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 8, 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))

Item 2.02. Results of Operations and Financial Condition.

On August 8, 2016, Proteon Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 8, 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: August 8, 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 August 8, 2016, issued by Proteon Therapeutics, Inc.

Proteon Therapeutics Announces Second Quarter 2016 Financial Results

WALTHAM, Mass., Aug. 08, 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 June 30, 2016, and recent business highlights.

"We made important progress in our Phase 3 clinical program evaluating vonapanitase, and we remain on track to report top-line data from our first Phase 3 study, PATENCY-1, this December," said Timothy Noyes, President and Chief Executive Officer of Proteon. "Physician and patient interest in the vonapanitase program remains high, and we continue to expect to complete enrollment in our second Phase 3 study, PATENCY-2, in the first quarter of 2017. Our cash position will fund operations into the fourth quarter of 2017, a year beyond our expected announcement of PATENCY-1 results."

Recent Highlights for 2016

Proteon continues to expect complete enrollment in PATENCY-2 in the first quarter of 2017. PATENCY-2, the second Phase 3 clinical study of investigational vonapanitase, is a multicenter, 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. Similar to PATENCY-1, the primary and secondary endpoints in PATENCY-2 include primary unassisted patency and secondary patency.

Management team strengthened with legal expertise. The Company strengthened its management team with the hiring of Matthew Kowalsky as Vice President of Legal. Matt brings legal expertise honed by his experience with the development and commercialization of pharmaceutical products globally during his time at Lantheus Medical Imaging (formerly Bristol-Myers Squibb Medical Imaging), Cubist Pharmaceuticals and Sanofi Genzyme.

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 Baird 2016 Global Healthcare Conference being held September 7th and 8th and the Rodman & Renshaw 18th Annual Global Investment Conference being held September 12th and 13th, both in New York City.
- Presentation at Dreiländertagung 2016 (Joint conference of the Swiss, German and Austrian Societies for Vascular Surgery) being held October 5th through 8th in Bern, Switzerland.

Second Quarter 2016 Financial Results

Cash position: Cash, cash equivalents and available-for-sale investments totaled \$53.7 million as of June 30, 2016, compared to \$65.3 million as of December 31, 2015. The decrease was driven by operational costs for the first six-month period of 2016.

Revenues: No revenues were recorded in the second quarter of 2016 or in the second quarter of 2015.

R&D expenses: Research and development expenses for the second quarter of 2016 were \$5.2 million as compared to \$3.1 million for the second 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 increased personnel costs.

G&A expenses: General and administrative expenses for the second quarter of 2016 were \$2.6 million as compared to \$1.9 million for the second quarter of 2015. The increase in G&A expenses was due primarily to higher personnel costs in the second quarter of 2016 than in the second quarter of 2015.

Other expense, net: Other expense, net for the second quarter of 2016 was \$0.1 million as compared to \$0.1 million for the second quarter of 2015. Other expense, net in the second quarter of 2016 included non-cash changes in the Swiss Franc denominated currency the Company held as of June 30, 2016 and the fair value associated with the forward foreign currency contracts the Company entered into in June 2015.

Net loss: Net loss for the second quarter of 2016 was \$7.9 million as compared to \$5.1 million for the second quarter of 2015. Net loss included stock-based compensation expense of \$0.9 million for the second quarter of 2016 and \$0.5 million for the second 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 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. The Company estimates that radiocephalic AVFs account for 35-40% of all AVFs created in the U.S. each year. 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 "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, 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-forsale 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 (the "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)

	 une 30, 2016	Dec	2015		
Cash, cash equivalents and available-for-sale investments	\$ 53,672	\$	65,263		
Prepaid expenses and other current assets	1,234		1,345		
Property and equipment, net and other non-current assets	757		930		
Total assets	\$ 55,663	\$	67,538		

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Accounts payable and accrued expenses	\$	4,497	\$	3,596
Other liabilities		241		537
Preferred stock, common stock and additional paid-in-capital		196,623		194,667
Accumulated deficit and accumulated other comprehensive income		(145,698)		(131,262)
Total liabilities and stockholders' deficit	\$	55,663	\$	67,538

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

	Three Months Ended June 30,			S	ix Months 3	inded June		
		2016	2015		2016			2015
Operating expenses:								
Research and development	\$	5,241	\$	3,090	\$	9,590	\$	5,723
General and administrative		2,613		1,891		5,083		3,878
Total operating expenses		7,854		4,981		14,673		9,601
Loss from operations		(7,854)		(4,981)		(14,673)		(9,601)
Other income (expense):								
Investment income		53		37		109		77
Other (expense) income, net		(104)		(128)		107		(128)
Total other (expense) income		(51)		(91)		216		(51)
Net loss	\$	(7,905)	\$	(5,072)	\$	(14,457)	\$	(9,652)
Net loss per share attributable to common stockholders - basic and		(0, (0)		(0.24)	_	(0.07)	_	(0.70)
diluted	\$	(0.48)	<u>\$</u>	(0.31)	\$	(0.87)	\$	(0.59)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	_1	6,561,239	16	5,449,937	_1	6,534,413	_1	6,449,316

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	\$	321	\$ 138	\$ 629	\$ 247
General and administrative		625	338	1,183	636
	Total \$	946	\$ 476	\$ 1,812	\$ 883

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

Realized (losses) gains from forward foreign currency contracts	\$ (10)	\$ (14)	\$ (4)	\$ (14)
Unrealized (losses) gains from forward foreign currency contracts	(53)	(112)	125	(112)
Total	\$ (63)	\$ (126)	\$ 121	\$ (126)

Investor Relations Contact

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