UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

[X] **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019
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

PROTEON 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.)**

200 West Street
Waltham, MA
(Address of principal executive offices)
02451
(Zip Code)
(781) 890-0102
(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 [X] 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 [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ]

Accelerated filer [ ]

Non-accelerated filer [ ]

Smaller reporting company [X]

Emerging growth company [X]

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 [X]

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	PRTO	Nasdaq Capital Market

As of October 28, 2019 there were 19,585,394 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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CAUTIONARY NOTE FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. You can identify these forward-looking statements by the use of words such as “outlook,” “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seeks,” “approximately,” “predicts,” “intends,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words. These forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. These forward-looking statements include, but are not limited to, statements about:

- the proposed merger with ArTara Therapeutics, Inc. and private placement expected to occur concurrently therewith;
- our evaluation of strategic alternatives with a goal to enhance stockholder value, including the proposed merger with ArTara Therapeutics, Inc., or if the proposed merger with ArTara Therapeutics, Inc, is not consummated, the possibility of a different merger or sale of the company, the sale of the company’s assets in one or more transactions to one or more third parties or a liquidation and dissolution of the company;
- our estimates regarding the amount of funds we require to fund our operations;
- our interpretation of the data from our completed Phase 2 and Phase 3 clinical trials for vonapanitase;
- our ability to continue as a going concern;
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing and plans for additional financing;
- our ability to remain listed on a national securities exchange;
- our estimates regarding general and administrative costs and salary and personnel costs and costs associated with being a public company;
- our intellectual property position;
- our plans to retain key personnel;
- future payment of dividends;
- the impact of accounting policies;
- the impact of changes in interest rates; and
- exposure to foreign currency exchange risks and our purchase of forward foreign currency contracts in the future.

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

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

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Proteon Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 9,349	$ 19,371
Restricted cash	22	-
Available-for-sale investments	-	2,496
Prepaid expenses and other current assets	277	1,369
Total current assets	9,648	23,236
Property and equipment, net	-	263
Restricted cash	-	22
Total assets	$ 9,648	$ 23,521
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 394	$ 441
Accrued expenses	1,219	2,637
Total current liabilities	1,613	3,078
Total liabilities	1,613	3,078
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized at September 30, 2019 and December 31, 2018:		
Series A convertible preferred stock 22,000 shares authorized at September 30, 2019 and December 31, 2018; 21,660 and 22,000 issued and outstanding at September 30, 2019 and at December 31, 2018, respectively	21,183	21,523
Common stock, $0.001 par value, 100,000,000 shares authorized at September 30, 2019 and December 31, 2018; 19,585,394 and 19,243,651 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	19	19
Additional paid-in capital	210,683	209,366
Accumulated deficit	(223,852)	(210,470)
Accumulated other comprehensive income	2	5
Total stockholders' equity	8,035	20,443
Total liabilities and stockholders' equity	$ 9,648	$ 23,521

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

Proteon Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 206	$ 2,354	$ 6,374	$ 9,185
General and administrative	1,385	2,268	7,240	6,802
Total operating expenses	1,591	4,622	13,614	15,987
Loss from operations	(1,591)	(4,622)	(13,614)	(15,987)
Other income:				
Investment income	53	113	231	311
Other income (expense), net	2	(1)	1	206
Total other income	55	112	232	517
Net loss	$ (1,536)	$ (4,510)	$ (13,382)	$ (15,470)
Foreign currency translation adjustment	$ (2)	$ -	$ (3)	$ (1)
Unrealized gain on available-for-sale investments	-	3	-	19
Comprehensive loss	$ (1,538)	$ (4,507)	$ (13,385)	$ (15,452)
Reconciliation of net loss to net loss attributable to common stockholders:				
Net loss	$ (1,536)	$ (4,510)	$ (13,382)	$ (15,470)
Net loss attributable to common stockholders	$ (1,536)	$ (4,510)	$ (13,382)	$ (15,470)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.08)	$ (0.25)	$ (0.69)	$ (0.87)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	19,585,394	17,824,186	19,476,487	17,725,095
Supplemental disclosure of stock-based compensation expense:				
Included in operating expenses, above, are the following amounts for non-cash stock-based compensation expense:				
Research and development	$ (26)	$ 298	$ 233	$ 877
General and administrative	122	606	744	1,770
Total	$ 96	$ 904	$ 977	$ 2,647

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

Proteon Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share and per share data)
(Unaudited)

	Series A Convertible Preferred Stock		Common Stock				
	Shares	Amount	Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
Balance at December 31, 2018	22,000	$ 21,523	19,243,651	$ 19	$ 209,366	$ (210,470)	$ 5	$ 20,443
Conversion of Series A convertible preferred stock into Common Stock	(340)	(340)	341,743	-	340	-	-	-
Stock-based compensation expense	-	-	-	-	780	-	-	780
Other comprehensive gain/(loss)	-	-	-	-	-	-	(2)	(2)
Net loss	-	-	-	-	-	(6,531)	-	(6,531)
Balance at March 31, 2019	21,660	21,183	19,585,394	19	210,486	(217,001)	3	14,690
Conversion of Series A convertible preferred stock into Common Stock	-	-	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	101	-	-	101
Other comprehensive gain/(loss)	-	-	-	-	-	-	1	1
Net loss	-	-	-	-	-	(5,315)	-	(5,315)
Balance at June 30, 2019	21,660	21,183	19,585,394	19	210,587	(222,316)	4	9,477
Conversion of Series A convertible preferred stock into Common Stock	-	-	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	96	-	-	96
Other comprehensive gain/(loss)	-	-	-	-	-	-	(2)	(2)
Net loss	-	-	-	-	-	(1,536)	-	(1,536)
Balance at September 30, 2019	**21,660**	**$ 21,183**	**19,585,394**	**$ 19**	**$ 210,683**	**$ (223,852)**	**$ 2**	**$ 8,035**
Balance at December 31, 2017	22,000	$ 21,523	17,674,729	$ 18	$ 202,953	$ (189,741)	$ (14)	$ 34,739
Issuance of common stock upon ESPP purchase	-	-	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	821	-	-	821
Other comprehensive gain/(loss)	-	-	-	-	-	-	10	10
Net loss	-	-	-	-	-	(6,081)	-	(6,081)
Balance at March 31, 2018	22,000	$ 21,523	17,674,729	$ 18	$ 203,774	$ (195,822)	$ (4)	$ 29,489
Issuance of common stock upon ESPP purchase	-	-	51,984	-	84	-	-	84
Stock-based compensation expense	-	-	-	-	922	-	-	922
Other comprehensive gain/(loss)	-	-	-	-	-	-	5	5
Net loss	-	-	-	-	-	(4,879)	-	(4,879)
Balance at June 30, 2018	22,000	$ 21,523	17,726,713	$ 18	$ 204,780	$ (200,701)	$ 1	$ 25,621
Issuance of common stock upon ESPP purchase	-	-	-	-	-	-	-	-
Issuance of common stock, net of issuance costs	-	-	1,494,579	1	2,852	-	-	2,853
Stock-based compensation expense	-	-	-	-	904	-		904
Other comprehensive gain/(loss)	-	-	-	-	-	-	3	3
Net loss	-	-	-	-	-	(4,510)	-	(4,510)
Balance at September 30, 2018	**22,000**	**$ 21,523**	**19,221,292**	**$ 19**	**$ 208,536**	**$ (205,211)**	**$ 4**	**$ 24,871**

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

Proteon Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (13,382)	$ (15,470)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation	279	83
Amortization of discount on available-for-sale securities	(4)	(35)
Foreign currency remeasurement loss	(3)	(25)
Stock-based compensation	977	2,647
Changes in:		
Prepaid expenses and other assets	1,082	589
Operating lease right-of-use asset	200	-
Interest receivable	10	(3)
Accounts payable and accrued expenses	(1,465)	(6,706)
Operating lease liability	(200)	-
Net cash used in operating activities	(12,506)	(18,920)
Investing activities		
Purchases of available-for-sale investments	-	(12,951)
Proceeds from maturities of available-for-sale investments	2,500	23,990
Proceeds from sale of available-for-sale investments	-	1,999
Purchase of property and equipment	(16)	(24)
Net cash provided by investing activities	2,484	13,014
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	-	2,853
Proceeds from issuance of common stock under ESPP	-	84
Net cash provided by financing activities	-	2,937
Effect of exchange rate changes on cash	-	24
Decrease in cash, cash equivalents and restricted cash	(10,022)	(2,945)
Cash, cash equivalents and restricted cash, beginning of period	19,393	21,192
Cash, cash equivalents and restricted cash, end of period	$ 9,371	$ 18,247

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

1. Organization and Operations

The Company

Proteon Therapeutics, Inc. (the "Company") is a biopharmaceutical company that has historically focused on the development of novel, first-in-class pharmaceuticals to address the medical needs of patients with kidney and vascular disease. The Company was formed in June 2001 and incorporated on March 24, 2006.

On March 28, 2019, the Company announced that its second Phase 3 trial, PATENCY-2, for vonapanitase did not meet its co-primary endpoints of fistula use for hemodialysis (p=0.328) and secondary patency (p=0.932). The PATENCY-2 clinical trial was the second of two randomized, double-blind Phase 3 trials, comparing a 30 microgram dose of investigational vonapanitase to placebo in patients with chronic kidney disease, or CKD, undergoing creation of a radiocephalic fistula for hemodialysis. Following the release of top-line data from the PATENCY-2 clinical trial of vonapanitase on March 28, 2019, the Company began to evaluate its strategic alternatives focusing on enhancing stockholder value. It is conducting the process with the assistance of financial and legal advisors and is evaluating the full range of potential strategic alternatives, including but not limited to, a merger or sale of the Company, including a sale of assets or intellectual property, business combinations, joint ventures, public and private capital raises and recapitalization options. As part of these efforts, on April 15, 2019, the Company announced the engagement of H.C. Wainwright & Co., LLC as its financial advisor to assist in the strategic review process. Since these efforts may not be successful, the Company is also considering other possible alternatives, including a wind-down of operations and a liquidation and dissolution of the Company. On September 23, 2019, the Company entered into a merger agreement with ArTara Therapeutics, Inc. ("ArTara"). The Company has discontinued substantially all its research and development activities, including a reduction in workforce, to reduce operating expenses while it evaluates these opportunities. As of September 30, 2019, the Company has terminated all but one of its employees. The Company has recorded severance costs of $2.9 million, all of which was recorded in the three months ended June 30, 2019. These severance related expenses were fully recorded in the three months ending June 30, 2019. The Company remains subject to a number of risks similar to other companies in the biotechnology industry, including compliance with government regulations, protection of proprietary technology, dependence on third parties and product liability.

Liquidity and Going Concern

As of September 30, 2019, the Company had cash and cash equivalents of $9.3 million. The Company believes that its existing cash and cash equivalents will be sufficient to fund its projected cash needs into 2020 and enable it to complete the proposed merger with ArTara, pursuant to which REM 1 Acquisition 1, Inc. (the "Merger Sub"), a wholly owned subsidiary of the Company, will be merged with and into ArTara, with ArTara surviving as a wholly owned subsidiary of the Company (the "Merger"). However, if there is a delay in completing the Merger, the Company will require additional capital to sustain its operations through such completion or the Company will need to pursue an immediate dissolution. If the Company needs additional capital, it would need to raise such capital through debt or equity financings, asset sales or other strategic transactions. However, there can be no assurances that the Company will be able to complete any such transaction on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition and may prevent it from completing the Merger. Accordingly, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The Company had an accumulated deficit of $223.9 million as of September 30, 2019. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to its administrative organization. Additionally, as stated above, the Company announced that its second Phase 3 trial, PATENCY-2, for vonapanitase did not meet its co-primary endpoints. As a result, the Company has discontinued substantially all its research and development activities to reduce operating expenses while it evaluates its strategic alternatives, including the Merger.

These conditions raise substantial doubt about its ability to continue as a going concern within one year after the date that the financial statements are issued. To alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, management has implemented a reduction in expenditures plan and as referenced above is pursuing a merger. While the current reduction in spending expenditure plans will allow the Company to fund its operations in the near-term, there can be no assurance that the Company will be able to achieve its future strategic alternatives raising substantial doubt about its ability to continue as a going concern.

Pursuant to the requirements of Accounting Standards Codification (ASC) 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

Under ASC 2015-40, the strategic alternatives being pursued by the Company, including the Merger, cannot be considered probable at this time because none of the Company's current plans have been finalized at the time of filing this Quarterly Report on Form 10-Q and the implementation of any such plan is not probable of being effectively implemented as none of the plans are entirely within the Company's control. Accordingly, substantial doubt is deemed to exist about the Company's ability to continue as a going concern within one year after the date these financial statements are issued.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Merger Agreement

On September 23, 2019, the Company entered into a merger agreement (the "Merger Agreement") with ArTara. Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, the Merger Sub, a wholly owned subsidiary of the Company, will merge with and into ArTara, with ArTara surviving as a wholly owned subsidiary of the Company.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of ArTara common stock outstanding immediately prior to the Effective Time (excluding certain shares to be canceled pursuant to the Merger Agreement and shares held by stockholders who have exercised and perfected appraisal rights will be converted into the right to receive a number of shares of the Company's common stock equal to the exchange ratio, as more fully described below.

The Merger is intended to qualify for U.S. federal income tax purposes as a reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

As promptly as practicable after the date of the Merger Agreement (but in no event later than 50 days following the date of the Merger Agreement), the parties will prepare and the Company will file with the U.S. Securities and Exchange Commission ("SEC") a Registration Statement on Form S-4 (the "Registration Statement") to register the shares of the Company's common stock to be issued at the Effective Time under the Securities Act, and the Company will seek the approval of its stockholders with respect to certain actions, including the following (collectively, the "Company Stockholder Matters"):

- the issuance of shares of the Company's common stock to ArTara's stockholders in connection with the transactions contemplated by the Merger Agreement and shares of the Company's capital stock to the institutional investors in the Private Placement, pursuant to The Nasdaq Stock Market LLC ("Nasdaq") rules;

- the amendment of the Company's certificate of incorporation (i) to effect immediately prior to the closing of the Merger a reverse split of all outstanding shares of the Company's common stock at a reverse stock split ratio of one new share for every 30 to 50 (or any number in between) shares outstanding (the "Reverse Split") and (ii) to effect immediately after the consummation of the Private Placement the automatic conversion of all outstanding shares of Series A Convertible Preferred Stock (the "Series A Preferred Stock") of the Company into shares of the Company's common stock, without given effect to any existing provision that limits the conversion rights of the Series A Preferred Stock (including, without limitation, the 9.985% beneficial ownership cap) (the "Series A Preferred Automatic Conversion"); and

- an amendment to the Company's Amended and Restated 2014 Equity Incentive Plan (the "Plan") to increase the shares available for issuance thereunder by such additional number of shares of the Company's common stock such that the total number of shares of the Company's common stock reserved for issuance under the Plan, after giving effect to such additional shares, would not exceed 15.2% of the shares of the Company's common stock outstanding immediately after the Effective Time, after giving effect to the Reverse Split, the Private Placement and the Series A Preferred Automatic Conversion, as determined by or on behalf of ArTara prior to the effectiveness of the Registration Statement (the "EIP Amendment").

The consummation of the Merger is also subject to the satisfaction or waiver of certain conditions, including, among other things, (i) approval by the Company's stockholders and ArTara's stockholders (other than with respect to the EIP Amendment), (ii) Nasdaq approval of the listing of the shares to be issued to ArTara equity holders in connection with the consummation of the Merger, (iii) satisfaction of all conditions precedent to the closing of the Private Placement (other than the consummation of the Merger and appointment of certain board members), (iv) absence of a material adverse effect since the date of the Merger Agreement, (v) the accuracy of the representations and warranties, subject to material adverse effect qualifications, (vi) compliance by the parties with their respective covenants in all material respects, (vii) the Subscription Agreement (as defined below) being in full force and effect and no less than $40.0 million to be committed thereunder and (viii) the Company having at least $0 in net cash as of the closing date of the Merger (the "Company Net Cash condition").

The Merger Agreement contains certain termination rights for both the Company and ArTara, and further provides that, upon termination of the Merger Agreement under specified circumstances, the Company may be required to pay to ArTara a termination fee of $0.8 million or ArTara may be required to pay to the Company a termination fee of $0.8 million, and in other circumstances each party may be required to reimburse the other party's expenses incurred, up to a maximum of $0.4 million.

In accordance with the terms of the Merger Agreement, (i) certain executive officers, directors and stockholders of ArTara (solely in their respective capacities as ArTara stockholders) have entered into support agreements with ArTara and the Company to vote all of their shares of ArTara capital stock in favor of adoption of the Merger Agreement and (ii) certain of the Company's executive officers, directors and stockholders (solely in their respective capacities as the Company's stockholders) have entered into support agreements with ArTara and the Company to vote all of their shares of the its common stock in favor of the Company's Stockholder Matters. Concurrently with the execution of the Merger Agreement, the Company's stockholder and certain officers, directors and stockholders of ArTara have entered into lock-up agreements pursuant to which they accepted certain restrictions on transfer of shares of its common stock for the 180-day period following the closing of the Merger.

At the Effective Time, the Company will effect a name change and it is anticipated that trading for the Company's securities will be listed on The Nasdaq Capital Market. Additionally, at the Effective Time, the Company's board of directors is expected to consist of seven members, with five such members designated by ArTara, one such member designated by the Company, and one such member who will be Mr. Jesse Shefferman, the Chief Executive Officer of the combined company.

Private Placement

In connection with the Merger, on September 23, 2019, the company has entered into a Subscription Agreement (the "Subscription Agreement") with certain institutional investors (the "Investors"), pursuant to which the Company has agreed to issue in a private placement (the "Private Placement") (i) up to 27,200 shares of the Company's Series 1 Convertible Non-Voting Preferred Stock, par value $0.001 per share (the "Series 1 Preferred Stock"), at a purchase price equal to 1,000 times the Common Stock Purchase Price (as defined below) and (ii) up to 15,300 shares of the Company's common stock (together with the Series 1 Preferred Stock, the "Private Placement Shares"), at a purchase price equal to (x) the Aggregate Valuation (as defined in the Merger Agreement) divided by the (y) the Post-Closing Parent Shares (as defined in the Merger Agreement) (the "Common Stock Purchase Price").

Pursuant to the Subscription Agreement, the holders of Series 1 Preferred Stock have preemptive rights to participate pro rata in the Company's future equity financings, subject to certain exceptions and limitations. In addition, following the issuance of the Private Placement Shares pursuant to the Subscription Agreement, certain of the Investors have rights to nominate directors to the Company's board of directors and non-voting board observers. The Company has also agreed not to take certain actions related to the business without the consent of the lead investor for so long as such lead investor continues to hold a minimum amount of the Private Placement Shares purchased under the Subscription Agreement.

Prior to the issuance of the Private Placement Shares, the Company intends to file a Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock (the "Certificate of Designation") with the Delaware Secretary of State. Thereunder, each share of Series 1 Preferred Stock will be convertible into 1,000 shares of the Company's common stock, at a conversion price initially equal to the Common Stock Purchase Price, 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 Preferred Stock by a holder into shares of the Company's 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 Exchange Act would beneficially own more than 9.99% of the total number of shares of the Company's 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 Preferred Stock will be entitled to a preference of $10.00 per share upon the Company's liquidation, and thereafter will share ratably in any distributions or payments on an as-converted basis with the holders of the Company's common stock. In addition, upon the occurrence of certain transactions that involve the Company's merger or consolidation, an exchange or tender offer, a sale of all or substantially all of the Company's assets or a reclassification of the Company's common stock, each share of Series 1 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 the Company's common stock issuable upon conversion of one share of Series 1 Preferred Stock would receive in connection with such transaction.

The Private Placement is expected to close immediately following the consummation of the Merger.

2. Summary of Significant Accounting Policies

Basis of Presentation, Principles of Consolidation and Use of Estimates

The unaudited interim condensed consolidated financial statements of the Company included herein have been prepared, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2018 and notes thereto, included in the Company's Annual Report on Form 10-K, as filed with the SEC on March 13, 2019.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary to fairly present the Company's financial position as of September 30, 2019, the results of its operations for the three and nine months ended September 30, 2019 and 2018, results of changes in stockholders equity for the nine months ended September 30, 2019 and 2018, and its cash flows for the nine months ended September 30, 2019 and 2018. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results for the year ending December 31, 2019, or for any future period.

The unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to stock-based compensation expense, clinical trial accruals and reported amounts of revenues and expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, available-for-sale investments, accounts payable, and accrued liabilities. The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurement and Disclosures*, established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available under the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents and available-for-sale investments. There have been no changes to the valuation methods utilized by the Company during the three and nine months ended September 30, 2019 and 2018. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the three and nine months ended September 30, 2019 and 2018.

Net Income (Loss) per Share Attributable to Common Stockholders

Basic net income (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net income per share is calculated by dividing the net income attributable to common stockholders by the weighted-average number of common equivalent shares outstanding for the period, including any dilutive effect from outstanding stock options and warrants using the treasury stock method.

The Company follows the two-class method when computing net income (loss) per share in periods when issued shares that meet the definition of participating securities are outstanding. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders when participating securities are outstanding, losses are not allocated to the participating securities. For purposes of calculating diluted net income per share attributable to common stockholders, preferred stock, stock options, warrants and convertible debt are considered common stock equivalents.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"), a new standard on revenue recognition providing a single, comprehensive revenue recognition model for all contracts with customers. The new revenue standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard was effective beginning January 1, 2018, with early adoption permitted. The Company adopted ASU 2017-09 during the quarter ended March 31, 2018. The adoption did not have a material impact on the consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842): Amendments to FASB Codification ("ASU 2016-02"), which increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. At the lease commencement date, the lessee must recognize a lease liability and right-of-use asset, which is initially measured at the present value of future lease payments. The Company adopted ASU 2016-01 at January 1, 2019 using the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and will not restate prior periods. It has have also elected to adopt the package of practical expedients permitted in Accounting Standards Codification Topic 842, or ASC 842. Accordingly, it is continuing to account for its existing operating lease as an operating lease under the new guidance, without reassessing whether the contract contains a lease under ASC 842 or whether classification of the operating leases would be different under ASC Topic 842, and to treat lease and non-lease components as a single lease component. The Company's sole lease at the adoption date was an operating lease for facilities and did not include any non-lease components.

As a result of the adoption of ASU 2016-02, on January 1, 2019, the Company recognized (a) a lease liability of approximately $0.2 million, which represents the present value of its remaining lease payments using an estimated incremental borrowing rate of 8%, (b) a right-of-use asset of approximately $0.2 million that will be expensed as operating lease expense over the term of the lease. Due to the adoption of the standard using the retrospective cumulative-effect adjustment method, there are no changes to previously reported results prior to January 1, 2019. Lease expense is not expected to change materially as a result of the adoption of ASU 2016-02.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"), which provides clarification regarding how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. This update is effective for annual and interim periods beginning after December 15, 2017, which required the Company to adopt these provisions in the first quarter of fiscal 2018 using a retrospective approach. The Company adopted ASU 2016-15 during the quarter ended March 31, 2018. The adoption did not have a material impact on the condensed consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows, Restricted Cash requiring restricted cash and restricted cash equivalents to be included with cash and cash equivalents on the statement of cash flows when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The guidance is effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard during the first quarter of 2018. Restricted cash is now included as a component of cash, cash equivalents, and restricted cash on the Company's unaudited condensed consolidated statement of cash flows. Restricted cash is recorded within other non-current assets in the accompanying unaudited condensed consolidated balance sheets. The Company adopted ASU 2016-18 during the quarter ended March 31, 2018. The inclusion of restricted cash increased the beginning balances of the unaudited consolidated statement of cash flows by $22,000 and the ending balances by $22,000 for both the nine months ended September 30, 2019 and 2018.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09"), which clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. Under ASU 2017-09, an entity will not apply modification accounting to a share-based payment award if the award's fair value, vesting conditions and classification as an equity or liability instrument are the same immediately before and after the change. ASU 2017-09 will be applied prospectively to awards modified on or after the adoption date. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company adopted ASU 2017-09 during the quarter ended March 31, 2018. The adoption did not have a material impact on the condensed consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 aims to simplify the accounting for share-based payments to nonemployees by aligning it to the accounting for share based payments to employees including determining the fair value of the award on the date of grant and recognizing the stock-based compensation expense as of the respective vesting date. The new standard also requires companies to elect to either measure the awards to nonemployees over an estimated expected term or contractual term as well as elect to estimate forfeitures or account for forfeitures as incurred. ASU 2018-07 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. The guidance will be effective for the Company on January 1, 2019. The Company adopted ASU 2018-07 during the quarter ended March 31, 2019. The adoption did not have an impact on the condensed consolidated financial statements as all outstanding non-employee share-based awards had vested prior to March 31, 2018.

3. Fair Value Measurements

Below is a summary of assets and liabilities measured at fair value (in thousands):

	As of September 30, 2019			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Cash equivalents	$ 9,101	$ -	$ -	$ 9,101
Total	$ 9,101	$ -	$ -	$ 9,101

	As of December 31, 2018			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Cash equivalents	$ 18,353	$ -	$ -	$ 18,353
Government securities	2,496	-	-	2,496
Total	$ 20,849	$ -	$ -	$ 20,849

As of September 30, 2019 and December 31, 2018, the Company's cash equivalents consist principally of money market funds and government debt securities with original maturities of 90 days or less. Government securities consist principally of government debt securities and money market funds which are classified as available-for-sale.

Available-for-sale securities at September 30, 2019 and December 31, 2018 consist of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
September 30, 2019				
Government securities				
(Due within 1 year)	$ -	$ -	$ -	$ -
	$ -	$ -	$ -	$ -
December 31, 2018				
Government securities				
(Due within 1 year)	$ 2,496	$ -	$ -	$ 2,496
	$ 2,496	$ -	$ -	$ 2,496

4. Property and Equipment, net

Property and equipment, net consists of the following (in thousands):

	As of	
	September 30, 2019	December 31, 2018
Computer equipment and software	$ -	$ 211
Furniture, fixtures, and other	-	365
Laboratory equipment	-	514
	-	1,090
Accumulated depreciation	-	(827)
Property and equipment, net	$ -	$ 263

Depreciation expense for the three and nine months ended September 30, 2019 was $0.1 million, and $0.3 million, respectively. Depreciation expense for the three and nine months ended September 30, 2018 was $22,000, and $0.1 million, respectively.

During the three months ended March 31, 2019, the Company voluntarily discontinued substantially all research and development activities. As a result, as of March 31, 2019 the Company performed an impairment assessment of the laboratory equipment used in development of vonapanitase by comparing the equipment's carrying value to its estimated fair value, which was determined based on the recoverability of the assets remaining value as of March 31, 2019. As of September 30, 2019, the Company performed an additional impairment assessment due to the expiration of their lease agreement. The fair value of the remaining assets including office furniture, computer hardware and software licenses were determined be impaired as the Company determined there to be no future use for the assets. The Company recorded an impairment charges of zero and $0.2 million during the three and nine months ended September 30, 2019. As of September 30, 2019, no property and equipment balance remained as a result of the impairment.

5. Commitments and Contingencies

Operating Lease

The Company's facility is located in Waltham, Massachusetts. In July 2018, it amended the lease extending its expiration to September 2019. During the three and nine months ended September 30, 2019, it recognized operating lease expense of $0.1 million and $0.2 million, respectively including property taxes and routine maintenance expense, which approximated its cash payments for the period. The lease expired as of September 30, 2019, and therefore the condensed consolidated balance sheet does not include an operating lease right-of-use asset or an operating lease liability in other assets and other current liabilities, respectively. As of September 30, 2019, there are no future minimum payments required under the operating lease. As of September 30, 2019, the Company has provided a security deposit in the amount of $22,000 to the lessor. The security deposit will be returned within 30 days of the expiration of the lease which occurred on September 30, 2019.

Restricted cash related to facilities leases

As of September 30, 2019 and December 31, 2018, the Company had $22,000 in an outstanding letter of credit to be used as collateral for leased premises. As of September 30, 2019 and December 31, 2018, the Company pledged an aggregate of $22,000 to the bank as collateral for the letter of credit, which is included in other current assets and non-current assets, respectively. The security deposit will be returned within 30 days of the expiration of the lease which occurred on September 30, 2019.

6. Stock-based Compensation

Stock Options

The following table summarizes stock option activity for employees:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	4,597,226	$ 5.12	7.4	$ 404
Granted	1,182,500	$ 2.66		
Exercised	-			
Forfeited (1)	(2,606,289)	$ 2.79		
Expired (1)	(2,400,590)	$ 6.51		
Outstanding at September 30, 2019	772,847	$ 4.89	7.3	$ -
Exercisable at September 30, 2019	476,390	$ 6.13	6.4	$ -
Vested or expected to vest at September 30, 2019 (2)	772,847	$ 4.89	7.3	$ -

(1) Represents the number of options cancelled during the nine months ended September 30, 2019 as a result of employees that were terminated due to the reduction in force.
(2) Represents the number of vested options at September 30, 2019 plus the number of unvested options expected to vest based on the unvested options outstanding at September 30, 2019.

Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan (ESPP) initially authorized the issuance of up to 140,500 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, 281,000 shares and any lower amount determined by the Company's Board of Directors prior to each such January 1st. As of September 30, 2019, as a result of an increase on January 1, 2019 of one percent of the outstanding shares as of the end of the fiscal year ending December 31, 2018, the 2014 ESPP authorized the issuance of up to 192,436 shares of Common Stock. The tenth offering under the 2014 ESPP began on July 1, 2019 and ended on September 30, 2019. No shares were issued during the three and nine months ended September 30, 2019. No shares and 51,984 shares were issued during the three and nine months ended September 30, 2018 under the 2014 ESPP. The Company incurred zero and $68,000 in stock-based compensation expense related to the 2014 ESPP for the three and nine months ended September 30, 2019 respectively. The Company incurred $20,000 and $0.1 million in stock-based compensation expense related to the 2014 ESPP for the three and nine months ended September 30, 2018, respectively.

Common Stock

The Company has the following shares of Common Stock reserved for future issuance:

	September 30, 2019	December 31, 2018
Conversion of Series A Preferred Stock	21,771,032	22,112,775
Stock-based compensation awards	6,818,214	5,163,957
Employee Stock Purchase Plan	118,120	118,120
Total	28,707,366	27,394,852

7. Income Taxes

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The Company has evaluated the positive and negative evidence bearing upon the Company's ability to realize the benefit of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has provided a full valuation allowance against its deferred tax assets. There were no significant income tax provisions or benefits for the nine months ended September 30, 2019 and 2018.

8. Net Loss per Share Attributable to Common Stockholders

As described in Note 2, Summary of Significant Accounting Policies, the Company computes basic and diluted loss per share using a methodology that gives effect to the impact of outstanding participating securities (the "two-class method"). As the three and nine months ended September 30, 2019 and 2018 resulted in net losses, there is no income allocation required under the two-class method or dilution attributed to weighted-average shares outstanding in the calculation of diluted loss per share.

The following Common Stock equivalents, presented on an as converted basis, were excluded from the calculation of net loss per share for the periods presented, due to their anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Outstanding stock options	772,847	4,597,226	772,847	4,597,226
Outstanding ESPP shares	-	26,642	-	26,642
Convertible preferred stock	21,771,032	22,112,775	21,771,032	22,112,775
	22,543,879	26,736,643	22,543,879	26,736,643

9. Restructuring Charges

In April 2019, the Board of Directors approved a plan ("2019 Restructuring Program") to reduce operating expenses as the Company evaluates its strategic alternatives following the release of top-line data from the PATENCY-2 clinical trial of vonapanitase on March 28, 2019. The restructuring initiatives are company-wide. The remainder of the charges are expected to be incurred by the end of the fiscal year ending December 31, 2019 ("Fiscal Year 2019"). These actions are expected to result in pre-tax charges of $2.9 million, all of which are anticipated to be cash expenditures and all of which were recorded in the three months ended June 30, 2019.

Changes in the restructuring accrual during the first nine months ended September 30, 2019 are summarized below (in thousands):

	As of December 31, 2018	Charges/(Benefits)	Payment/Other	As of September 30, 2019
2019 Restructuring Program				
Employee Severance	$ -	$ 2,854	$ (1,834)	$ 1,020
Total	$ -	$ 2,854	$ (1,834)	$ 1,020

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 biopharmaceutical company that has historically focused on the development of novel, first-in-class pharmaceuticals to address the medical needs of patients with kidney and vascular disease. Our product candidate, vonapanitase, is a recombinant human elastase that we developed to improve vascular access outcomes in patients with chronic kidney disease, or CKD, undergoing or preparing for hemodialysis, a lifesaving treatment that cannot be conducted without a functioning vascular access.

On March 28, 2019, we announced that our second Phase 3 trial, PATENCY-2, for vonapanitase in radiocephalic fistulas did not meet its co-primary endpoints of fistula use for hemodialysis (p=0.328) and secondary patency (p=0.932). The PATENCY-2 clinical trial was the second of two randomized, double-blind Phase 3 trials, comparing a 30 microgram dose of investigational vonapanitase to placebo. We reported top-line results for the first Phase 3 clinical trial, PATENCY-1, in December 2016 and published these results in the Journal of Vascular Surgery in January 2019. As in PATENCY-1, the PATENCY-2 clinical trial enrolled patients with chronic kidney disease undergoing surgical creation of a radiocephalic fistula for hemodialysis. Patients were randomized 2:1, vonapanitase to placebo, and were followed for a period of twelve months. In March 2018, we completed enrollment of a total of 603 treated patients at 39 centers in the U.S. and Canada. Based on the top-line results of the PATENCY-2 clinical trial, we are no longer planning to submit a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or FDA, or a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for investigational vonapanitase.

Due to the results of the PATENCY-2 clinical trial, we started taking steps beginning in April 2019 to reduce operating expenses while we evaluate our strategic alternatives with a goal to enhance stockholder value. To assist with this process, our Board engaged a financial advisory firm, H.C. Wainwright & Co. LLC, to help explore its strategic alternatives, including a possible merger or sale of the Company, a sale of part or all of its assets, and collaboration and licensing arrangements as further discussed in the section titled "Merger Agreement." On September 23, 2019, the Company and ArTara announced the signing of the Merger Agreement. Although we have entered into the Merger Agreement and intend to consummate the Merger, there is no assurance that it will be able to successfully consummate the Merger on a timely basis, or at all.

We also began a plan in April 2019 to reduce personnel and expenses to preserve capital and further reduce our operations consistent with our decision to discontinue research and development activities. As of September 30, 2019, we have terminated all but one of our employees. In 2019, we expect to incur severance costs of $2.9 million related to these terminations. These severance related expenses were fully recorded in the three months ending June 30, 2019.

We commenced business operations in June 2001 and incorporated in March 2006. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of vonapanitase, protecting our intellectual property and providing general and administrative support for these operations. To date, we have not generated any product revenue and have primarily financed our operations through the private placement of our equity securities, business development activities, convertible note financings, and our initial public offering, or IPO, completed in October 2014.

As of September 30, 2019, we had received an aggregate of $200.1 million in net proceeds comprised of $115.5 million from the issuance of private equity securities, $7.7 million from the issuance of convertible notes, $10.0 million from business development activities, $0.2 million from government grants, $62.5 million from our IPO and $4.2 million from the sale of Common Stock under our now-terminated at-the-market, or ATM, program with Cowen and Company, LLC.

We have never been profitable and have incurred net losses in each year since inception. As of September 30, 2019, we had an accumulated deficit of $223.9 million and our net loss for the three and nine months ended September 30, 2019 was $1.5 million and $13.4 million, respectively. While we expect to incur significant expenses for the foreseeable future, we expect our research and development expenses to decrease significantly as we continue to discontinue research and development activities and focus on evaluating our strategic alternatives with the goal to enhance stockholder value, including the Merger or, if the Merger is not completed, the possibility of another merger or sale of the Company.

As of September 30, 2019, we had approximately $9.3 million in existing cash and cash equivalents. Although we believe that our cash and cash equivalents at September 30, 2019 will be sufficient to fund our operating expenses and capital expenditure requirements into 2020 and enable us to complete the Merger with ArTara, we may not have sufficient cash on hand to fund our current operations for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. However, if there is a delay in completing the Merger, we will require additional capital to sustain our operations through such completion or we will need to pursue an immediate dissolution. If we need additional capital, we would need to raise such capital through debt or equity financings, asset sales or other strategic transactions. However, there can be no assurances that we will be able to complete any such transaction on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition and may prevent us from completing the Merger. Accordingly, these factors, among others, raise substantial doubt about our ability to continue as a going concern. For more information, refer to "—Liquidity and Capital Resources" below and Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We do not expect to generate revenue from product sales. We have no manufacturing facilities and all of our manufacturing activities were contracted out to third parties. Additionally, we have used third-party clinical research organizations, or CROs, to carry out its clinical development activities and we do not yet have a sales organization.

Recent Events

Merger Agreement

After we conducted a diligent and extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic transaction, which included the careful evaluation and consideration of proposals from interested parties, and following extensive negotiation with ArTara, on September 23, 2019, we entered into the Merger Agreement with ArTara. Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, the Merger sub will merge with and into ArTara, with ArTara surviving as our wholly owned subsidiary.

Subject to the terms and conditions of the Merger Agreement, at the Effective Time, each share of ArTara common stock outstanding immediately prior to the Effective Time (excluding certain shares to be canceled pursuant to the Merger Agreement and shares held by stockholders who have exercised and perfected appraisal rights will be converted into the right to receive a number of shares of our common stock equal to the exchange ratio, as more fully described below.

The Merger is intended to qualify for U.S. federal income tax purposes as a reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Under the exchange ratio formula in the Merger Agreement and after giving effect to the Reverse Split assuming that the reverse split ratio is equal to one new share of our common stock for every 40 shares of issued common stock outstanding immediately prior to the split effective time, as of immediately after the closing of the Merger, but prior to the consummation of the Private Placement, as more fully described below, the former ArTara equity holders immediately before the Merger are expected to own approximately 73.39% of the Fully-Diluted Common Stock of the Company, and our equity holders immediately before the Merger are expected to own approximately 26.61% of the Fully-Diluted Common Stock of the Company. The exchange ratio will be adjusted to the extent that our net cash is greater than $3,550,000 or less than $2,950,000 (collectively, the “Target Parent Net Cash Range”); provided, however, that (i) if the initial filing of the Registration Statement is made after October 15, 2019, then the lower limit of the Target Parent Net Cash Range shall be decreased by $200,000, (ii) if the initial filing of the Registration Statement is made by us after October 30, 2019, then the lower limit of the Target Parent Net Cash Range shall be decreased by an additional $250,000 (with additional decreases of $250,000 to be made for delayed filings each 16th and 1st of each month, commencing November 1, 2019), (iii) if ArTara does not provide us with the Company No Divestiture Notice and, if prior to receipt of the Company No Divestiture Notice, we have not provided to ArTara the Parent Divestiture Notice, then the lower limit of the Target Parent Net Cash Range shall be decreased by 100% of the costs and expenses that we incur to maintain the divestiture assets through closing and (iv) if ArTara provides the Company No Divestiture Notice to us, and if, prior to receipt of the Company No Divesture Notice, we have not provided a Parent Divestiture Notice, then the lower limit of the Target Parent Net Cash Range shall be decreased by $0.4 million. The exchange ratio formula includes ArTara’s outstanding stock options and our outstanding stock options and the number of shares of our common stock issuable upon conversion of all outstanding shares of our Series A Preferred Stock. After the consummation of the Merger, the Private Placement and the Series A Preferred Automatic Conversion, and after giving effect to the Reverse Split assuming that the reverse split ratio is equal to one new share of our common stock for every 40 shares of issued common stock outstanding immediately prior to the split effective time, certain institutional investors participating in the Private Placement are expected to own 60.93% of the Fully-Diluted Common Stock of the Company, the former ArTara equity holders immediately before the Merger are expected to own approximately 28.67% of the Fully-Diluted Common Stock of the Company, and our equity holders immediately before the Merger are expected to own approximately 10.39% of the Fully-Diluted Common Stock of the Company, subject to the adjustments described above.

As promptly as practicable after the date of the Merger Agreement (but in no event later than 50 days following the date of the Merger Agreement), the parties will prepare and we will file with the SEC the Registration Statement to register the shares of our common stock to be issued at the Effective Time under the Securities Act, and we will seek the approval of its stockholders with respect to certain actions, including the following:

- the issuance of shares of our common stock to ArTara's stockholders in connection with the transactions contemplated by the Merger Agreement and shares of our capital stock to the institutional investors in the Private Placement, pursuant to Nasdaq rules;

- the amendment of our certificate of incorporation (i) to effect immediately prior to the closing of the Merger the Reverse Split and (ii) to effect immediately after the consummation of the Private Placement the Series A Preferred Automatic Conversion; and

- the EIP Amendment.

Concurrently with the execution of the Merger Agreement, we delivered to ArTara the written consent of the holders of 92.7% of the shares of our Series A Preferred Stock outstanding as of September 23, 2019 approving the Series A Preferred Automatic Conversion.

The consummation of the Merger is also subject to the satisfaction or waiver of certain conditions, including, among other things, (i) approval by our stockholders and ArTara’s stockholder (other than with respect to the EIP Amendment), (ii) Nasdaq approval of the listing of the shares to be issued to ArTara equity holders in connection with the consummation of the Merger, (iii) satisfaction of all conditions precedent to the closing of the Private Placement (other than the consummation of the Merger and appointment of certain board members), (iv) absence of a material adverse effect since the date of the Merger Agreement, (v) the accuracy of the representations and warranties, subject to material adverse effect qualifications, (vi) compliance by the parties with their respective covenants in all material respects, (vii) the Subscription Agreement (as defined below) being in full force and effect and no less than $40.0 million to be committed thereunder and (viii) us having at least $0 in net cash as of the closing date of the Merger.

The Merger Agreement contains certain termination rights for both us and ArTara, and further provides that, upon termination of the Merger Agreement under specified circumstances, we may be required to pay to ArTara a termination fee of $0.8 million or ArTara may be required to pay to us a termination fee of $0.8 million, and in other circumstances each party may be required to reimburse the other party's expenses incurred, up to a maximum of $0.4 million.

In accordance with the terms of the Merger Agreement, (i) certain executive officers, directors and stockholders of ArTara (solely in their respective capacities as ArTara stockholders) have entered into support agreements with ArTara and us to vote all of their shares of ArTara capital stock in favor of adoption of the Merger Agreement and (ii) certain of our executive officers, directors and stockholders (solely in their respective capacities as our stockholders) have entered into support agreements with ArTara and us to vote all of their shares of our common stock in favor of the our Stockholder Matters. Concurrently with the execution of the Merger Agreement, our stockholder and certain officers, directors and stockholders of ArTara have entered into lock-up agreements pursuant to which they accepted certain restrictions on transfer of shares of our common stock for the 180-day period following the closing of the Merger.

At the Effective Time, we will effect a name change and it is anticipated that trading for our securities will be listed on The Nasdaq Capital Market. Additionally, at the Effective Time, our board of directors is expected to consist of seven members, with five such members designated by ArTara, one such member designated by us, and one such member who will be Mr. Jesse Shefferman, the Chief Executive Officer of the combined company.

Private Placement

In connection with the Merger, on September 23, 2019, we entered into a Subscription Agreement (the “Subscription Agreement”) with certain institutional investors (the “Investors”), pursuant to which we have agreed to issue in a private placement (the “Private Placement”) (i) up to 27,200 shares of our Series 1 Convertible Non-Voting Preferred Stock, par value $0.001 per share (the “Series 1 Preferred Stock”), at a purchase price equal to 1,000 times the Common Stock Purchase Price (as defined below) and (ii) up to 15,300 shares of our common stock (together with the Series 1 Preferred Stock, the “Private Placement Shares”), at a purchase price equal to (x) the Aggregate Valuation (as defined in the Merger Agreement) divided by the (y) the Post-Closing Parent Shares (as defined in the Merger Agreement) (the “Common Stock Purchase Price”).

Pursuant to the Subscription Agreement, the holders of Series 1 Preferred Stock have preemptive rights to participate pro rata in our future equity financings, subject to certain exceptions and limitations. In addition, following the issuance of the Private Placement Shares pursuant to the Subscription Agreement, certain of the Investors have rights to nominate directors to our board of directors and non-voting board observers. We have also agreed not to take certain actions related to the business without the consent of the lead investor for so long as such lead investor continues to hold a minimum amount of the Private Placement Shares purchased under the Subscription Agreement.

Prior to the issuance of the Private Placement Shares, we intend to file a Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock (the "Certificate of Designation") with the Delaware Secretary of State. Thereunder, each share of Series 1 Preferred Stock will be convertible into 1,000 shares of our common stock, at a conversion price initially equal to the Common Stock Purchase Price, 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 Preferred Stock by a holder into shares of our 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 Exchange Act would beneficially own more than 9.99% of the total number of shares of our common stock issued and outstanding after giving effect to such conversion. Upon written notice to us, 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 Preferred Stock will be entitled to a preference of $10.00 per share upon our liquidation, and thereafter will share ratably in any distributions or payments on an as-converted basis with the holders of our common stock. In addition, upon the occurrence of certain transactions that involve our merger or consolidation, an exchange or tender offer, a sale of all or substantially all of our assets or a reclassification of our common stock, each share of Series 1 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 our common stock issuable upon conversion of one share of Series 1 Preferred Stock would receive in connection with such transaction.

The Private Placement is expected to close immediately following the consummation of the Merger.

Financial Overview

Research and Development Expenses

Research and development expenses consisted primarily of costs incurred for the development of vonapanitase and costs associated with the discontinuation of our research and development activities, which include:

- employee-related expenses, including salaries, benefits, travel, stock-based compensation expense and severance payments;
- expenses incurred under agreements with clinical research organizations, or CROs and investigative sites that conducted our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials;

- costs associated with regulatory operations; and

- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

In April 2019, we initiated plans to discontinue research and development activities to reduce operating expenses. We will continue to expense the remaining research and development costs to operations as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Our efforts to discontinue development activities include the following:

- we closed the 39 clinical sites that participated in our second Phase 3 trial, PATENCY-2, and terminated the long-term follow-up patient registry;

- we had planned to enroll up to an additional 16 patients in a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease, or PAD before the end of 2019 and to follow each of these patients for period of up to seven months. However, based on our current operating plan, we have decided not to continue patient enrollment in the Phase 1 trial evaluating vonapanitase in PAD; and

- we have discontinued all activities relating to the manufacture of clinical trial materials in support of our clinical trials and process validation activities that were undertaken in anticipation of a potential BLA submission.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel, including stock-based compensation and travel expenses, 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.

Investment Income

Investment income consists of interest income earned on our cash, cash equivalents and marketable securities.

Other Income (Expense), Net

Other income (expense), net consists of the gain realized from non-cash gains and losses from currency exchange rate fluctuations on transactions or balances denominated in a foreign currency.

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.

There have been no material changes to our accounting policies from those described in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 13, 2019. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 13, 2019.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		
	2019	**2018**	**Period-to-Period Change**
Operating expenses:			
Research and development	$ 206	$ 2,354	$ (2,148)
General and administrative	1,385	2,268	(883)
Total operating expenses	1,591	4,622	(3,031)
Loss from operations	(1,591)	(4,622)	3,031
Other income:			
Investment income	53	113	(60)
Other income (expense), net	2	(1)	3
Total other income	55	112	(57)
Net Loss	$ (1,536)	$ (4,510)	$ 2,974

Research and Development Expenses. The following table identifies research and development expenses on both an external and internal basis for the three months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		
	2019	**2018**	**Period-to-Period Change**
External vonapanitase research and development expenses	$ 171	$ 1,269	$ (1,098)
Internal research and development expenses	35	1,085	(1,050)
Total research and development expenses	$ 206	$ 2,354	$ (2,148)

During the three months ended September 30, 2019, our total research and development expenses decreased by $2.1 million compared to the three months ended September 30, 2018 primarily due to $1.1 million in decreased external research and development expenses and $1.0 million in decreased internal research and development expenses. The decrease of $1.1 million in external expenses was primarily driven by $0.7 million in decreased expenses for our completed clinical trials and $0.3 million in decreased expenses in our manufacturing expenses. The decrease of our internal research and development expenses of $1.0 million in the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 was primarily due to our reduction in force.

General and Administrative Expenses. During the three months ended September 30, 2019, our total general and administrative expenses were $0.9 million lower as compared to the three months ended September 30, 2018 primarily due to our reduction in force in the three months ended September 30, 2019 as compared to the three months ended September 30, 2018.

Investment Income. During the three months ended September 30, 2019, investment income decreased by an immaterial amount.

Other Income (Expense), Net. During the three months ended September 30, 2019, other expense, net, increased by an immaterial amount.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,		
	2019	**2018**	**Period-to-Period Change**
Operating expenses:			
Research and development	$ 6,374	$ 9,185	$ (2,811)
General and administrative	7,240	6,802	438
Total operating expenses	13,614	15,987	(2,373)
Loss from operations	(13,614)	(15,987)	2,373
Other income:			
Investment income	231	311	(80)
Other income, net	1	206	(205)
Total other income	232	517	(285)
Net Loss	$ (13,382)	$ (15,470)	$ 2,088

Research and Development Expenses. The following table identifies research and development expenses on both an external and internal basis for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,		
	2019	2018	Period-to-Period Change
External vonapanitase research and development expenses	$ 3,764	$ 5,821	$ (2,058)
Internal research and development expenses	2,610	3,364	(753)
Total research and development expenses	$ 6,374	$ 9,185	$ (2,811)

During the nine months ended September 30, 2019, our total research and development expenses decreased by $2.8 million compared to the nine months ended September 30, 2018 primarily due to $2.0 million in decreased external research and development expenses and $0.8 million in decreased internal research and development expenses. The decrease of $2.0 million in external expenses was primarily driven by $1.5 million in decreased expenses for our completed clinical trials and $0.5 million in decreased expenses in our manufacturing expenses. Internal research and development expenses decreased by $0.8 million in the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 primarily due to our reduction in force.

General and Administrative Expenses. During the nine months ended September 30, 2019, our total general and administrative expenses were $0.4 million higher as compared to the nine months ended September 30, 2018 primarily due to increased expenses to support our ongoing corporate activities, including expenses related to the Merger, in the nine months ended September 30, 2019.

Investment Income. During the nine months ended September 30, 2019 investment income decreased by an immaterial amount.

Other Income, Net. During the nine months ended September 30, 2019, other income, net, decreased by $0.2 million as compared to the nine months ended September 30, 2018 primarily due to foreign currency remeasurement gain for cash denominated in Swiss Francs.

Liquidity and Capital Resources

Overview

Since our inception and through the nine months ended September 30, 2019, we had received $200.1 million in net proceeds comprised of $115.5 million from the issuance of private equity securities, $7.7 million from the issuance of convertible notes, $10.0 million from business development activities, $0.2 million from government grants, $62.5 million from our IPO and $4.2 million from the sale of Common Stock under our now-terminated at-the-market, or ATM, program with Cowen and Company, LLC. As of September 30, 2019, our cash and cash equivalents totaled $9.3 million.

Operating Capital Requirements

We expect to incur ongoing operating losses for the foreseeable future as we evaluate our strategic alternatives, including the Merger or, if the Merger is not completed, the possibility of another merger or sale of the Company. Even if we consummate the Merger, or another strategic transaction, the combined company may not be able to complete the clinical development of vonapanitase and obtain approval of vonapanitase from the FDA or EMA.

Although we believe that our cash and cash equivalents as of September 30, 2019 will be sufficient to fund our operations into 2020 and enable us to complete the Merger with ArTara, we may not have sufficient cash on hand to fund our current operations for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. However, if there is a delay in completing the Merger, we will require additional capital to sustain our operations through such completion or we will need to pursue an immediate dissolution. If we need additional capital, we would need to raise such capital through debt or equity financings, asset sales or other strategic transactions. However, there can be no assurances that we will be able to complete any such transaction on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition and may prevent it from completing the Merger. Accordingly, these factors, among others, raise substantial doubt about our ability to continue as a going concern.

Pursuant to the requirements of Accounting Standards Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about our ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. See Note 1 to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a further discussion of our liquidity and the conditions and events which raise substantial doubt regarding our ability to continue as a going concern.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including:

- our ability to identify and consummate a strategic transaction for the Company;
- the timing and nature of any strategic transactions that we undertake;
- whether we enter into a partnership or business combination;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims.

Cash Flows

The following table summarizes our sources and uses of cash for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (12,506)	$ (18,920)
Net cash provided by investing activities	2,484	13,014
Net cash provided by financing activities	-	2,937
Effect of exchange rate changes on cash	-	24
Net decrease in cash, cash equivalents, and restricted cash	$ (10,022)	$ (2,945)

Comparison of the Nine Months Ended September 30, 2019 and 2018

Net cash used in operating activities was $12.5 million for the nine months ended September 30, 2019 compared to $18.9 million for the nine months ended September 30, 2018. The decrease of $6.4 million in cash used in operating activities was primarily driven by a $4.3 million decrease in cash outflows related to changes in the components of working capital combined with a decrease in our net loss of $2.1 million, as compared to the nine months ended September 30, 2018.

Net cash provided by investing activities was $2.5 million for the nine months ended September 30, 2019 compared to $13.0 million provided in the nine months ended September 30, 2018. The change of $10.5 million in cash provided by investing activities was driven by a decrease in cash inflows of $23.5 million due to lower proceeds from maturities and sales of available-for-sale investments offset by $13.0 million decrease in cash outflows in the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

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.

Contractual Obligations

As of September 30, 2019 there are no outstanding contractual obligations.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act, or JOBS Act was enacted in the United States. Section 107 of the JOBS Act provides that an “emerging growth company,” or EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies.

Item 3. Qualitative and Quantitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2019, we had cash equivalents of $9.3 million consisting primarily of investments in U.S. Treasuries and certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

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

As of September 30, 2019, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2019, 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 nine months ended September 30, 2019, we implemented certain internal controls in connection with our adoption of ASC 842. 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 we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Quarterly Report on Form 10-Q, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Any investment in our Common Stock involves a high degree of risk. The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. We refer you to our "Cautionary Note Regarding Forward-Looking Statements," which identifies certain forward-looking statements contained in this report that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to our Business

For risks related to our business, please refer to the section titled "Item 1A. Risk Factors" set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as filed with the SEC on March 13, 2019, as updated by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, as filed with the SEC on May 8, 2019 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as filed with the SEC on August 7, 2019, which report is incorporated by reference herein.

Risks Related to the Proposed Merger

If the Merger with ArTara is not consummated, our business could suffer materially and our stock price could decline.

The consummation of the Merger with ArTara is subject to the satisfaction of a number of closing conditions, including the receipt of approvals from our stockholder at a special meeting of the stockholders, our successful application for initial listing with Nasdaq, the satisfaction of the Company Net Cash condition and other closing conditions. For a more detailed discussion of the Proteon Net Cash condition and other closing conditions, see the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Events—Merger Agreement*." We are targeting a closing of the Merger by year end 2019.

If the Merger is not consummated, we may be subject to a number of material risks, and its business and stock price could be adversely affected, as follows:

- we have incurred and expects to continue to incur significant expenses related to the Merger with ArTara, even if the Merger is not consummated.
- The Merger Agreement contains covenants restricting our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the Merger Agreement and the closing of the Merger. As a result, significant business decisions and transactions before the closing of the Merger require the consent of ArTara. Accordingly, we may be unable to pursue business opportunities that would otherwise be in its best interest as a standalone company.
- we have invested significant time and resources in the transaction process and if the Merger Agreement is terminated we will have limited prospects.
- we could be obligated to pay ArTara a $750,000 termination fee in connection with the termination of the Merger Agreement and could be required to reimburse ArTara's expenses incurred, up to a maximum of $350,000, depending on the reason for the termination.
- Subject to and in accordance with the Merger Agreement, we may divest certain of its assets in anticipation of the consummation of the Merger, and if the Merger Agreement is terminated such divestiture may result in having a negative impact on our prospects as a standalone company.

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive benefit to our stockholders that is currently expected to be derived from the Merger. Due to the lengthy nature of the strategic process, the further passage of time will diminish cash available. In such circumstances, our board of directors may elect to, among other things, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we receive may be less attractive than the benefit to our stockholders that is currently expected to be derived from the Merger.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes and other causes.

In general, either party can refuse to complete the Merger if there is a material adverse change affecting the other party following September 23, 2019, the date of the Merger Agreement. However, some types of changes do not permit either party to refuse to complete the Merger, even if such changes would have a material adverse effect on us or ArTara, to the extent they resulted from the following (unless, in some cases, they have a disproportionate effect on us or ArTara, as the case may be):

- changes in the general business or economic conditions affecting the industry in which we and ArTara, and our and their respective affiliates, operate;
- any natural disaster or any acts of war, armed hostilities or terrorism;
- changes in financial, banking or securities markets;
- the taking of any action required to be taken by the Merger Agreement;
- any change in the stock price or trading volume of our common stock (except that any effect causing or contributing to any change in stock price or trading volume of our common stock may be taken into account in determining whether a material adverse effect on us has occurred, unless such effects are otherwise excepted);
- the failure to meet internal or analysts' expectations or projections or the results of operations ;
- any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies;
- any change in, or any compliance with or action taken for the purpose of complying with, any law or GAAP (or interpretations of any law or GAAP);
- resulting from the announcement of the Merger Agreement or the pendency of the Contemplated Transactions (including, without limitation, any action, suit or proceeding against us or any of its officers or directors that is seeking to challenge or restrain the Merger or related transactions); or
- resulting from the taking of any action or the failure to take any action that is required to be taken or not to be taken by the Merger Agreement.

If adverse changes occur but we and ArTara must still complete the Merger, the combined company's stock price may suffer.

The market price of the combined company's common stock may decline as a result of the Merger.

The market price of the combined company's common stock may decline as a result of the Merger for a number of reasons, including if:

- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;

- the effect of the Merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or

- investors react negatively to the effect on the combined company's business and prospects from the Merger.

Our stockholders may not realize the benefit currently anticipated to be derived from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the Merger, our current stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit currently anticipated to be derived from the Merger. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price following the Merger. Even if the combined company is able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time. The combined company will incur significant transaction costs as a result of the Merger, including investment banking, legal and accounting fees. In addition, the combined company will incur significant consolidation and integration expenses which cannot be accurately estimated at this time. Actual transaction costs may substantially exceed estimates and may have an adverse effect on the combined company's financial condition and operating results.

During the pendency of the Merger, we will be subject to contractual limitations set forth in the Merger Agreement that restrict our ability to enter into business combination transactions with another party.

Covenants in the Merger Agreement impede our ability to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, we are prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of our common stock, a tender offer for our common stock, a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to our stockholders.

Because the Merger will result in an ownership change under Section 382 of the Internal Revenue Code (the "Code") for us, our pre-merger net operating loss carryforwards and certain other tax attributes will be subject to limitations. The net operating loss carryforwards and other tax attributes of the combined company may also be subject to limitations as a result of ownership changes.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code ("Section 382"), the corporation's net operating loss carryforwards and certain other tax attributes arising before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. The amount of the annual limitation is determined based on a corporation's value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. Similar rules may apply under state tax laws. The Merger will result in an ownership change for us and, accordingly, our net operating loss carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after the Merger. Additional ownership changes in the future could result in additional limitations on our and the combined organization's net operating loss carryforwards. Consequently, even if the combined organization achieves profitability, it may not be able to utilize a material portion of our or the combined organization's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

The exchange ratio is not adjustable based on the market price of our common stock so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.

At the Effective Time, outstanding shares of ArTara capital stock will be converted into shares of our common stock. Applying the exchange ratio, as of immediately after the closing of the Merger and after giving effect to the Reverse Split, but prior to the consummation of the Private Placement, the former ArTara equity holders immediately before the Merger are expected to own approximately 73.39% of the Fully-Diluted Common Stock of the Company, and our equity holders immediately before the Merger are expected to own approximately 26.61% of the Fully-Diluted Common Stock of the Company. After the consummation of the Reverse Split, the Merger, the Private Placement and the Series A Preferred Automatic Conversion, the Investors participating in the Private Placement are expected to own 60.93% of the Fully-Diluted Common Stock of the Company, the former ArTara equity holders immediately before the Merger are expected to own approximately 28.67] of the Fully-Diluted Common Stock of the Company, and our equity holders immediately before the Merger are expected to own approximately 10.39% of the Fully-Diluted Common Stock of the Company, subject to adjustment based on the our net cash balance (as described in the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Events—Merger Agreement*") prior to the completion of the Merger.

Any changes in the market price of our common stock before the completion of the Merger will not affect the number of shares ArTara stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then ArTara equity holders could receive merger consideration with substantially lower value. Similarly, if before the completion of the Merger the market price of our common stock increases from the market price on the date of the Merger Agreement, then ArTara equity holders could receive merger consideration with substantially more value for their shares of ArTara capital stock than the parties had negotiated for in the establishment of the exchange ratio. The Merger Agreement does not include a price-based termination right. Because the exchange ratio does not adjust as a result of changes in the value of our common stock, for each one percentage point that the market value of our common stock rises or declines, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration issued to ArTara equity holders.

We may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of our management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. We may become involved in this type of litigation in connection with the Merger, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business and the business of the combined company, and insurance coverage may not be sufficient to cover all related costs and damages.

Risks Related to the Proposed Reverse Split

The Reverse Split may not increase the combined company's stock price over the long-term.

The principal purpose of the Reverse Split is to increase the per-share market price of the combined company's common stock above the minimum bid price requirement under the Nasdaq rules so that the listing of the combined company and the shares of the combined company common stock being issued in the Merger on Nasdaq will be approved. It cannot be assured, however, that the Reverse Split will accomplish this objective for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of the combined company's common stock, it cannot be assured that the Reverse Split will increase the market price of its common stock by a multiple of the reverse stock split ratio mutually agreed by ArTara and us, or result in any permanent or sustained increase in the market price of the combined company's common stock, which is dependent upon many factors, including the combined company's business and financial performance, general market conditions, and prospects for future success. Thus, while the stock price of the combined company might meet the continued listing requirements for Nasdaq initially, it cannot be assured that it will continue to do so.

The Reverse Split may decrease the liquidity of the combined company's common stock.

Although our board of directors believes that the anticipated increase in the market price of the combined company's common stock could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the Reverse Split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for the combined company's common stock.

The Reverse Split may lead to a decrease in the combined company's overall market capitalization.

Should the market price of the combined company's common stock decline after the Reverse Split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the Reverse Split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of the combined company's common stock will remain the same after the Reverse Split is effected, or that the Reverse Split will not have an adverse effect on the combined company's stock price due to the reduced number of shares outstanding after the Reverse Split.

Risks Related to Our Common Stock

Our common stock may be delisted from the Nasdaq Capital Market if we are unable to maintain compliance with Nasdaq's continued listing standards.

Nasdaq imposes, among other requirements, continued listing standards including minimum bid and public float requirements. The price of our common stock must trade at or above $1.00 to comply with Nasdaq's minimum bid requirement for continued listing on the Nasdaq Capital Market.

On May 10, 2019, we received a deficiency letter from Nasdaq, which indicated that we were not in compliance with the minimum bid price requirement set forth in Nasdaq rules for continued listing on The Nasdaq Global Market. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were granted a grace period of 180 calendar days, or until November 6, 2019, to regain compliance with the minimum bid price requirement. During the compliance period, our common stock continued to be listed and traded on The Nasdaq Global Market. Because we do not anticipate being able to regain compliance with the minimum bid price requirement during the compliance period, we submitted an application to transfer the listing of our common stock to The Nasdaq Capital Market, which, according to Nasdaq listing rules, affords us an additional 180-day compliance period to comply with the minimum bid price requirement. The transfer application also requires us to submit a letter stating our intention to effect the Reverse Split during the second compliance period, which we have done. The application to transfer the listing of our common stock was granted on September 30, 2019, effective October 7, 2019. If we fail to regain compliance with the minimum bid price requirement during the second compliance period, our common stock could be subject to delisting. Additionally, if we fail to comply with any other continued listing standards of Nasdaq, our common stock will also be subject to delisting. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria

Any delisting of our common stock could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Furthermore, if our common stock were delisted it could adversely affect our ability to complete one or more strategic transactions for the company, to obtain financing for the continuation of our operations and/or result in the loss of confidence by investors, customers, suppliers and employees.

If the proposed Merger is not completed, the market price of our common stock may continue to be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Factors affecting the trading price of our common stock may include:

- our failure to consummate another strategic transaction and the value of such other transaction including whether it is deemed to enhance stockholder value or deliver expected benefits;
- our failure to develop and commercialize vonapanitase or any additional product candidates;
- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about our operating results;
- adverse results or delays in preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for vonapanitase or any additional product candidates;
- success of competitive products;
- adverse developments concerning our collaborations and our manufacturers;
- inability to obtain adequate product supply for any product candidate for clinical trials or commercial sale or inability to do so at acceptable prices;
- the termination of a collaboration or the inability to establish additional collaborations;
- unanticipated serious safety concerns related to the use of any of vonapanitase or any additional product candidates;
- our ability to effectively manage our growth;
- the size and growth, if any, of the targeted market;
- our operating results failing to meet the expectation of securities analysts or investors in a particular period or failure of securities analysts to publish reports about us or our business;
- changes in financial estimates and recommendations by securities analysts concerning us, our market opportunity, or the biotechnology and pharmaceutical industries in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- overall performance of the equity markets;
- announcements by us or our competitors of acquisitions, new product candidates or programs, significant contracts, commercial relationships or capital commitments;
- our ability to successfully market vonapanitase or any additional product candidates;
- changes in laws and regulations affecting our business, including but not limited to clinical trial requirements for approvals;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for vonapanitase or any additional product candidates;
- commencement of, or involvement in, litigation involving us, our general industry, or both;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale;
- additions or departures of key scientific or management personnel;
- any major change in our board or management;
- changes in accounting practices;
- ineffectiveness of our internal control over financial reporting;
- sales of substantial amounts of our common stock by our directors, executive officers or significant stockholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

Broad market and industry factors may materially harm the market price of our common stock irrespective of our operating performance. The stock market in general, and Nasdaq and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of ours, may not be predictable. A loss of investor confidence in the market for pharmaceutical, biopharmaceutical and biotechnology stocks or the stocks of other companies which investors perceive to be similar to us, or the stock market in general, could depress our stock price regardless of our business, prospects, financial conditions or results of operations.

The resale of the shares of our common stock issuable upon the conversion of our Series A Convertible Preferred Stock could adversely affect the prevailing market price of our common stock and cause stockholders to experience dilution.

On August 2, 2017, we issued and sold 22,000 shares of our Series A Convertible Preferred Stock, par value $0.001 per share, for a purchase price of $1,000 per share, or an aggregate purchase price of $22.0 million. Each share of Series A Convertible Preferred Stock is convertible into approximately 1,005 shares of our common stock at a conversion price of $0.9949 per share, provided that any conversion of Series A Convertible Preferred Stock by a holder into shares of Common Stock is prohibited if, as a result of such conversion, the holder, together with our affiliates and any other person or entity whose beneficial ownership of our common stock would be aggregated with such holder's for purposes of Section 13(d) of the Exchange Act, would beneficially own more than 9.985% of the total number of shares of our common stock issued and outstanding after giving effect to such conversion (the "Blocker"). Pursuant to the registration statement that we filed with the SEC for the resale by holders of our Series A Preferred Convertible Stock, as selling stockholders, of the aggregate 22,112,775 shares of our common stock that are issuable upon conversion of the Series A Convertible Preferred Stock, the outstanding shares of Series A Convertible Preferred Stock may, at each holder's election, be converted into our common stock, subject to the Blocker. Although we cannot predict if and when the holders of Series A Convertible Preferred Stock may sell such shares in the public market, any converted shares of our common stock will be available for immediate resale and be able to be freely sold in the open market. The conversion of shares of Series A Convertible Preferred Stock into shares of our common stock will result in substantial dilution to holders of our common stock. Further, the sale of a significant amount of these shares of our common stock in the open market or the perception that these sales may occur could adversely affect prevailing market prices of our common stock, including causing the market price of our common stock to decline or become highly volatile.

The concentration of our capital stock ownership with insiders will likely limit your ability to influence corporate matters.

As of December 31, 2018, our executive officers, directors, current 5% or greater stockholders, and their respective affiliates together beneficially own or control, in aggregate, more than 50% of the shares of our outstanding common stock. As a result, these executive officers, directors and principal stockholders, acting together, will have substantial influence over most matters that require approval by our stockholders, including the election of directors, any merger, consolidation or sale of all or substantially all or of our assets or any other significant corporate transaction. Corporate action might be taken even if other stockholders oppose such action. These stockholders may delay or prevent a change of control or otherwise discourage a potential acquirer from attempting to obtain control of us, even if such change of control would benefit our other stockholders. This concentration of stock ownership may adversely affect investors' perception of our corporate governance or delay, prevent or cause a change in control of us, any of which could adversely affect the market price of our common stock.

We will continue to incur substantial costs as a result of operating as a public company, and our management will continue to devote substantial time to new compliance initiatives and corporation governance policies.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, and rules of the SEC and those of Nasdaq impose various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, 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 control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting the later of our second annual report on Form 10-K or the first annual report on Form 10-K following the date on which it is no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that it incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

We do not expect to pay any cash dividends for the foreseeable future.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies, including us, have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Provisions in our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware and federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit such stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware and federal courts within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This 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 employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

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

Use of Proceeds from Unregistered Securities

None.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Item 5. Other Information

Not applicable.

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.

Date: October 31, 2019

PROTEON THERAPEUTICS, INC.

By: /s/ Timothy P. Noyes
Timothy P. Noyes
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: October 31, 2019

By: /s/ George A. Eldridge
George A. Eldridge
Senior Vice President, Chief Financial Officer,
Treasurer and Secretary
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit No.		Description
31.1	*	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	*	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	*	Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Balance Sheets as of September 30, 2019 (unaudited) and the Consolidated Balance Sheets as of December 31, 2018; (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the nine months ended September 30, 2019 and 2018; and (iii) the Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30th, 2019 and 2018; and (iv) the notes to the Condensed Consolidated Financial Statements (unaudited).

*Exhibits filed herewith
** Exhibits furnished herewith.

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, Timothy P. Noyes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2019 of Proteon 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.

/s/ Timothy P. Noyes
Timothy P. Noyes
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: October 31, 2019

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, George A. Eldridge, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2019 of Proteon 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.

/s/ George A. Eldridge
George A. Eldridge
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer)

Date: October 31, 2019

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 Proteon Therapeutics, Inc. (the "Corporation") on Form 10-Q for the fiscal quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy P. Noyes, as President and Chief Executive Officer of the Corporation, and I, George A. Eldridge, Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary 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: October 31, 2019

By: /s/ Timothy P. Noyes
Timothy P. Noyes
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: October 31, 2019

By: /s/ George A. Eldridge
George A. Eldridge
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
(Principal Financial 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.