
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): October 31, 2019

Proteon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-36694
(Commission File Number)

20-4580525
(I.R.S. Employer Identification Number)

200 West Street, Waltham, MA 02451
(Address of Principal Executive Offices) (Zip Code)

(781) 890-0102
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
Common stock, \$0.001 par value per share	PRTO	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
Emerging growth company

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

Introductory Comment

Throughout this Current Report on Form 8-K, the terms “we,” “us,” “our,” “Company” and “Proteon” refer to Proteon Therapeutics, Inc.

Item 2.02. Results of Operations and Financial Condition.

On October 31, 2019, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2019. A copy of such press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference in its entirety.

The information in this Current Report on Form 8-K under Item 2.02, including the exhibit attached hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit
No.

Description

[99.1](#) [Press Release, dated October 31, 2019, issued by Proteon Therapeutics, Inc. announcing its Third Quarter 2019 Financial Results](#)

SIGNATURE

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 hereunto duly authorized.

Proton Therapeutics, Inc.

Date: October 31, 2019

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

EXHIBIT INDEX

Exhibit No. Description

99.1 [Press Release, dated October 31, 2019, issued by Proteon Therapeutics, Inc. announcing its Third Quarter 2019 Financial Results](#)

Proteon Therapeutics Announces Third Quarter 2019 Financial Results

WALTHAM, Mass., Oct. 31, 2019 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. ("Proteon" or the "Company") (Nasdaq: PRTO), a 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, today announced its financial results for the quarter ended September 30, 2019, and recent events.

Recent Events

Signing of Definitive Merger Agreement Announced. On September 23, 2019, Proteon announced it had entered into a definitive agreement in which a wholly-owned subsidiary of Proteon will merge, in an all-stock transaction, with ArTara Therapeutics, Inc., a private clinical stage biopharmaceutical company developing treatments for rare and specialty diseases with significant unmet therapeutic needs ("ArTara"). The merged company will focus on advancing ArTara's pipeline of transformative late-stage, de-risked rare and specialty diseases assets. Upon stockholder approval, the combined company is expected to operate under the name ArTara Therapeutics, Inc. and trade on the Nasdaq Capital Market under the ticker symbol TARA. The transaction has been unanimously approved by the Board of Directors of both companies, and is expected to close by year end 2019, subject to customary conditions, including approval by Proteon and ArTara stockholders and the satisfaction of the conditions under the stock purchase agreement for the private investment described below.

Concurrent \$42.5 Million of Funding at Merger Closing Announced. A syndicate of healthcare dedicated investors have concurrently entered into a stock purchase agreement to invest \$42.5 million in the combined company. This financing will help fund the development of ArTara's lead assets TARA-002 and IV Choline Chloride and such funding is expected to be consummated concurrently with the closing of the merger transaction, which is expected by year end 2019.

Third Quarter 2019 Financial Results

Cash, cash equivalents and available-for-sale investments totaled \$9.3 million as of September 30, 2019, compared to \$10.8 million as of June 30, 2019. The decrease was primarily driven by operational costs for the three-month period ending September 30, 2019.

R&D expenses: Research and development expenses for the third quarter of 2019 were \$0.2 million as compared to \$2.4 million for the third quarter of 2018. The decrease in R&D expenses was due primarily to decreased external research and development expenses in the third quarter of 2019 as compared to the third quarter of 2018.

G&A expenses: General and administrative expenses for the third quarter of 2019 were \$1.4 million as compared to \$2.3 million for the third quarter of 2018. The decrease in G&A expenses was due primarily to decreased expenses related to our reduction in force in the third quarter of 2019 as compared to the third quarter of 2018.

Net loss: Net loss for the third quarter of 2019 was \$1.5 million as compared to \$4.5 million for the third quarter of 2018. Net loss included stock-based compensation expense of \$0.1 million for the third quarter of 2019 and \$0.9 million for the third quarter of 2018.

Financial guidance: The Company expects that its cash, cash equivalents and available-for-sale investments will be sufficient to fund its operations into 2020, based on the Company's current operating plan.

About Proteon Therapeutics

Proteon Therapeutics has historically been focused on improving the health of patients with kidney and vascular diseases through the development of novel, first-in-class therapeutics. Proteon's lead product candidate, vonapanitase, is an investigational drug intended to improve hemodialysis vascular access outcomes. Proteon has announced in March 2019 top-line results from PATENCY-2, a Phase 3 clinical trial evaluating vonapanitase in patients with chronic kidney disease undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. The PATENCY-2 trial did not reach statistical significance on either of the co-primary endpoints of fistula use for hemodialysis and secondary patency. Proteon has also evaluated investigational vonapanitase in Phase 1 clinical trials in patients with peripheral artery disease, or PAD. For more information, please visit www.proteontx.com.

No Offer or Solicitation:

This press release shall not constitute an offer to sell, or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No public offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Additional Information About the Proposed Transaction and Where to Find it

Proteon intends to file a registration statement on Form S-4 with the U.S. Securities and Exchange Commission (the "SEC"), which will contain a proxy statement/prospectus and other relevant materials, and plans to file with the SEC other documents regarding the proposed transaction with ArTara. The final proxy statement/prospectus will be sent to the stockholders of Proteon in connection with the Proteon's special meeting of stockholders to be held to vote on matters relating to the proposed transaction. The proxy statement/prospectus will contain information about Proteon, ArTara, the proposed transaction, and related matters. **STOCKHOLDERS OF PROTEON ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS THEY WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS OF PROTEON SHOULD CONSIDER BEFORE MAKING A DECISION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS.** In addition to receiving the proxy statement/prospectus and proxy card by mail, Proteon stockholders will also be able to obtain the proxy statement/prospectus, as well as other filings containing information about Proteon, without charge, from the SEC's website at www.sec.gov or, without charge, by directing a written request to: Proteon Therapeutics, Inc., 200 West St. Waltham, MA 02451, Attention: Investor Relations.

Participants in the Solicitation

Proteon, ArTara and their respective executive officers, directors, certain members of management and certain employees may be deemed, under

the SEC rules, to be participants in the solicitation of proxies from Proteon stockholders with respect to the matters relating to the proposed transaction. Information regarding Proteon's executive officers and directors is available in Proteon's proxy statement on Schedule 14A for its 2018 annual meeting of stockholders, filed with the SEC on April 26, 2018 and Proteon's Annual Report on Form 10-K and the amendment thereto for the year-ended December 31, 2018. These documents are available free of charge at the SEC's website at www.sec.gov or by going to Proteon's investor and media page on its corporate website at www.proteontherapeutics.com. Additional information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of proxies in connection with the proposed transaction, and a description of their direct and indirect interests in the proposed transaction, which may differ from the interests of Proteon's stockholders generally, will be set forth in the proxy statement/prospectus that Proteon intends to file with the SEC in connection with its stockholder vote on matters relating to the proposed transaction. Proteon stockholders will be able to obtain this information by reading the proxy statement/prospectus when it becomes available.

Cautionary Note Regarding Forward-Looking Statements

Certain statements contained in this press release regarding matters that are not historical facts are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). These include statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, stockholders are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. We use words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on management expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the forward-looking statements due to a number of factors, including, but not limited to, risks relating to the completion of the proposed transaction with ArTara, including the need for Proteon's and ArTara's stockholder approval and the satisfaction of certain closing conditions; the anticipated financing to be completed concurrently with the closing of the proposed transaction; the business and prospects of the combined company following the proposed transaction; and the sufficiency of the Company's cash, cash-equivalents and available-for-sale investments to fund the Company's operations. Risks and uncertainties that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: the closing of the proposed transaction; ArTara's plans to develop and commercialize its product candidates, including TARA-002, and Choline Chloride; the timing, costs and outcomes of ArTara's planned clinical trials; expectations regarding potential market size; the timing of the availability of data from ArTara's clinical trials; the timing of any planned investigational new drug application or new drug application; ArTara's plans to research, develop and commercialize its current and future product candidates; ArTara's ability to successfully collaborate with existing collaborators or enter into new collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of ArTara's product candidates; ArTara's commercialization, marketing and manufacturing capabilities and strategy; ArTara's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to ArTara's competitors and industry; the impact of government laws and regulations; ArTara's ability to protect its intellectual property position; and ArTara's estimates regarding future revenue, expenses, capital requirements, and the need for and timing of additional financing following the proposed transaction. These risks, as well as other risks associated with the proposed transaction, will be more fully discussed in the proxy statement/prospectus that will be included in the registration statement on Form S-4 that will be filed by Proteon with the U.S. Securities and Exchange Commission (the "SEC") in connection with the proposed transaction. Additional risks and uncertainties are identified and discussed in Proteon's Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 13, 2019, and Proteon's subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as filed with the SEC, particularly in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Forward-looking statements included in this press release are based on information available to Proteon as of the date of this press release. Proteon does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release.

Proteon Therapeutics, Inc. Consolidated Balance Sheet Data (In thousands)

	September 30, 2019	December 31, 2018
Cash, cash equivalents and available-for-sale investments	\$ 9,349	\$ 21,867
Prepaid expenses and other current assets	299	1,369
Property and equipment, net and other non-current assets	-	285
Total assets	\$ 9,648	\$ 23,521
Accounts payable, accrued expenses and other current liabilities	\$ 1,613	\$ 3,078
Preferred Stock, common stock and additional paid-in-capital	231,885	230,908
Accumulated deficit and accumulated other comprehensive income	(223,850)	(210,465)
Total liabilities and stockholders' deficit	\$ 9,648	\$ 23,521

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

	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	<u>1,591</u>	<u>4,622</u>	<u>13,614</u>	<u>15,987</u>
Loss from operations	(1,591)	(4,622)	(13,614)	(15,987)
Other income (expense):				
Investment income	53	113	231	311
Other income (expense), net	2	(1)	1	206
Total other (expense) income	<u>55</u>	<u>112</u>	<u>232</u>	<u>517</u>
Net loss	<u>\$ (1,536)</u>	<u>\$ (4,510)</u>	<u>\$ (13,382)</u>	<u>\$ (15,470)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.25)</u>	<u>\$ (0.69)</u>	<u>\$ (0.87)</u>
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	<u>19,585,394</u>	<u>17,824,186</u>	<u>19,476,487</u>	<u>17,725,095</u>

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	<u>\$ 96</u>	<u>\$ 904</u>	<u>\$ 977</u>	<u>\$ 2,647</u>

Investor Contact

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