# 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 7, 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 a	ppropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following
rovisions:	
[ ]	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
	0.11.1.

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 7, 2016, Proteon Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2016. 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, as amended, or the Exchange Act, except as otherwise expressly stated in such filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

#### Exhibit No. Description

99.1 Press Release, dated November 7, 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: November 7, 2016

By: <u>/s/ George A. Eldridge</u>
George A. Eldridge
Senior Vice President & Chief Financial Officer

# EXHIBIT INDEX

# Exhibit No. Description

99.1 Press Release, dated November 7, 2016, issued by Proteon Therapeutics, Inc.

#### **Proteon Therapeutics Announces Third Quarter 2016 Financial Results**

WALTHAM, Mass., Nov. 07, 2016 (GLOBE NEWSWIRE) -- Proteon Therapeutics, Inc. (Nasdaq:PRTO), a company developing novel, first-in-class therapeutics to address the medical needs of patients with kidney and vascular diseases, today announced its financial results for the quarter ended September 30, 2016, and recent business highlights.

"We are making strong progress in our Phase 3 program for investigational vonapanitase," said Timothy Noyes, President and Chief Executive Officer of Proteon. "PATENCY-1 top-line results are expected in December, and our second Phase 3 trial, PATENCY-2, is on track to complete patient enrollment in the first quarter of 2017."

#### **Recent Highlights for 2016**

Overview of Phase 1 clinical program of vonapanitase in peripheral artery disease (PAD) presented at the 28th Transcatheter Cardiovascular Therapeutics (TCT) Conference. Dr. Ehrin J. Armstrong, Associate Professor, Medicine-Cardiology at University of Colorado School of Medicine and Director, Interventional Cardiology VA Eastern Colorado Healthcare System, discussed Proteon's two additional Phase 1 clinical studies evaluating vonapanitase in patients with PAD. These multicenter, dose-escalation studies will evaluate the safety and technical feasibility of a single administration of vonapanitase as a monotherapy and as an adjunct to angioplasty for patients with PAD.

**Board of Directors strengthened with additional operating and leadership expertise.** Proteon strengthened its Board of Directors with the appointment of Paul J. Hastings as Chairman. Paul brings substantial experience in the board room having been a lead director and/or chairman at multiple biotechnology companies. He also brings significant operational and commercial experience, having successfully led several biotechnology companies as their chief executive officer.

#### **Key Milestones for 2016 and Early 2017**

- Report top-line data in December 2016 for PATENCY-1, the first Phase 3 clinical study of investigational vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula (AVF) for hemodialysis.
- Complete enrollment in the first quarter of 2017 for PATENCY-2, the second Phase 3 clinical study of investigational vonapanitase.

### **Upcoming Events**

- Presentation at the Stifel 2016 Healthcare Conference on November 16<sup>th</sup> at 8:00 a.m. in New York City.
- Participation in the Oppenheimer Life Sciences Summit on November 29<sup>th</sup> in New York City.

#### **Third Quarter 2016 Financial Results**

**Cash position:** Cash, cash equivalents and available-for-sale investments totaled \$47.0 million as of September 30, 2016, compared to \$65.3 million as of December 31, 2015. The decrease was driven by operational costs for the first nine-month period of 2016.

**R&D expenses:** Research and development expenses for the third quarter of 2016 were \$4.8 million as compared to \$3.1 million for the third quarter of 2015. The increase in R&D expenses was due primarily to increased expenses for our manufacturing prevalidation and validation efforts; increased external clinical expenses related to our ongoing radiocephalic AVF Phase 3 clinical trials and our PAD Phase 1 clinical trials; and increased personnel costs.

**G&A expenses:** General and administrative expenses for the third quarter of 2016 were \$2.3 million as compared to \$2.0 million for the third quarter of 2015. The increase in G&A expenses was due primarily to higher personnel costs in the third quarter of 2016 than in the third quarter of 2015.

**Net loss:** Net loss for the third quarter of 2016 was \$7.1 million as compared to \$5.4 million for the third quarter of 2015. Net loss included stock-based compensation expense of \$0.7 million for the third quarter of 2016 and \$0.6 million for the third quarter of 2015.

**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 designed to treat vessel injury response that leads to blockages in blood vessels and reduced blood flow. 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 (AVF) for hemodialysis, and two Phase 1 clinical trials in patients with peripheral artery disease

(PAD). 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.

#### **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 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 two Phase 1 clinical trials in patients with 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 "estimates," "anticipates," "expects," "plans," "intends," "may," or "will," 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 of vonapanitase, 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, including peripheral artery disease (PAD), 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 clinical studies of vonapanitase in patients with PAD, 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 nonclinical or clinical studies 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 U.S. 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 ("SEC") on March 14, 2016, and our subsequent Quarterly Reports on Form 10-Q and 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)

	Sep	otember 30, 2016	December 31, 2015		
Cash, cash equivalents and available-for-sale investments	\$	46,974	\$	65,263	
Prepaid expenses and other current assets		1,749		1,345	
Property and equipment, net and other non-current assets		672		930	
Total assets	\$	49,395	\$	67,538	
Accounts payable and accrued expenses	\$	4,777	\$	3,596	
Other liabilities		98		537	
Preferred stock, common stock and additional paid-in-capital		197,327		194,667	
Accumulated deficit and accumulated other comprehensive income		(152,807)		(131,262)	
Total liabilities and stockholders' deficit		49,395	\$	67,538	

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

	Three Months Ended September 30,				Nine Months Ended September 30,				
	2016 2015		2016			2015			
Operating expenses:		_				_			
Research and development	\$	4,842	\$	3,078	\$	14,432	\$	8,801	
General and administrative		2,324		2,004		7,407		5,882	
Total operating expenses		7,166		5,082		21,839		14,683	
Loss from operations		(7,166)		(5,082)		(21,839)		(14,683)	
Other income (expense):									
Investment income		46		34		155		111	
Other (expense) income, net		13		(335)		120		(463)	
Total other (expense) income		59		(301)		275		(352)	
Net loss	\$	(7,107)	\$	(5,383)	\$	(21,564)	\$	(15,035)	
Net loss per share attributable to common stockholders - basic and diluted	\$	(0.43)	\$	(0.33)	\$	(1.30)	\$	(0.92)	
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	16	5,582,276	16	5,466,945	1	16,550,483	1	6,455,257	
		(0.43)							
Supplemental disclosure of stock-based compensation expense and loss from currency									

# 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	\$	168	\$	184	\$	797	\$	431
General and administrative		519		427		1,702		1,063
Total	\$	687	\$	611	\$	2,499	\$	1,494
Included in other expense, above, are the following amounts from forward foreign currency contracts:								
Realized (losses) gains from forward foreign currency contracts	\$	(4)	\$	-	\$	(8)	\$	(14)
Unrealized (losses) gains from forward foreign currency contracts		2		(314)		127		(426)
Total	\$	(2)	\$	(314)	\$	119	\$	(440)

#### **Investor Relations Contact**

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### **Media Contact**

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