

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 13, 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 May 13, 2015, Proteon Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 May 13, 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: May 13, 2015

Proteon Therapeutics, Inc.

By: /s/ TIMOTHY P. NOYES
Timothy P. Noyes
President & Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May13, 2015, issued by Proteon Therapeutics, Inc.

Proteon Therapeutics Announces First Quarter 2015 Financial Results

WALTHAM, Mass., May 13, 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 March 31, 2015, and recent business highlights.

"Proteon continues to make significant clinical and operational progress in advancing the development of vonapanitase," said Timothy Noyes, President and Chief Executive Officer of Proteon. "Most importantly, we are ahead of our original clinical enrollment schedule in our first Phase 3 clinical trial and expect to be fully enrolled by the end of 2015. Further, we expect to enroll the first patient in our second Phase 3 clinical trial of vonapanitase during the second quarter, on track with guidance."

Highlights for First Quarter of 2015

Faster enrollment of first Phase 3 clinical study of vonapanitase (formerly known as PRT-201). In March 2015, the Company revised its goal for 2015 to complete full enrollment sooner than expected and currently expects enrollment to be complete prior to the end of 2015. The first Phase 3 trial is a randomized, double-blind, placebo-controlled study expected to enroll 300 patients with chronic kidney disease (CKD) undergoing surgical creation of an 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 AVF abandonment. With Proteon's new expectation for enrollment, the Company continues to expect data to be available in the first quarter of 2017.

Positive long-term follow-up data presented. In late March 2015, three years of clinical follow-up data from the Company's AVF Phase 2 clinical study of vonapanitase, an investigational drug, was presented at the National Kidney Foundation's (NKF) 2015 Spring Clinical Meetings in Dallas. The Phase 2 multicenter, randomized, double-blind, placebo-controlled clinical study evaluated safety and efficacy of a single application of vonapanitase delivered immediately after surgical creation of an AVF. Data from the long-term analysis demonstrated a trend of prolonged primary patency, the study's primary endpoint, and a statistically significant improvement in the rate of corrective procedures, a secondary endpoint, over more than three years of follow-up for the 30 mcg vonapanitase dose as compared to placebo.

Key Milestones for 2015

- Expect to treat the first patient by June 30th in Proteon's second AVF Phase 3 clinical study of vonapanitase.
- Plan to present in the second half of 2015 results from the Company's ongoing peripheral artery disease (PAD) Phase 1 clinical study of vonapanitase.
- Expect to complete enrollment by year-end in Proteon's first AVF Phase 3 clinical study of vonapanitase.

First Quarter 2015 Financial Results

Cash position: Cash, cash equivalents and available-for-sale investments totaled \$79.5 million as of March 31, 2015, compared to \$83.6 million as of December 31, 2014. The decrease was driven by operational costs for the three-month period.

Revenues: No revenues were recorded in the first quarter of 2015 or in the first quarter of 2014.

R&D expenses: Research and development expenses for the first quarter of 2015 were \$2.6 million as compared to \$1.2 million for the first quarter of 2014. The increase was due primarily to the initiation of Proteon's Phase 3 clinical study in the third quarter of 2014.

G&A expenses: General and administrative expenses for the first quarter of 2015 were \$2.0 million as compared to \$0.7 million for the first quarter of 2014. The increase was due primarily to higher personnel costs in 2015 than in 2014 and higher expenses associated with being a public, reporting company starting in the fourth quarter of 2014.

Other income: Other income for the first quarter of 2015 was \$0.04 million as compared to (\$0.9) million for the first quarter of 2014. The increase was due primarily to higher average cash balances and debt outstanding in the first quarter of 2014 that was converted to equity later in the year and was not outstanding in the first quarter of 2015.

Net loss: Net loss for the first quarter of 2015 was \$4.6 million as compared to \$2.8 million for the first quarter of 2014. Net loss includes stock-based compensation expense of \$0.4 million for the first quarter of 2015 and \$0.02 million for the first 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 2018.

About Vonapanitase

Vonapanitase (formerly PRT-201) is an investigational drug designed 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 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 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 is currently being evaluated in 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, vonapanitase (formerly PRT-201), is designed 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 a Phase 3 clinical trial in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis and 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 those regarding the initiation of the second phase 3 clinical study, patient enrollment in the phase 3 clinical study, timing for availability of data, timing for presentation of data from our AVF Phase 2 clinical study, timing to present results for our ongoing PAD Phase 1 clinical study, ability to fund 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 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 March 31, 2015, as filed with the Securities and Exchange Commission on May 13, 2015, 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 presentation.

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

	March 31,	December 31,
	2015	2014
Cash, cash equivalents and available-for-sale investments	\$ 79,525	\$ 83,595
Prepaid expenses and other current assets	1,208	1,006
Property and equipment, net and other non-current assets	194	197
Total assets	<u>\$ 80,927</u>	<u>\$ 84,798</u>
Accounts payable and accrued expenses	\$ 2,634	\$ 2,338
Preferred Stock, common stock and additional paid-in-capital	192,747	192,340
Accumulated deficit and accumulated other comprehensive loss	(114,454)	(109,880)
Total liabilities and stockholders' deficit	<u>\$ 80,927</u>	<u>\$ 84,798</u>

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

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Operating expenses:		
Research and development	\$ 2,633	\$ 1,189
General and administrative	1,987	744
Total operating expenses	4,620	1,933
Loss from operations	(4,620)	(1,933)
Other income (expense):		
Interest income (expense), net	40	(828)
Other income	--	(70)
Total other income (expense)	40	(898)
Net loss	\$ (4,580)	\$ (2,831)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.28)	\$ (18.09)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	16,448,688	240,138

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	\$ 110	\$ 10
General and administrative	297	7
Total	\$ 407	\$ 17

Investor Contact

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