

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))

Introductory Comment

Throughout this Current Report on Form 8-K, the terms "we," "us," "our," "Company" and "Proteon" refer to Proteon Therapeutics, Inc.

Item 7.01. Regulation FD Disclosure.

On August 13, 2015, the Company issued a press release announcing top-line results from the Phase 1 study of its investigational drug vonapanitase in patients with symptomatic peripheral artery disease. The press release is attached to this Current Report as Exhibit 99.1.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference 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/ TIMOTHY P. NOYES
Timothy P. Noyes
President & Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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Proteon Therapeutics Announces Top-Line Results From Phase 1 Study of Investigational Drug Vonapanitase in Patients With Symptomatic Peripheral Artery Disease

Encouraging Data Indicate Catheter-Based Administration of Vonapanitase Was Generally Well-Tolerated and Technically Feasible

WALTHAM, Mass., Aug. 13, 2015 (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 top-line results from its Phase 1 study of investigational vonapanitase in patients with symptomatic peripheral artery disease (PAD). This study evaluated the safety and technical feasibility of a single treatment of vonapanitase via a drug-delivery catheter on atherosclerotic human arteries. The data indicate that catheter-based treatment with vonapanitase was generally well tolerated and technically feasible.

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 an endovascular micro-infusion Catheter. Christopher D. Owens, M.D., Associate Professor of Surgery Division of Vascular and Endovascular Surgery at the University of California San Francisco, was the principal investigator for the study.

"There is a significant unmet medical need to improve results in patients with symptomatic PAD," said Dr. Owens. "The safety and technical feasibility results of this Phase 1 study are encouraging, and merit further study of vonapanitase in patients with PAD, to explore whether vonapanitase will demonstrate efficacy in the improvement of symptomatic PAD results."

Proteon continues to conduct a full analysis of safety and technical feasibility data from the study. Proteon expects that complete data from this Phase 1 study will be presented at an upcoming medical meeting.

"This Phase 1 study in patients with symptomatic PAD complements Proteon's ongoing clinical development in patients with chronic kidney disease undergoing surgical creation of an arteriovenous fistula for hemodialysis," said Timothy P. Noyes, President and CEO of Proteon. "Based on these results, we plan to further study whether the local delivery of vonapanitase could potentially provide a clinical benefit to patients with PAD, and we are currently evaluating our potential next steps in this clinical area."

This is the sixth clinical study evaluating vonapanitase. Proteon is currently evaluating vonapanitase in two Phase 3 clinical studies in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula (AVF) for hemodialysis, and previously completed three clinical studies evaluating vonapanitase in patients with CKD undergoing surgical creation of an AVF or arteriovenous graft (AVG) for hemodialysis.

About Peripheral Artery Disease (PAD)

Patients with peripheral artery disease (PAD) of the lower extremity experience stenosis, or blockage, formation in the arteries providing blood to the legs. These patients typically present with exercise-induced leg pain, a condition known as intermittent claudication. Patients with claudication are unable to adequately maintain their activities of daily living because they quickly experience pain that can be resolved only through rest. Severe cases result in critical limb ischemia, or lack of blood flow, and the possibility of gangrene or tissue death and the need for amputation. Current surgical and interventional procedures are often ineffective and lack durability, resulting in ongoing suffering for patients. PAD is a global problem affecting a large number of people throughout the industrialized world. Approximately eight million Americans have some form of PAD.

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 has completed a Phase 1 clinical study 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 studies in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis and has completed a Phase 1 clinical study 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 potential surgical and endovascular applications for vonapanitase, the potential for vonapanitase to provide a clinical benefit for patients with PAD, the potential treatment of renal and vascular diseases with vonapanitase, the effect of vonapanitase in patients with CKD and number of persons with CKD, timing of completing enrollment for the Phase 3 trials, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as filed with the Securities and Exchange Commission on May 13, 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 press release.

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