

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): August 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 August 13, 2015, Proteon Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 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 August 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: August 13, 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 August 13, 2015, issued by Proteon Therapeutics, Inc.

Proteon Therapeutics Announces Second Quarter 2015 Financial Results

WALTHAM, Mass., Aug. 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 June 30, 2015, and recent business highlights.

"I am pleased that the first Phase 3 clinical study of vonapanitase is on track to complete enrollment by the end of the year and that we recently enrolled our first patient in our second Phase 3 clinical study of vonapanitase," said Timothy Noyes, President and Chief Executive Officer of Proteon.

Recent Highlights for 2015

Enrollment in the first Phase 3 clinical study of investigational vonapanitase (formerly known as PRT-201) is on track for completion by year-end. In March 2015, the Company accelerated its 2015 guidance to complete full enrollment in the first Phase 3 clinical study prior to year-end 2015, earlier than expected. Proteon remains on track to achieve this goal. The first Phase 3 study is a randomized, double-blind, placebo-controlled study expected to enroll 300 patients 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 AVF abandonment. The Company continues to expect that data from its first Phase 3 study will be available in the first quarter of 2017.

First patient enrolled in second Phase 3 clinical study of vonapanitase. The Company recently announced enrollment of the first patient in its second Phase 3 study of vonapanitase. The second Phase 3 study, like the first Phase 3 study, 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 as the first Phase 3 clinical study. The Company has not provided guidance as to when data from the second Phase 3 study will be available.

Top-line results from Phase 1 clinical study of vonapanitase. The Company recently announced top-line results in 14 patients from its Phase 1 study of vonapanitase with symptomatic peripheral artery disease (PAD). The open-label, single center Phase 1 dose escalation study enrolled 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 endpoint of the study was safety and the secondary endpoint 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.

Key Milestones for 2015

- Plans to present at an upcoming medical meeting results from the Company's PAD Phase 1 clinical study of vonapanitase.
- Expects to complete enrollment by year-end in Proteon's first AVF Phase 3 clinical study of vonapanitase.

Second Quarter 2015 Financial Results

Cash position: Cash, cash equivalents and available-for-sale investments totaled \$74.7 million as of June 30, 2015, compared to \$83.6 million as of December 31, 2014. The decrease was driven by operational costs for the first six-month period of 2015.

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

R&D expenses: Research and development expenses for the second quarter of 2015 were \$3.1 million as compared to \$1.6 million for the second quarter of 2014. The increase in R&D expenses was due primarily to patient enrollment and follow-up visit expenses in Proteon's first ongoing Phase 3 clinical study, which commenced in the third quarter of 2014, the initiation and start-up expenses of Proteon's second Phase 3 clinical study in the second quarter of 2015, and increased manufacturing expenses associated with pre-validation activities.

G&A expenses: General and administrative expenses for the second quarter of 2015 were \$1.9 million as compared to \$0.9 million for the second 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 expenses: Other expenses for the second quarter of 2015 were \$0.1 million as compared to \$0.1 million for the second quarter of 2014. While unchanged from the second quarter of 2014, other expenses included non-cash changes in the Swiss Franc denominated currency the Company held as of June 30, 2015 and the fair value associated with the forward foreign currency contracts Proteon entered into in June 2015.

Net loss: Net loss for the second quarter of 2015 was \$5.1 million as compared to \$2.6 million for the second quarter of 2014. Net loss included stock-based compensation expense of \$0.5 million for the second quarter of 2015 and \$0.03 million for the second 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.

Foreign currency hedging: In the second quarter of 2015, Proteon entered into forward foreign currency contracts to reduce its foreign currency exposure through 2016 under a contract with the manufacturer of Proteon's active pharmaceutical ingredient (API). Proteon's contract with such manufacturer requires Proteon to make payments in Swiss Francs. In the future, Proteon may purchase additional forward foreign currency contracts for forecasted expenses denominated in other foreign currencies.

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 two Phase 3 clinical trials 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 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 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 two Phase 3 clinical trials in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis and recently 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 those regarding the overall patient enrollment in the second Phase 3 clinical study of vonapanitase, the timing of completion of patient enrollment in the first Phase 3 clinical study of vonapanitase, timing for availability of data from the first and second Phase 3 studies of vonapanitase, timing to present results for our ongoing PAD Phase 1 clinical study 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 surgical and endovascular applications of vonapanitase, 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 June 30, 2015, as filed with the Securities and Exchange Commission on August 13, 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 presentation.

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

June 30,	December 31,
2015	2014

Cash, cash equivalents and available-for-sale investments	\$ 74,736	\$ 83,595
Prepaid expenses and other current assets	1,052	1,006
Property and equipment, net and other non-current assets	787	197
Total assets	\$ 76,575	\$ 84,798
Accounts payable, accrued expenses and other liabilities	\$ 2,816	\$ 2,338
Preferred Stock, common stock and additional paid-in-capital	193,282	192,340
Accumulated deficit and accumulated other comprehensive loss	(119,523)	(109,880)
Total liabilities and stockholders' deficit	\$ 76,575	\$ 84,798

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 3,090	\$ 1,596	\$ 5,704	\$ 2,785
General and administrative	1,891	912	3,900	1,656
Total operating expenses	<u>4,981</u>	<u>2,508</u>	<u>9,603</u>	<u>4,441</u>
Loss from operations	(4,981)	(2,508)	(9,603)	(4,441)
Other income (expense):				
Interest income (expense), net	37	(26)	77	(854)
Other expense	(128)	(29)	(128)	(99)
Total other income (expense)	<u>(91)</u>	<u>(55)</u>	<u>(51)</u>	<u>(953)</u>
Net loss	<u>\$ (5,072)</u>	<u>\$ (2,563)</u>	<u>\$ (9,654)</u>	<u>\$ (5,394)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.31)</u>	<u>\$ (18.55)</u>	<u>\$ (0.59)</u>	<u>\$ (36.64)</u>
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	<u>16,449,937</u>	<u>240,374</u>	<u>16,449,316</u>	<u>240,254</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	\$ 138	\$ 11	\$ 247	\$ 21
General and administrative	338	21	636	28
Total	<u>\$ 476</u>	<u>\$ 32</u>	<u>\$ 883</u>	<u>\$ 49</u>

Included in other expense, above, are the following amounts from forward foreign currency contracts:

Realized losses from forward foreign currency contracts	\$ (14)	\$ --	\$ (14)	\$ --
Unrealized losses from forward foreign currency contracts	(112)	--	(112)	--
Total	<u>\$ (126)</u>	<u>\$ --</u>	<u>\$ (126)</u>	<u>\$ --</u>

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