

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 12, 2015

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
(Address of Principal Executive Offices)

02451
(Zip Code)

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

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))

Item 2.02. Results of Operations and Financial Condition.

On November 12, 2015, Proteon Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2015. 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, including the exhibit attached hereto, in this Current Report on Form 8-K shall not be deemed "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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 12, 2015, issued by Proteon Therapeutics, Inc.

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.

Date: November 12, 2015

Proteon Therapeutics, Inc.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 12, 2015, issued by Proteon Therapeutics, Inc.

Proteon Therapeutics Announces Third Quarter 2015 Financial Results

-Enrollment in PATENCY-1 Completed Ahead of Schedule-

-Data from PATENCY-1 Expected in December 2016-

-Proteon to Hold Research and Development Day in New York on November 20-

WALTHAM, Mass., Nov. 12, 2015 (GLOBE NEWSWIRE) -- Proteon Therapeutics Inc. (Nasdaq:PRTO), 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 September 30, 2015, and recent business highlights.

"I am thrilled that we were able to complete enrollment ahead of schedule in PATENCY-1, the first of two Phase 3 clinical studies of vonapanitase we are currently conducting," said Timothy Noyes, President and Chief Executive Officer of Proteon. "What is even more exciting is that we expect to report top-line data from PATENCY-1 in December 2016, which is also ahead of schedule."

Recent Highlights for 2015

Enrollment completed in PATENCY-1, the first Phase 3 clinical study of investigational vonapanitase (formerly known as PRT-201). PATENCY-1 is a multicenter, randomized, double-blind, placebo-controlled study that enrolled 311 patients in the United States with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula (AVF) for hemodialysis. The primary efficacy endpoint is primary unassisted patency, defined as the time from AVF creation until a thrombosis or a procedure to restore or maintain patency. The secondary efficacy endpoint is secondary patency, defined as the time from AVF creation until AVF abandonment. The Company expects to report top-line data from PATENCY-1 in December 2016.

Enrollment continues according to plan in PATENCY-2, the second Phase 3 clinical study of vonapanitase. The Company announced enrollment of the first patient in PATENCY-2 this past quarter. PATENCY-2, like PATENCY-1, is a randomized, double-blind, placebo-controlled study expected to enroll 300 patients with CKD undergoing surgical creation of a radiocephalic AVF for hemodialysis. The primary and secondary efficacy endpoints are the same in PATENCY-2 as they are in PATENCY-1. The Company expects to complete enrollment in PATENCY-2 in the first quarter of 2017.

Top-line results from Phase 1 clinical study in peripheral artery disease (PAD) of vonapanitase presented at the 27th Transcatheter Cardiovascular Therapies (TCT). The open-label, single center Phase 1 dose escalation study enrolled 14 patients being treated with balloon angioplasty due to symptomatic PAD of the superficial femoral or popliteal artery. Immediately following successful angioplasty, vonapanitase was delivered to the arterial wall using the Mercator MedSystems Bullfrog® Micro-Infusion Catheter. The primary outcome measure of the study was safety and the secondary outcome measure was technical feasibility of drug delivery via the catheter. The data suggested that catheter-based treatment with vonapanitase was generally well tolerated and technically feasible. The results were presented by Christopher D. Owens, M.D., Associate Professor of Surgery Division of Vascular and Endovascular Surgery at the University of California San Francisco, who was the principal investigator of the study.

Board of Directors and management team strengthened with the addition of manufacturing, commercial and regulatory expertise. In the last four months, the Company appointed to the Board Scott Canute, formerly President of Global Manufacturing Operations at Eli Lilly and Company and President of Global Manufacturing and Corporate Operations at Genzyme Corporation. Also, the Company appointed Anthony (Tony) Kingsley, who until recently was Executive Vice President, Global Commercial Operations at Biogen and former Partner at McKinsey & Company. In addition, Proteon strengthened its management team with the hiring of Jennifer Panagoulas as Vice President of Regulatory Affairs. Jennifer brings global regulatory expertise from her time at Alnylam Pharmaceuticals and Genzyme Corporation.

Key Milestones for 2016

- Report top-line data from PATENCY-1 in December 2016.
- Initiate two clinical studies of vonapanitase in patients with peripheral artery disease (PAD).

Upcoming Events

- Presentation at Stifel 2015 Healthcare Conference on November 17th in New York City.
- Research and Development Day on November 20th in New York City.
- Presentation by Keith Ozaki, M.D. at the 42nd Annual VEITH Symposium on November 21st in New York City.
- Presentation at Oppenheimer & Co. 26th Annual Healthcare Conference on December 9th in New York City.

Third Quarter 2015 Financial Results

Cash position: Cash, cash equivalents and available-for-sale investments totaled \$70.5 million as of September 30, 2015, compared to \$83.6 million as of December 31, 2014. The decrease was driven by operational costs for the first nine-month period of 2015.

Revenues: No revenues were recorded in the third quarter of 2015, as compared to \$2.9 million in the third quarter of 2014 related to deferred revenue recognized as revenue upon the expiration in August 2014 of residual rights under an option agreement originally entered into in 2009.

R&D expenses: Research and development expenses for the third quarter of 2015 were \$3.1 million as compared to \$1.8 million for the third quarter of 2014. The increase in R&D expenses was due primarily to patient enrollment and follow-up visit expenses in PATENCY-1, which commenced in the third quarter of 2014; the initiation and patient enrollment expenses of PATENCY-2, which enrolled its first patient in the third quarter of 2015; and increased manufacturing expenses associated with certain pre-validation activities.

G&A expenses: General and administrative expenses for the third quarter of 2015 were \$2.0 million as compared to \$1.0 million for the third quarter of 2014. The increase in G&A expenses was due primarily to higher personnel costs in 2015 than in 2014 and higher expenses associated with being a public reporting company. The Company became a public reporting company in the fourth quarter of 2014.

Other expense: Other expense for the third quarter of 2015 was \$0.3 million as compared to \$5.3 million for the third quarter of 2014. Other expense in the third quarter of 2015 included non-cash changes in the Swiss Franc denominated currency the Company held as of September 30, 2015 and the fair value associated with the forward foreign currency contracts the Company entered into in June 2015. Other expense in the third quarter of 2014 was related to the non-cash increase in the fair value of the liability associated with the Series D Preferred Stock investor rights obligation. The Series D investor rights obligation was settled during October 2014 as part of our initial public offering and the liability decreased to zero.

Net loss: Net loss for the third quarter of 2015 was \$5.4 million as compared to \$5.2 million for the third quarter of 2014. Net loss included stock-based compensation expense of \$0.6 million for the third quarter of 2015 as compared to \$0.2 million for the third quarter of 2014.

Financial guidance: The Company expects that its cash, cash equivalents and available-for-sale investments will be sufficient to fund its operations into the fourth quarter of 2017.

About Vonapanitase

Vonapanitase (formerly PRT-201) is an investigational drug intended to improve arteriovenous fistula (AVF) patency, the period of time during which an AVF remains open with adequate blood flow to enable hemodialysis. Vonapanitase is applied in a single administration and is currently being studied in two Phase 3 clinical trials (PATENCY-1 and PATENCY-2) in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Vonapanitase has received fast track and orphan drug designations from the U.S. Food and Drug Administration (FDA), and orphan medicinal product designation from the European Commission, for hemodialysis vascular access indications. Vonapanitase may have multiple surgical and endovascular applications in which vessel injury leads to blockages in blood vessels and reduced blood flow, and has completed a Phase 1 clinical trial in patients with symptomatic 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 (formerly PRT-201), is an investigational drug intended to improve arteriovenous fistula (AVF) patency, the period of time during which an AVF remains open with adequate blood flow to enable hemodialysis. Proteon is currently evaluating vonapanitase in two Phase 3 clinical trials in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic AVF for hemodialysis and has completed a Phase 1 clinical trial in patients with symptomatic peripheral artery disease (PAD). For more information, please visit www.proteontherapeutics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential," or, in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements, including when data from the PATENCY-1 Phase 3 clinical study will be available, the overall patient enrollment in the PATENCY-2 Phase 3 clinical study of vonapanitase, when data from the PATENCY-2 Phase 3 clinical study will be available, the potential surgical and endovascular applications for vonapanitase, the potential treatment of renal and vascular diseases with vonapanitase, the effect of vonapanitase in patients with CKD, whether vonapanitase improves AVF patency, timing of future clinical studies in PAD of vonapanitase, the sufficiency of the Company's cash, cash-equivalents and available-for-sale investments to fund the Company's operations, the amount of expenses to be incurred in connection with the Lonza contract, the Company's potential purchase of additional forward currency contracts 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 our operating expenses and capital expenditure requirements for the period anticipated; whether data from early clinical trials 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 Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether we can successfully commercialize and market our product candidates, are described more fully in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on November 12, 2015, and our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on March 20, 2015, and our 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 our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this press release represent our estimates and assumptions only as of the date of this press release and, except as required by law, we undertake 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)
(unaudited)

	September 30, 2015	December 31, 2014
Cash, cash equivalents and available-for-sale investments	\$ 70,548	\$ 83,595
Prepaid expenses and other current assets	829	1,006
Property and equipment, net and other non-current assets	907	197
Total assets	\$ 72,284	\$ 84,798
Accounts payable, accrued expenses and other liabilities	\$ 3,252	\$ 2,338
Preferred stock, common stock and additional paid-in-capital	193,935	192,340
Accumulated deficit and accumulated other comprehensive loss	(124,903)	(109,880)
Total liabilities and stockholders' deficit	\$ 72,284	\$ 84,798

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

	Three Months Ended September 30, 2015		Nine Months Ended September 30, 2015	
	2015	2014	2015	2014
Revenue	\$ --	\$ 2,948	\$ --	\$ 2,948
Operating expenses:				
Research and development	3,078	1,773	8,801	4,558
General and administrative	2,004	1,041	5,882	2,697
Total operating expenses	5,082	2,814	14,683	7,255
Loss from operations	(5,082)	134	(14,683)	(4,307)
Other income (expense):				
Interest income (expense), net	34	10	111	(844)
Other expense	(335)	(5,325)	(463)	(5,424)
Total other income (expense)	(301)	(5,315)	(352)	(6,268)
Net loss	\$ (5,383)	\$ (5,181)	\$ (15,035)	\$ (10,575)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.33)	\$ (31.00)	\$ (0.91)	\$ (67.65)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	16,466,945	240,610	16,455,257	240,375

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	\$ 184	\$ 47	\$ 431	\$ 68
General and administrative	<u>427</u>	<u>138</u>	<u>1,063</u>	<u>166</u>
Total	<u>\$ 611</u>	<u>\$ 185</u>	<u>\$ 1,494</u>	<u>\$ 234</u>

Included in other expense, above, are the following amounts of non-cash loss from forward foreign currency contracts:

Realized losses from forward foreign currency contracts	\$ --	\$ --	\$ (14)	\$ --
Unrealized losses from forward foreign currency contracts	<u>(314)</u>	<u>--</u>	<u>(426)</u>	<u>--</u>
Total	<u>\$ (314)</u>	<u>\$ --</u>	<u>\$ (440)</u>	<u>\$ --</u>

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