

---

**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): May 8, 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))

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 May 8, 2019, the Company issued a press release announcing its financial results for the first quarter ended March 31, 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 Items 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 May 8, 2019, issued by Proteon Therapeutics, Inc. announcing its First 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.

**Proteon Therapeutics, Inc.**

Date: May 8, 2019

By: /s/ George A. Eldridge  
George A. Eldridge  
Senior Vice President & Chief Financial Officer

---

## EXHIBIT INDEX

Exhibit No. Description

99.1 [Press Release, dated May 8, 2019, issued by Proteon Therapeutics, Inc. announcing its First Quarter 2019 Financial Results](#)

## Proteon Therapeutics Announces First Quarter 2019 Financial Results

WALTHAM, Mass., May 08, 2019 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq: PRT0), a company developing novel, first-in-class pharmaceuticals to address the medical needs of patients with kidney and vascular diseases, today announced its financial results for the quarter ended March 31, 2019, and recent events.

### Recent Events

**PATENCY-2 Trial Misses Statistical Significance on Both Co-Primary Endpoints.** On March 28, 2019, the Company announced top-line results from PATENCY-2, its Phase 3 clinical trial of investigational vonapanitase in patients with chronic kidney disease, or CKD, undergoing creation of a radiocephalic fistula for hemodialysis. The PATENCY-2 clinical trial had two co-primary endpoints (i) fistula use for hemodialysis and (ii) secondary patency, or time from surgical creation of the fistula to its abandonment. Neither endpoint reached statistical significance in PATENCY-2. The PATENCY-2 clinical trial was the second of two randomized, double-blind Phase 3 trials, comparing investigational vonapanitase to placebo. As to safety in the PATENCY-2 trial, the proportions of patients experiencing adverse events were comparable between the vonapanitase and placebo arms of the study. The most common adverse events were consistent with medical events experienced by patients with CKD undergoing creation of a radiocephalic fistula.

**Engaged H.C. Wainwright to Assist in Strategic Review.** On April 15, 2019, Proteon announced it had engaged H.C. Wainwright & Co., LLC as its financial advisor to assist in the strategic review process. Potential strategic alternatives that may be explored or evaluated as part of this review include, but are not limited to, an acquisition, merger, business combination or other strategic transaction involving Proteon. There is no defined timeline for completion of the review process.

**Reduction in Headcount and Discontinuation of Substantially all R&D Activities.** We initiated a plan in April 2019 to reduce personnel and expenses to preserve capital and further reduce our operations consistent with our decision to discontinue substantially all research and development activities. We expect to devote significant time and resources to identifying and evaluating strategic alternatives, however, there can be no assurance that such activities will result in any agreements or transactions that will enhance shareholder value.

### First Quarter 2019 Financial Results

Cash, cash equivalents and available-for-sale investments totaled \$16.8 million as of March 31, 2019, compared to \$21.9 million as of December 31, 2018. The decrease was primarily driven by operational costs for first three-month period of 2019.

**R&D expenses:** Research and development expenses for the first quarter of 2019 were \$4.0 million as compared to \$4.1 million for the first quarter of 2018. The decrease in R&D expenses was due primarily to decreased internal research and development expenses in the first quarter of 2019 as compared to the first quarter of 2018.

**MG&A expenses:** Marketing, general and administrative expenses for the first quarter of 2019 were \$2.6 million as compared to \$2.3 million for the first quarter of 2018. The increase in MG&A expenses was due primarily to increased expenses to support our ongoing corporate activities and increased expenses associated with being a public, reporting company in the first quarter of 2019 as compared to the first quarter of 2018.

**Net loss:** Net loss for the first quarter of 2019 was \$6.5 million as compared to \$6.1 million for the first quarter of 2018. Net loss included stock-based compensation expense of \$0.8 million for the first quarter of 2019 and \$0.8 million for the first 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 is 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](http://www.proteontx.com).

### Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are, or may be deemed to be, "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "estimates," "anticipates," "expects," "plans," "intends," "may," or "will," their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including the whether and when the Company may complete a strategic review process or related transaction, the potential surgical and endovascular applications for vonapanitase, including PAD, the sufficiency of the Company's cash, cash-

equivalents and available-for-sale investments to fund the Company's operations, and those relating to future events or our future financial performance or condition, involve substantial known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors, including whether our cash resources will be sufficient to fund the Company's operating expenses and capital expenditure requirements for the period anticipated; whether data from early nonclinical or clinical studies will be indicative of the data that will be obtained from future clinical trials; whether vonapanitase will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether the Company can successfully commercialize and market its product candidates, are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission ("SEC") on March 13, 2019, and the Company'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." In light of the significant uncertainties in the Company's forward-looking statements, no person should place undue reliance on these statements or regard these statements as a representation or warranty by the Company or any other person that the Company will achieve its objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this press release represent the Company's estimates and assumptions only as of the date of this press release and, except as required by law, the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this press release.

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

	<b>March 31, 2019</b>	<b>December 31, 2018</b>
Cash, cash equivalents and available-for-sale investments	\$ 16,763	\$ 21,867
Prepaid expenses and other current assets	1,170	1,369
Property and equipment, net and other non-current assets	127	285
<b>Total assets</b>	<b>\$ 18,060</b>	<b>\$ 23,521</b>
Accounts payable, accrued expenses and other current liabilities	\$ 3,370	\$ 3,078
Preferred Stock, common stock and additional paid-in-capital	231,688	230,908
Accumulated deficit and accumulated other comprehensive income	(216,998)	(210,465)
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 18,060</b>	<b>\$ 23,521</b>

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

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Operating expenses:		
Research and development	\$ 4,048	\$ 4,071
General and administrative	2,589	2,294
Total operating expenses	6,637	6,365
Loss from operations	(6,637)	(6,365)
Other income (expense):		

Investment income	105	92
Other income (expense), net	1	192
Total other (expense) income	<u>106</u>	<u>284</u>
Net loss	<u>\$ (6,531)</u>	<u>\$ (6,081)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.34)</u>
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	<u>19,255,042</u>	<u>17,674,729</u>

**Supplemental disclosure of stock-based compensation expense and loss from currency forward contracts:**

Included in operating expenses, above, are the following amounts for non-cash stock based compensation expense:

Research and development	\$ 255	\$ 267
General and administrative	525	554
Total	<u>\$ 780</u>	<u>\$ 821</u>

**Investor Contact**

George Eldridge, Proteon Therapeutics, Senior Vice President and Chief Financial Officer  
781-890-0102 x1026  
geldridge@proteontherapeutics.com