any current or future rights Employee may have under Section 220 of the Delaware General Corporation Law (and similar rights under other applicable law) to inspect, or make copies and extracts from, the Company's stock ledger, any list of its stockholders, or any other books and records of the Company or any of its affiliates or subsidiaries, in Employee's capacity as a holder of stock, shares, units, options, or any other equity instrument.

21. No Representations. Employee represents that Employee has had an opportunity to consult with an attorney, and has carefully read and understands the scope and effect of the provisions of this Agreement. Employee has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement. Employee acknowledges that there has been an opportunity to negotiate the terms of this Agreement and that the Agreement will not be interpreted as an employer promulgated agreement.

22. Waiver. No Party shall be deemed to have waived any right, power or privilege under this Agreement or any provisions hereof unless such waiver shall have been duly executed in writing and delivered to the Party to be charged with such waiver. The failure of any Party at any time to insist on performance of any of the provisions of this Agreement shall in no way be construed to be a waiver of such provisions, nor in any way to affect the validity of this Agreement or any part hereof. No waiver of any breach of this Agreement shall be held to be a waiver of any other subsequent breach.

23. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

24. Attorneys' Fees. Except with regard to a legal action challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, in the event that either Party brings an action to enforce or effect its rights under this Agreement, the prevailing Party shall be entitled to recover its costs and expenses, including the costs of arbitration, litigation, court fees, and reasonable attorneys' fees incurred in connection with such an action.

25. Entire Agreement. This Agreement represents the entire agreement and understanding between the Company and Employee concerning the subject matter of this Agreement and Employee's employment with and separation from the Company and the events leading thereto and associated therewith, and supersedes and replaces any and all prior agreements and understandings concerning the subject matter of this Agreement and Employee's relationship with the Company, including the Executive Employment Agreement, with the exception of the arbitration provision in the Executive Employment Agreement, the Confidentiality Agreement, the ISO Stock Agreements, and the RSU Stock Agreements.

26. No Oral Modification. This Agreement may only be amended in a writing signed by Employee and the Company's Chief Executive Officer.

27. Governing Law. This Agreement shall be governed by the laws of the State of New York, without regard for choice-of-law provisions. Employee consents to personal and exclusive jurisdiction and venue in the State of New York.

28. Effective Date. Employee understands that this Agreement shall be null and void if not executed by Employee, and returned to the Company, within the twenty-one (21) day period set forth above. Each Party has seven (7) days after that Party signs this Agreement to revoke it. This Agreement will become effective on the eighth (8th) day after Employee signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date").

29. Counterparts. This Agreement may be executed in counterparts that may be executed, exchanged, and delivered by facsimile, photo, e-mail PDF, Docusign/Echosign or a similarly accredited secure signature service, or other electronic transmission or signature. Each counterpart will be deemed an original and all of which counterparts taken together shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned.

30. 409A. The Parties intend that this Agreement will be administered in accordance with Section 409A of the Internal Revenue Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Internal Revenue Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Internal Revenue Code. The Parties agree that this Agreement may be amended, as reasonably requested by either Party, and as may be necessary to fully comply with Section 409A of the Internal Revenue Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either Party.

31. Voluntary Execution of Agreement. Employee understands and agrees that Employee executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Employee's claims against the Company and any of the other Releasees. Employee acknowledges that:

(a) Employee has read this Agreement;

(b) Employee has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Employee's own choice or has elected not to retain legal counsel;

(c) Employee understands the terms and consequences of this Agreement and of the releases it contains; and

(d) Employee is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

JULIO CASOY, an individual

Dated: July 23, 2020

/s/ Julio Casoy
Julio Casoy

PROTARA THERAPEUTICS, INC.

Dated: July 23, 2020

By /s/ Jesse Shefferman
Jesse Shefferman
Chief Executive Officer

EXHIBIT A

[Confidentiality Agreement]

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 June 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: July 31, 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 June 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: July 31, 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 June 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: July 31, 2020

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

Date: July 31, 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.