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): November 7, 2018

Proteon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36694**	**20-4580525**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 [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. [ ]

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 November 7, 2018, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2018. 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 November 7, 2018, issued by Proteon Therapeutics, Inc. announcing its Third Quarter 2018 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: November 7, 2018

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

EXHIBIT INDEX

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EXHIBIT 99.1

Proteon Therapeutics Announces Third Quarter 2018 Financial Results

WALTHAM, Mass., Nov. 07, 2018 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq: PRTO), a company developing novel, first-in-class therapeutics to address the medical needs of patients with kidney and vascular diseases, today announced its financial results for the quarter ended September 30, 2018, and recent business highlights.

"We made excellent progress in the third quarter of 2018," said Timothy Noyes, President and Chief Executive Officer of Proteon. "We remain on track to release top-line data from the Phase 3 PATENCY-2 clinical trial in March 2019 and to file a BLA later in 2019 if the results are positive. We continue preparing to build the commercial infrastructure to launch investigational vonapanitase, if approved by FDA."

Recent Highlights for 2018

Phase 3 PATENCY-2 clinical trial continues to follow patients, with top-line data expected in March 2019. PATENCY-2 is a multicenter, randomized, double-blind, placebo-controlled trial of investigational vonapanitase that treated 603 patients in the United States and Canada with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. The study's co-primary endpoints are fistula use for hemodialysis and secondary patency (i.e., time to fistula abandonment), each of which demonstrated improvements in PATENCY-1 using the same definitions as in PATENCY-2. If PATENCY-2 is successful in showing statistical significance ($p \leq 0.05$) on each of the co-primary endpoints, Proteon expects to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the second half of 2019 and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in 2020.

Raised $3 million through Proteon's "at-the-market" (ATM) program. New Leaf Venture Partners LLC purchased approximately 1.5 million shares of common stock in September 2018. With this additional funding, Proteon now has sufficient capital to operate into Q1 2020, or almost a year past the expected release of top-line data from the PATENCY-2 trial, based on the Company's current operating plan.

Important amendment to the supply agreement with Lonza. An amendment to the supply agreement between Proteon and Lonza was signed in May 2018, securing a potential long-term commercial supply of active pharmaceutical ingredient (API) for vonapanitase. Lonza has manufactured API for Proteon at its microbial manufacturing facility in Visp, Switzerland, since 2009. The amendment extends the term of the supply agreement until 2029.

Enrollment continues in a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD). The multicenter, randomized, double-blind, placebo-controlled Phase 1 dose escalation trial is expected to enroll 24 symptomatic PAD patients being treated with balloon angioplasty of an artery below the knee and to follow each patient for up to seven months. Immediately following successful angioplasty, vonapanitase or placebo is delivered to the arterial wall using the Mercator MedSystems Bullfrog® Micro-Infusion Catheter. The primary outcome measure of the trial is safety and the secondary outcome measure is technical feasibility of study drug delivery via the catheter.

Live case broadcast at The Amputation Prevention Symposium (AMP) in Chicago of patient treatment in the Phase 1 PAD study. Lawrence Garcia, M.D., director of interventional cardiology and co-director of vascular medicine at St. Elizabeth's Medical Center in Boston presented a live case in which a patient underwent angioplasty followed by administration of vonapanitase or placebo.

Phase 3 PATENCY-1 clinical results recently presented. Results of PATENCY-1 were presented recently at the (i) Vascular Access Society of Britain and Ireland Annual Meeting in Portsmouth England, (ii) Controversies in Dialysis Access (CiDA) in Washington, DC, and (iii) Innovations in Dialysis: Expediting Advances Symposium (IDEAS) in Seattle, WA.

Key Upcoming Milestones

- Complete enrollment of 24 patients in the PAD Phase 1 trial by the fourth quarter of 2018.
- Release top-line data from PATENCY-2 in March 2019.

Upcoming Events

- Presentation at the Stifel 2018 Healthcare Conference November 13th in New York City, NY.
- Presentation by Keith Ozaki, M.D., at the 45th Annual VEITH Symposium on November 17th in New York City.

Third Quarter 2018 Financial Results

Cash, cash equivalents and available-for-sale investments totaled $26.2 million as of September 30, 2018, compared to $42.1 million as of December 31, 2017. The decrease was primarily driven by operational costs for the first nine-month period of 2018.

R&D expenses: Research and development expenses for the third quarter of 2018 were $2.4 million as compared to $10.3 million for the third quarter of 2017. The decrease in R&D expenses was due primarily to decreased expenses for our manufacturing validation efforts and for our ongoing clinical trials in the third quarter of 2018 as compared to the third quarter of 2017.

MG&A expenses: Marketing, general and administrative expenses for the third quarter of 2018 were $2.3 million as compared to $2.0 million for the third quarter of 2017. The increase in MG&A expenses was due primarily to higher overhead and personnel expenses in the third quarter of 2018 as compared to the third quarter of 2017.

Net loss: Net loss for the third quarter of 2018 was $4.5 million as compared to $12.3 million for the third quarter of 2017. Net loss included stock-based compensation expense of $0.9 million for the third quarter of 2018 and $0.7 million for the third quarter of 2017.

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

About Vonapanitase

Vonapanitase is an investigational drug intended to improve hemodialysis vascular access outcomes. Vonapanitase is applied in a single administration and is currently being studied in a Phase 3 clinical trial in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Vonapanitase has received Breakthrough Therapy, Fast Track and Orphan Drug designations from the FDA, and Orphan Medicinal Product designation from the European Commission, for hemodialysis vascular access indications. In addition, vonapanitase may have other surgical and endovascular applications in diseases or conditions in which vessel injury leads to blockages in blood vessels and reduced blood flow. Proteon is currently conducting a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD).

About Proteon Therapeutics

Proteon Therapeutics is committed to 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 completed enrollment in PATENCY-2, a Phase 3 clinical trial evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Proteon is also evaluating vonapanitase in a Phase 1 clinical trial in patients with PAD. For more information, please visit 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,” in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including the number of patients to be enrolled in and the timing of enrollment in the Company’s ongoing Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD), when the Company expects to release top-line data from the PATENCY-2 trial, whether and when the Company may submit a Biologics License Application (BLA) in the United States, the effect or benefit of vonapanitase in patients with chronic kidney disease (CKD), whether vonapanitase improves fistula use for hemodialysis or secondary patency, the potential long-term commercial supply of active pharmaceutical ingredient (API) for vonapanitase, 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 into the first quarter of 2020, 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, 2017, as filed with the Securities and Exchange Commission (“SEC”) on March 14, 2018, 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)

	September 30, 2018	December 31, 2017
Cash, cash equivalents and available-for-sale investments	$ 26,212	$ 42,141
Prepaid expenses and other current assets	871	1,339
Property and equipment, net and other non-current assets	322	499
Total assets	**$ 27,405**	**$ 43,979**
Accounts payable and accrued expenses	$ 2,534	$ 9,240
Preferred Stock, common stock and additional paid-in-capital	230,078	224,494
Accumulated deficit and accumulated other comprehensive income	(205,207)	(189,755)

Total liabilities and stockholders' deficit	**$ 27,405**	**$ 43,979**

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,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 2,354	$ 10,336	$ 9,185	$ 18,473
General and administrative	2,268	1,970	6,802	6,299
Total operating expenses	4,622	12,306	15,987	24,772
Loss from operations	(4,622)	(12,306)	(15,987)	(24,772)
Other income (expense):				
Investment income	113	83	311	161
Other income (expense), net	(1)	(84)	206	198
Total other (expense) income	112	(1)	517	359
Net loss	$ (4,510)	$ (12,307)	$ (15,470)	$ (24,413)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.25)	$ (1.08)	$ (0.87)	$ (1.82)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	17,824,186	17,574,371	17,725,095	17,158,032

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	$ 298	$ 235	$ 877	$ 841
General and administrative	606	512	1,770	1,618
Total	$ 904	$ 747	$ 2,647	$ 2,459

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