

**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): March 20, 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 March 20, 2015, Proteon Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2014. 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 March 20, 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: March 20, 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 March 20, 2015, issued by Proteon Therapeutics, Inc.

Proteon Therapeutics Announces Fourth Quarter and Full-Year 2014 Financial Results

WALTHAM, Mass., March 20, 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 year ended December 31, 2014, and recent business highlights.

"In 2014, Proteon made significant clinical and operational progress in advancing the development of vonapanitase, formerly known as PRT-201," said Timothy Noyes, President and Chief Executive Officer of Proteon. "Notably, we initiated the first Phase 3 clinical study of vonapanitase for patients with chronic kidney disease undergoing surgical creation of an arteriovenous fistula to enable hemodialysis. In support of this registration program, we also commenced the CMC validation effort for vonapanitase. Finally, we raised approximately \$87 million in successful equity offerings to fund development and this additional capital will allow Proteon to accelerate initiation of its second Phase 3 clinical study of vonapanitase."

2014 Highlights

Initiated Phase 3 clinical study of vonapanitase. In July 2014, the Company treated its first patient in a Phase 3 clinical study of its lead product, vonapanitase. This randomized, double-blind, placebo-controlled study is 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. Patient enrollment is progressing as expected, and the Company continues to expect data to be available in the first quarter of 2017.

Commenced manufacturing validation effort. As part of the Company's effort to prepare (and assuming a successful outcome in its ongoing Phase 3 clinical study), Proteon accelerated its Chemistry, Manufacturing, and Controls, or CMC, activities and initiated the validation work.

Completed enrollment in peripheral artery disease (PAD) Phase 1 clinical study. The Company completed full enrollment of its Phase 1 clinical study in patients with symptomatic PAD of the superficial femoral or popliteal artery. Immediately following successful angioplasty, patients received vonapanitase delivered to the arterial wall via a drug delivery catheter. The Company expects data from this study to be released in the second half of 2015.

Obtained Generic name assignment from USAN and WHO. The United States Adopted Names Council (USAN) and the World Health Organization's International Nonproprietary Name group assigned "vonapanitase" as the official generic or non-proprietary name for the Company's lead product PRT-201.

Strengthened balance sheet. The Company raised approximately \$87.0 million in net proceeds to fund operations, including an initial public offering (IPO) in the fourth quarter that raised approximately \$62.5 million and a private placement in May 2014 that raised approximately \$24.5 million.

Key Milestones for 2015

- Plan to present in late March up to three years of data from the Company's AVF Phase 2 clinical study of vonapanitase.
- 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 PAD Phase 1 clinical study of vonapanitase.
- Expect to complete enrollment by yearend in Proteon's first AVF Phase 3 clinical study of vonapanitase.

Fourth Quarter and Full-Year 2014 Financial Results

Cash position: Cash, cash equivalents and available-for-sale investments totaled \$83.6 million as of December 31, 2014, compared to \$5.2 million as of December 31, 2013. The increase was driven by net proceeds of \$87.0 million from financings partially offset by cash used to fund operations.

Revenues: Revenue in 2014 was \$2.9 million and related to deferred revenue recognized as revenue upon the expiration in August 2014 of residual rights under an option agreement with a major pharmaceutical company originally entered into in 2009.

R&D expenses: Research and development expenses for 2014 were \$6.4 million as compared to \$4.0 million for 2013. The increase was due primarily to the initiation of its Phase 3 clinical study in the third quarter of 2014.

G&A expenses: General and administrative expenses for 2014 were \$4.1 million as compared to \$3.1 million for 2013. The increase was due primarily to higher personnel costs in 2014 than in 2013 and expenses associated with being a public reporting company starting in the fourth quarter of 2014.

Other income: Other income for 2014 was \$5.1 million as compared to \$0.1 million for 2013. The increase was due primarily to the change in fair value of the investor rights and obligations issued in connection with the Series D preferred stock in our May

2014 private placement. The Series D preferred stock investor rights were either exercised or extinguished upon the closing of the Company's IPO.

Net loss: Net loss for 2014 was \$3.3 million as compared to a net loss of \$7.9 million for 2013. Net loss includes stock-based compensation expense of \$0.5 million for 2014 and \$0.2 million for 2013.

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 (PRT-201)

Vonapanitase (formerly PRT-201) is an investigational recombinant human elastase that is being studied for its ability to improve outcomes in patients suffering from vascular disease. Elastase has been shown in preclinical settings to reduce neointimal hyperplasia formation, which may result in improved blood flow and prolonged vessel patency. Vonapanitase has received fast track and orphan drug designations from the Food and Drug Administration and orphan medicinal product designation from the European Commission for hemodialysis vascular access indications.

About Proteon Therapeutics

Proteon Therapeutics Inc. is developing novel, first-in-class pharmaceuticals to address the medical needs of patients with kidney and vascular diseases. The company is headquartered in Waltham, Mass. For additional 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 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 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, 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)

	<u>December 31,</u>	<u>2014</u>	<u>2013</u>
Cash, cash equivalents and available-for-sale investments	\$	83,595	\$ 5,152
Prepaid expenses and other current assets		1,006	178
Property and equipment, net and other non-current assets		<u>197</u>	<u>329</u>
Total assets		<u>\$ 84,798</u>	<u>\$ 5,659</u>

Accounts payable and accrued expenses	\$ 2,338	\$ 1,383
Other liabilities	--	8,385
Preferred Stock, common stock and additional paid-in-capital	192,340	96,405
Accumulated deficit and accumulated other comprehensive loss	(109,880)	(100,514)
Total liabilities and stockholders' deficit	<u>\$ 84,798</u>	<u>\$ 5,659</u>

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

	Year Ended December 31,		
	2014	2013	2012
Revenue	\$ 2,948	\$ --	\$ --
Operating expenses:			
Research and development	6,432	3,994	5,907
General and administrative	<u>4,096</u>	<u>3,128</u>	<u>2,089</u>
Total operating expenses	<u>10,528</u>	<u>7,122</u>	<u>7,996</u>
Loss from operations	(7,580)	(7,122)	(7,996)
Other income (expense):			
Interest (expense) income, net	(833)	(857)	20
Other income	<u>5,071</u>	<u>67</u>	<u>6</u>
Total other income (expense)	<u>4,238</u>	<u>(790)</u>	<u>26</u>
Net loss	<u>\$ (3,342)</u>	<u>\$ (7,912)</u>	<u>\$ (7,970)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (3.16)</u>	<u>\$ (59.66)</u>	<u>\$ (61.16)</u>
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	<u>3,064,507</u>	<u>235,184</u>	<u>230,607</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	\$ 114	\$ 106	\$ 46
General and administrative	<u>345</u>	<u>49</u>	<u>64</u>
Total	<u>\$ 459</u>	<u>\$ 155</u>	<u>\$ 110</u>

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