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): December 13, 2016

Proteon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36694**	**20-4580525**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

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 December 13, 2016, the Company issued a press release announcing the release of data from its first Phase 3 clinical trial with investigational vonapanitase, PATENCY-1. The press release is attached to this Current Report as Exhibit 99.1 hereto and is incorporated herein by reference.

Further, officers and representatives of the Company will present to various investors and stockholders beginning December 13, 2016 using the presentation materials furnished as Exhibit 99.2 hereto and which are incorporated herein by reference.

The information in this report (including Exhibits 99.1 and 99.2) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “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

Exhibit No.	Description
99.1	Press Release, dated December 13, 2016, issued by Proteon Therapeutics, Inc.
99.2	Presentation materials to be used by officers and other representatives of 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: December 13, 2016

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

EXHIBIT INDEX

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EXHIBIT 99.1

Proteon Therapeutics Announces Top-Line Data from Phase 3 PATENCY-1 Clinical Trial of Investigational Vonapanitase in Patients with CKD

- Trial Did Not Meet Primary Efficacy Endpoint -

- Important Secondary and Tertiary Endpoint Data and Enrollment in Second Phase 3 Ongoing -

- Conference Call Scheduled for 8:30 AM ET -

WALTHAM, Mass., Dec. 13, 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 that its first Phase 3 clinical trial with investigational vonapanitase, PATENCY-1, did not meet its primary endpoint of improved primary unassisted patency compared to placebo (p=0.254). However, the top-line results for the trial's secondary endpoint suggested that vonapanitase may improve secondary patency compared to placebo (p=0.048). Data from one of the trial's three tertiary endpoints also suggested vonapanitase may improve unassisted fistula use for hemodialysis (p=0.035) and any use of the fistula (unassisted or assisted) for hemodialysis (p=0.006). Adverse events reported for vonapanitase were similar to placebo.

PATENCY-1 evaluated the safety and efficacy of a single dose of vonapanitase in patients with chronic kidney disease (CKD) receiving or expecting to receive hemodialysis who underwent surgical creation of a radiocephalic arteriovenous fistula. The multicenter, randomized, double-blind, placebo-controlled clinical trial enrolled 313 patients at 31 medical centers in the United States. Patients in the trial were followed for up to one year.

The trial's primary endpoint, primary unassisted patency, is the length of time from fistula surgical creation to the first occurrence of a fistula thrombosis or corrective procedure to restore or maintain patency (blood flow). In PATENCY-1, vonapanitase-treated patients had a 17% reduction in the risk of primary unassisted patency loss over one year, compared to placebo (p=0.254). At the end of one year, 42% of patients who received vonapanitase retained primary unassisted patency, compared to 31% of placebo-treated patients.

The Kaplan-Meier curves for primary unassisted patency can be accessed in Figure 1: http://www.globenewswire.com/NewsRoom/AttachmentNg/fae4524b-a782-4332-87fd-550fa9fb87c2

PATENCY-1's secondary endpoint, secondary patency, is the length of time from surgical creation until fistula abandonment (final failure). In PATENCY-1, vonapanitase-treated patients had a 34% reduction in the risk of secondary patency loss over one year, compared to placebo (p=0.048). At the end of one year, 74% of vonapanitase-treated patients maintained secondary patency, compared to 61% of placebo-treated patients.

The Kaplan-Meier curves for secondary patency can be accessed in Figure 2: http://www.globenewswire.com/NewsRoom/AttachmentNg/0e48c0e7-33e4-4053-8ecb-ee40f1dd2248

Top-line results also included the following tertiary endpoint data:

- Use for Hemodialysis. 39.2% of vonapanitase-treated patients achieved unassisted use of their fistula for dialysis, compared to 25.0% of placebo-treated patients (p=0.035). 63.9% of vonapanitase-treated patients used their fistula for dialysis (unassisted or assisted), compared to 44.4% of placebo-treated patients (p=0.006). Use for hemodialysis was defined as continuous use of the fistula for hemodialysis for at least 90 days or, if hemodialysis was not initiated at least 90 days prior to the patient's last visit, for at least 30 days prior to the patient's last visit and in use at the patient's last visit. Unassisted use was defined as use without prior loss of primary unassisted patency.

- Unassisted Maturation. 62.9% of vonapanitase-treated patients reached unassisted maturation, compared to 53.4% of placebo-treated patients (p=0.109). Unassisted maturation by ultrasound criteria, a tertiary endpoint, was defined as achieving a vein diameter ≥4 millimeters and blood flow ≥500 milliliters per minute by three months without loss of primary patency.

- Rate of Procedures to Restore or Maintain Patency. Over one year, vonapanitase-treated patients had 1.10 procedures per patient per year versus placebo-treated patients who had 1.48 procedures per patient per year (p=0.479). Procedures included thrombectomy, angioplasty, stent deployment and surgical revision.

The proportions of patients reporting adverse events (AEs) were comparable between the vonapanitase and placebo arms of the study. The most common AEs were consistent with medical events experienced by CKD patients undergoing radiocephalic fistula surgery and are summarized in the table below.

Proportions of Patients Experiencing Common Adverse Events

Adverse Events	**Vonapanitase N=209**	**Placebo N=102**
Vascular stenosis	38.3%	40.2%
Fistula thrombosis	19.6%	26.5%
Hypoaesthesia (numbness)	5.3%	4.9%
Procedural pain	4.8%	5.9%

Note: Includes any adverse event that occurred in at least 5% of patients in either treatment group.

“We are disappointed that the study missed the primary endpoint. However, it appears that vonapanitase had a drug effect and we are encouraged by the secondary patency and fistula use for hemodialysis findings in this trial, both of which we believe are clinically important,” said Steven Burke, M.D., Senior Vice President and Chief Medical Officer of Proteon Therapeutics. “We plan to review the full data set from PATENCY-1 and further investigate these findings in our ongoing Phase 3 clinical trial, PATENCY-2.”

“We want to thank the clinical investigators and the patients and their families who volunteered to participate in PATENCY-1. We have always recognized that this is an important and complex area of clinical development and Proteon remains committed to the dialysis patient community,” stated Timothy Noyes, President and Chief Executive Officer of Proteon Therapeutics. “Because of the clinical importance of fistula abandonment and fistula use for hemodialysis to both patients and physicians, we plan to increase the planned enrollment of PATENCY-2 and look for other ways to use these results to guide our development efforts.”

As of November 30, 2016, Proteon had cash, cash equivalents and available-for-sale investments of $43.3 million. The Company expects these financial resources will be sufficient to fund its operations into the third quarter of 2018 based upon changes to our operating plan that we intend to implement.

Conference Call and Webcast

Proteon is hosting a webcast and conference call today, December 13, at 8:30 a.m. ET to discuss the top-line data from PATENCY-1. To access the conference call, please dial 844-263-8297 (U.S.) or 478-219-0006 (international) with Conference ID # 35676163. A live, listen-only webcast will also be accessible on the Investors & Media page of www.proteontx.com, including accompanying slides. A replay of the conference call will be available for two weeks on the Proteon website or by dialing 855-859-2056 (U.S.) or 404-537-3406 (international) and using Conference ID # 35676163.

About PATENCY-1 and PATENCY-2

PATENCY-1 and PATENCY-2 are Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trials in patients with chronic kidney disease (CKD) receiving or expecting to receive hemodialysis and undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. The studies were designed to evaluate, over one year, whether a single administration of 30 micrograms of vonapanitase can improve radiocephalic fistula patency, the period of time during which a fistula remains open with adequate blood flow to enable hemodialysis. Proteon today announced results of PATENCY-1, which enrolled 313 patients at 31 centers in the United States. Proteon continues to enroll patients in PATENCY-2, the second Phase 3 clinical trial. Proteon expects to reach enrollment of 300 patients in this trial at approximately 40 centers in the United States and Canada in the first quarter of 2017. Proteon expects to report top-line results from PATENCY-2 in the second quarter of 2018.

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 undergo chronic hemodialysis, which requires a high-flow vascular access to repeatedly connect the patient’s bloodstream to a hemodialysis machine for this life-saving treatment. The preferred form of vascular access for hemodialysis is a radiocephalic arteriovenous fistula, created when a surgeon connects a vein to an artery in the lower arm, resulting in a substantial increase in blood flow and vein dilation. No FDA approved preventative treatments currently exist to improve fistula patency.

About Vonapanitase

Vonapanitase (formerly PRT-201) is an investigational drug intended to improve arteriovenous fistula patency, the period of time during which a fistula remains open with adequate blood flow to enable hemodialysis. Vonapanitase is applied in a single administration and is currently being studied in a Phase 3 program 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. In addition, vonapanitase may have other surgical and endovascular applications in diseases or conditions in which vessel injury leads to blockages in blood vessels and reduced blood flow. Proteon is currently conducting two Phase 1 clinical trials of vonapanitase in patients with 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, is an investigational drug intended to improve arteriovenous fistula patency, the period of time during which a fistula remains open with adequate blood flow to enable hemodialysis. Proteon is currently evaluating vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula. Proteon today released results from its first Phase 3 trial, PATENCY-1, and is currently enrolling patients in an additional Phase 3 clinical trial, PATENCY-2. Proteon is also evaluating vonapanitase in two Phase 1 clinical trials in patients with peripheral artery disease (PAD). For more information, please visit www.proteontx.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 the number of patients to be enrolled in and the timing of enrollment in the PATENCY-2 Phase 3 clinical study of vonapanitase, when the Company expects to report top-line data from the PATENCY-2 Phase 3 clinical study of vonapanitase, the potential treatment of renal and vascular diseases with vonapanitase, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves AVF patency or use, the potential surgical and endovascular applications for vonapanitase, including PAD, the sufficiency of the Company’s cash, cash-equivalents and available-for-sale investments to fund the Company’s operations into the third quarter of 2018, 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.

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PROTEON
THERAPEUTICS™
PATENCY-1 Top-Line Results
December 13, 2016
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Cautionary Note Regarding Forward-Looking Statements

This presentation 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 the number of patients to be enrolled in and the timing of enrollment in the PATENCY-2 Phase 3 clinical study of vonapanitase, when the Company expects to report top-line data from the PATENCY-2, the potential treatment of renal and vascular diseases with vonapanitase, the effect of vonapanitase in patients with chronic kidney disease, whether vonapanitase improves fistula patency or use, whether vonapanitase may inhibit cell migration, the potential surgical and endovascular applications for vonapanitase, the sufficiency of the Company's cash, cash-equivalents and available-for-sale investments to fund the Company's operations into the third quarter of 2018, timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product candidates, 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 the 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 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 presentation represent our estimates and assumptions only as of the date of this presentation 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 presentation.

This presentation also contains estimates, projections and other information concerning our industry, our business, and the markets for our drug candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

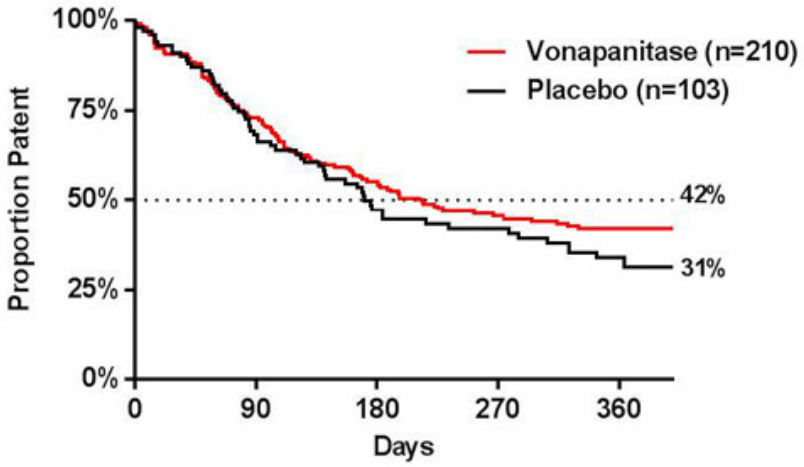
PROTEON THERAPEUTICS

PATENCY-1 Design

Design	Randomized, double-blind, placebo-controlled
Patients	300 patients in U.S. Radiocephalic AVFs 12 months of follow-up
Doses	Vonapanitase 0.03 mg vs. placebo (2:1)
Endpoints	Primary: Primary Unassisted Patency Secondary: Secondary Patency Tertiary: Unassisted Maturation Rate of Procedures Use for Hemodialysis

PROTEON THERAPEUTICS

PATENCY-1: Primary Unassisted Patency



Hazard ratio 0.83, 95% CI: 0.61 – 1.14, p=0.254

Definition of Primary Unassisted Patency

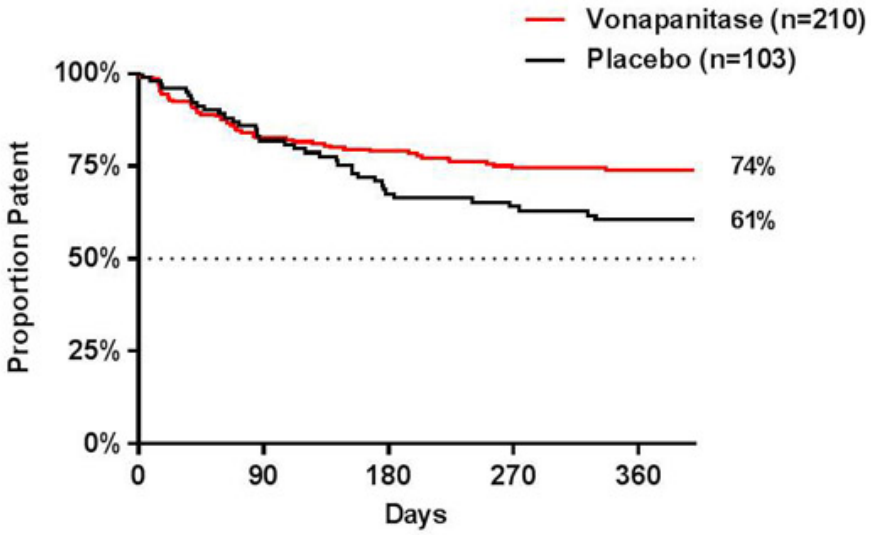
- Time from fistula surgical creation to first thrombosis or procedure to restore or maintain patency

Results

- Vonapanitase showed a 17% reduction in the risk of primary unassisted patency loss (p=0.254). This was not a statistically significant result.

PROTEON THERAPEUTICS

PATENCY-1: Secondary Patency



Hazard ratio 0.66, 95% CI: 0.43 – 1.00, p=0.048

Definition of Secondary Patency

- Time from fistula surgical creation to abandonment of the fistula

Results

- Vonapanitase showed a 33% reduction in the risk of secondary patency loss (p=0.048).

PROTEON THERAPEUTICS

Vonapanitase Adverse Events Similar to Placebo

Adverse Events	Vonapanitase (n=209)	Placebo (n=102)
Vascular stenosis	38.3%	40.2%
Fistula thrombosis	19.6%	26.5%
Hypoaesthesia (numbness)	5.3%	4.9%
Procedural pain	4.8%	5.9%

Note: Includes any adverse event that occurred in at least 5% of patients in either treatment group.

PROTEON THERAPEUTICS

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PATENCY-1 Top-Line Results

December 13, 2016