

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 2, 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 November 2, 2015, Proteon issued a press release announcing that the Company has completed enrollment of its first Phase 3 clinical study of investigational drug vonapanitase (formerly PRT-201). In addition, Proteon announced that the Company expects to report top-line data in December 2016. The Phase 3 study is evaluating the safety and efficacy of a single treatment of vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula (AVF) for hemodialysis. The press release is attached to this Current Report as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1 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 into any registration statement or other document filed 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 2, 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: November 2, 2015

Proteon Therapeutics, Inc.

By: /s/ GEORGE A. ELDRIDGE
George A. Eldridge
Senior Vice President & Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 2, 2015, issued by Proteon Therapeutics, Inc.

Proteon Therapeutics Completes Enrollment in PATENCY-1, First Phase 3 Clinical Study of Investigational Vonapanitase

Company Expects to Report Top-Line Data in December of 2016

WALTHAM, Mass., Nov. 2, 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 that it has completed enrollment in PATENCY-1, the first of two Phase 3 clinical studies of investigational vonapanitase (formerly PRT-201), the company's lead development candidate. The Company expects that top-line data from this study will be available in December of 2016.

PATENCY-1 is a multicenter, randomized, double-blind, placebo-controlled clinical study evaluating the safety and efficacy of a single administration of vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula (AVF) for hemodialysis. Vonapanitase, a recombinant human elastase, is an investigational drug that is intended to improve AVF patency, the period of time during which an AVF remains open with adequate blood flow to enable hemodialysis.

The study enrolled 311 patients at 31 centers in the United States. Immediately after surgical creation of a radiocephalic AVF, each patient received either 30 micrograms of vonapanitase or placebo, delivered in a single, local administration to the external surface of the AVF. The primary efficacy endpoint is primary unassisted patency, the time from AVF creation until a thrombosis or a procedure to restore or maintain patency. The secondary efficacy endpoint is secondary patency, the time from AVF creation until AVF abandonment. Patients will be evaluated for safety and efficacy outcomes for 12 months.

"Completing enrollment in the first Phase 3 study of vonapanitase ahead of schedule is a significant achievement for Proteon," said Timothy Noyes, President and Chief Executive Officer of Proteon. "As there are no therapies currently available to prolong AVF patency, study enrollment benefited from strong interest in the physician community."

Proteon continues to enroll patients in PATENCY-2, the second Phase 3 clinical study of vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic AVF for hemodialysis. That study will enroll 300 patients at approximately 40 centers in the United States and Canada.

About Chronic Kidney Disease, Hemodialysis and Vascular Access

In the most severe stage of chronic kidney disease (CKD), also known as kidney failure, the kidneys can no longer function to sustain life. The majority of patients with kidney failure require hemodialysis and need a high-flow vascular access to repeatedly connect the patient's bloodstream to a hemodialysis machine for this life-saving, chronic treatment. Three times per week for three to four hours each session, blood is pumped from the body and passed through a dialysis machine that removes waste and excess water normally excreted by the kidneys. The preferred form of vascular access, used by two-thirds of hemodialysis patients in the United States, is an arteriovenous fistula (AVF). An AVF is created when a surgeon connects a vein to an artery, typically at the wrist or elbow, resulting in a substantial increase in blood flow and vein dilation. A radiocephalic AVF is created between the radial artery and cephalic vein at the wrist.

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 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 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 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 those regarding when data from the PATENCY-1 Phase 3 clinical study will be available, 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 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 June 30, 2015, as filed with the Securities and Exchange Commission on August 13, 2015 and 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, 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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