
**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 14, 2016

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 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))
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Item 2.02. Results of Operations and Financial Condition.

On March 14, 2016, Proteon Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 14, 2016, 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.

Proteon Therapeutics, Inc.

Date: March 14, 2016

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 14, 2016, issued by Proteon Therapeutics, Inc.

Proteon Therapeutics Announces Fourth Quarter and Full-Year 2015 Financial Results

WALTHAM, Mass., March 14, 2016 (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, 2015, and recent business highlights.

“In 2015, Proteon continued to demonstrate our ability to meet and exceed our projected timelines,” said Timothy Noyes, President and Chief Executive Officer of Proteon. “Our clinical team has done a fantastic job in completing enrollment in PATENCY-1 ahead of schedule, allowing us to expect top-line data in December 2016, which is also ahead of schedule. I am also pleased that we raised sufficient capital in our IPO such that we can fund operations into the fourth quarter of 2017, approximately one year after we expect top-line data from PATENCY-1.”

2015 Highlights

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 in August 2015. 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. Primary unassisted patency and secondary patency are primary and secondary efficacy endpoints in PATENCY-2, as in PATENCY-1. The Company expects to complete enrollment in PATENCY-2 in the first quarter of 2017.

Positive long-term follow-up data presented. Three years of clinical follow-up data from the Company’s AVF Phase 2 Registry study of vonapanitase were presented at the National Kidney Foundation’s (NKF) 2015 Spring Clinical Meetings in Dallas, Texas. The Phase 2 multicenter, randomized, double-blind, placebo-controlled clinical study evaluated the safety and efficacy of a single application of vonapanitase delivered immediately after surgical creation of an AVF through 12 months follow-up. Patients with a patent AVF at the end of the Phase 2 study were eligible for continued follow-up in a long-term observational Registry. Data from the long-term Registry analysis demonstrated a trend of prolonged primary patency, and a statistically significant improvement in the rate of corrective procedures, over more than three years of follow-up for patients who were previously treated with 30 mcg vonapanitase dose in the Phase 2 study as compared to placebo. Safety data were not collected in the Registry.

Top-line results from Phase 1 clinical study of vonapanitase in patients with peripheral artery disease (PAD) announced; data presented at the 27th Transcatheter Cardiovascular Therapeutics (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. In 2016, Proteon intends to initiate two other Phase 1 trials in PAD.

Board of Directors and management team strengthened with the addition of manufacturing, commercial, regulatory and quality 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 to the Board Anthony (Tony) Kingsley, who 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 Scott Toner as Senior Vice President of Marketing, Jennifer Panagoulas as Vice President of Regulatory Affairs, and Michael Bauer as Vice President of Quality.

Key Milestones for 2016

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

Upcoming Events

- Presentation at the 2016 Vascular Access for Hemodialysis Symposium on May 14th in Chicago.

Fourth Quarter and Full-Year 2015 Financial Results

Cash position: Cash, cash equivalents and available-for-sale investments totaled \$65.3 million as of December 31, 2015, compared to \$83.6 million as of December 31, 2014. The decrease was driven by operational costs for 2015.

Revenues: No revenues were recorded in 2015, as compared to \$2.9 million in 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 2015 were \$12.4 million as compared to \$6.4 million for 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; increased manufacturing expenses associated with certain pre-validation activities; and increased personnel costs.

G&A expenses: General and administrative expenses for 2015 were \$8.5 million as compared to \$4.1 million for 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 2015 was \$0.7 million as compared to \$5.1 million for 2014. Other expense in 2015 included non-cash changes in the Swiss Franc denominated currency the Company held as of December 31, 2015 and the fair value associated with the forward foreign currency contracts the Company entered into in June 2015. Other expense in 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 2015 was \$21.4 million as compared to \$3.3 million for 2014. Net loss included stock-based compensation expense of \$2.2 million for 2015 and \$0.5 million for 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 AVF 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 (PATENCY-1 and PATENCY-2) 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 the Company expects to report top-line data from the PATENCY-1 Phase 3 clinical study, the number of patients to be enrolled in and the timing of completion of enrollment in the PATENCY-2 Phase 3 clinical study of vonapanitase, 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 into the fourth quarter of 2017, 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 Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on March 14, 2016, 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)

	December 31,	
	2015	2014
Cash, cash equivalents and available-for-sale investments	\$ 65,263	\$ 83,595
Prepaid expenses and other current assets	1,345	1,006
Property and equipment, net and other non-current assets	930	197
Total assets	<u>\$ 67,538</u>	<u>\$ 84,798</u>
Accounts payable and accrued expenses	\$ 3,596	\$ 2,338
Other liabilities	537	-
Preferred Stock, common stock and additional paid-in-capital	194,667	192,340
Accumulated deficit and accumulated other comprehensive loss	(131,262)	(109,880)
Total liabilities and stockholders' deficit	<u>\$ 67,538</u>	<u>\$ 84,798</u>

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

	Year Ended December 31,		
	2015	2014	2013
Revenue	\$ -	\$ 2,948	\$ -
Operating expenses:			
Research and development	12,381	6,432	3,994
General and administrative	8,489	4,096	3,128
Total operating expenses	<u>20,870</u>	<u>10,528</u>	<u>7,122</u>
Loss from operations	(20,870)	(7,580)	(7,122)
Other income (expense):			
Interest income (expense)	144	(833)	(857)
Other (expense) income	(651)	5,071	67
Total other (expense) income	<u>(507)</u>	<u>4,238</u>	<u>(790)</u>
Net loss	<u>\$ (21,377)</u>	<u>\$ (3,342)</u>	<u>\$ (7,912)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (1.30)</u>	<u>\$ (3.16)</u>	<u>\$ (59.66)</u>
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	<u>16,464,123</u>	<u>3,064,507</u>	<u>235,184</u>

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	\$	650	\$	114	\$	106
General and administrative		<u>1,514</u>		<u>345</u>		<u>49</u>
Total	\$	<u>2,164</u>	\$	<u>459</u>	\$	<u>155</u>

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

Realized losses from forward foreign currency contracts	\$	(52)	\$	-	\$	-
Unrealized losses from forward foreign currency contracts		<u>(537)</u>		<u>-</u>		<u>-</u>
Total	\$	<u>(589)</u>	\$	<u>-</u>	\$	<u>-</u>

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