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): May 10, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
Emerging growth company [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Introductory Comment

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

Item 2.02. Results of Operations and Financial Condition.

On May 10, 2017, the Company issued a press release announcing its financial results for the first quarter ended March 31, 2017. 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.

Item 7.01. Regulation FD Disclosure.

On May 10, 2017, the Company issued a press release announcing that its investigational treatment, vonapanitase, has received Breakthrough Therapy designation from the U.S. Food and Drug Administration. The press release is attached to this Current Report as Exhibit 99.2 hereto and is incorporated herein by reference.

The information in this Current Report on Form 8-K under Items 2.02 and 7.01, including the exhibits attached hereto, 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 liabilities 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 May 10, 2017, issued by Proteon Therapeutics, Inc. announcing its First Quarter 2017 Financial Results
99.2	Press Release, dated May 10, 2017, issued by Proteon Therapeutics, Inc. announcing FDA Breakthrough Therapy Designation for Vonapanitase

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: May 10, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated May 10, 2017, issued by Proteon Therapeutics, Inc. announcing its First Quarter 2017 Financial Results
99.2	Press Release, dated May 10, 2017, issued by Proteon Therapeutics, Inc. announcing FDA Breakthrough Therapy Designation for Vonapanitase

Exhibit 99.1

Proteon Therapeutics Announces First Quarter 2017 Financial Results

WALTHAM, Mass., May 10, 2017 (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 financial results for the quarter ended March 31, 2017, and recent business highlights.

“Proteon continues to make significant clinical progress evaluating vonapanitase for patients with chronic kidney disease and peripheral artery disease,” said Timothy Noyes, President and Chief Executive Officer of Proteon. “We are greatly encouraged by the FDA’s recent decision to award vonapanitase Breakthrough Therapy designation and we remain on track to complete enrollment in our Phase 3 PATENCY-2 trial in the first quarter of 2018. Additionally, we are on track to enroll 24 patients in our Phase 1 clinical trial in patients with peripheral artery disease by the end of the year.”

Recent Highlights for 2017

Vonapanitase receives Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for increasing arteriovenous fistula secondary patency (i.e., survival of the fistula without abandonment) and use for hemodialysis in patients on or expected to initiate hemodialysis. Secondary patency and use for hemodialysis are the co-primary endpoints in PATENCY-2, Proteon’s ongoing pivotal Phase 3 clinical trial evaluating investigational vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. The FDA awards Breakthrough Therapy designations to expedite the development and review of investigational drugs that are intended to treat serious or life-threatening conditions and have demonstrated preliminary clinical evidence that the treatment may offer a substantial improvement over currently available therapies on one or more clinically significant endpoints.

Written confirmation from the FDA on PATENCY-2 Protocol Amendment. Proteon received written confirmation from the FDA that, if the Phase 3 PATENCY-2 trial is successful in showing statistical significance ($p \leq 0.05$) on each of the co-primary endpoints, the PATENCY-2 trial together with data from previously completed studies would provide the basis for a Biologics License Application (BLA) submission as a single pivotal study. Proteon amended the protocol for the PATENCY-2 trial in the first quarter of 2017 following Proteon’s review of the complete data sets from the PATENCY-1 trial and interactions with the FDA. The protocol amendment reordered the existing endpoints, establishing secondary patency and fistula use for hemodialysis as co-primary endpoints, and increased the planned enrollment from 300 to 500 patients. Proteon further increased the planned enrollment to 600 patients in the second quarter of 2017.

PATENCY-2 enrollment on track for completion in Q1 2018. PATENCY-2 is a multicenter, randomized, double-blind, placebo-controlled Phase 3 study expected to enroll 600 patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis in the United States and Canada. The study’s co-primary endpoints are secondary patency and fistula use for hemodialysis, each of which demonstrated improvements in PATENCY-1 using the same definitions as in PATENCY-2. Enrollment of 600 patients is expected in the first quarter of 2018 and Proteon expects to report top-line data in the first quarter of 2019.

Phase 3 PATENCY-1 clinical results were presented at the (i) American Society of Diagnostic and Interventional Nephrology 13th Annual Scientific meeting in New Orleans, LA, (ii) 10th Congress of the Vascular Access Society in Ljubljana, Slovenia, (iii) National Kidney Foundation 2017 Spring Clinical Meetings in Orlando, FL, and (iv) Charing Cross Symposium (CX 2017) in London, England.

The Company continues enrollment in a Phase 1 clinical study of vonapanitase in patients with peripheral artery disease (PAD). The multicenter, randomized, double-blind, placebo-controlled Phase 1 dose escalation study is expected to enroll this year 24 symptomatic PAD patients being treated with balloon angioplasty of an artery below the knee and to follow each patient for up to seven months. Immediately following successful angioplasty, vonapanitase or placebo is delivered to the arterial wall using the Mercator MedSystems Bullfrog® Micro-Infusion Catheter. The primary outcome measure of the study will be safety and the secondary outcome measure will be technical feasibility of study drug delivery via the catheter.

Upcoming Key Milestones

- Enroll 24 patients in the PAD Phase 1 trial before the end of 2017.
- Complete enrollment of 600 patients in PATENCY-2 in the first quarter of 2018.

Upcoming Events

- Presentations at the JMP Securities Life Science Conference June 20-21 in New York City, NY.

First Quarter 2017 Financial Results

Cash, cash equivalents and available-for-sale investments totaled $34.1 million as of March 31, 2017, compared to $41.3 million as of December 31, 2016. The decrease was driven by operational costs for the first three-month period of 2017.

R&D expenses: Research and development expenses for the first quarter of 2017 were $4.2 million as compared to $4.3 million for the first quarter of 2016. The decrease in R&D expenses was due primarily to a decrease in our manufacturing pre-validation and validation expenses in the first quarter of 2017 as compared to the first quarter of 2016.

G&A expenses: General and administrative expenses for the first quarter of 2017 were $2.2 million as compared to $2.5 million for the first quarter of 2016. The decrease in G&A expenses was due primarily to lower corporate overhead expenses and lower expenses associated with being a public reporting company in the first quarter of 2017 than in the first quarter of 2016.

Net loss: Net loss for the first quarter of 2017 was $6.5 million as compared to $6.6 million for the first quarter of 2016. Net loss included stock-based compensation expense of $0.8 million for the first quarter of 2017 and $0.9 million for the first quarter of 2016.

Financial guidance: The Company expects that its cash, cash equivalents and available-for-sale investments will be sufficient to fund its operations into the third quarter of 2018.

About Vonapanitase

Vonapanitase is an investigational drug intended to improve hemodialysis vascular access outcomes. 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 breakthrough therapy, fast track and orphan drug designations from the 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 a Phase 1 clinical trial 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 hemodialysis vascular access outcomes. Proteon is currently enrolling patients in PATENCY-2, a Phase 3 clinical trial evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Proteon is also evaluating vonapanitase in a Phase 1 clinical trial in patients with 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 Company’s ongoing clinical trials of vonapanitase, when the Company expects to report top-line data from the PATENCY-2 trial, whether the PATENCY-2 trial will serve as a single pivotal trial or additional studies will be necessary to support a BLA submission, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves fistula patency or use for hemodialysis, 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, 2016, as filed with the Securities and Exchange Commission (“SEC”) on March 16, 2017, 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)

	March 31, 2017	December 31, 2016
Cash, cash equivalents and available-for-sale investments	$ 34,132	$ 41,317
Prepaid expenses and other current assets	1,255	1,438
Property and equipment, net and other non-current assets	637	765
Total assets	**$ 36,024**	**$ 43,520**
Accounts payable and accrued expenses	$ 3,023	$ 5,079
Other liabilities		
Preferred Stock, common stock and additional paid-in-capital	199,276	198,218
Accumulated deficit and accumulated other comprehensive income	(166,275)	(159,777)
Total liabilities and stockholders' deficit	**$ 36,024**	**$ 43,520**

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

	Three Months Ended March 31,	
	2017	2016
Operating expenses:		
Research and development	$ 4,246	$ 4,349
General and administrative	2,234	2,470
Total operating expenses	6,480	6,819
Loss from operations	(6,480)	(6,819)
Other income (expense):		
Investment income	32	56
Other (expense) income, net	(50)	211
Total other (expense) income	(18)	267
Net loss	$ (6,498)	$ (6,552)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.39)	$ (0.40)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	16,636,201	16,507,586

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	$ 298	$ 308
General and administrative	547	558
Total	$ 845	$ 866

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

Realized (losses) gains from forward foreign currency contracts	$ -	$ 6
Unrealized (losses) gains from forward foreign currency contracts	-	178
Total	$ -	$ 184

Investor Contact
George Eldridge, Proteon Therapeutics, Senior Vice President and Chief Financial Officer
781-890-0102
geldridge@proteontherapeutics.com

Media Contact
Ann Stanesa, Ten Bridge Communications
617-230-0347
proteon@tenbridgecommunications.com

Exhibit 99.2

Proteon Therapeutics Receives FDA Breakthrough Therapy Designation for Vonapanitase

WALTHAM, Mass., May 10, 2017 (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 investigational treatment, vonapanitase, has received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for increasing arteriovenous fistula secondary patency (i.e., survival of the fistula without abandonment) and use for hemodialysis in patients on or expected to initiate hemodialysis.

Secondary patency and fistula use for hemodialysis are the co-primary endpoints of Proteon's ongoing pivotal Phase 3 clinical trial, PATENCY-2. As previously announced, the FDA has confirmed that the PATENCY-2 trial together with data from previously completed studies would provide the basis for a Biologics License Application (BLA) submission as a single pivotal study if PATENCY-2 is successful in showing statistical significance ($p \leq 0.05$) on each of the co-primary endpoints.

The FDA awards Breakthrough Therapy designations to expedite the development and review of drugs that are intended to address a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may offer a substantial improvement over available therapies on one or more clinically significant endpoints. Proteon's Breakthrough Therapy designation is supported by data from PATENCY-1, the Company's first Phase 3 clinical trial evaluating vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula. In that study, vonapanitase demonstrated clinically meaningful improvements in secondary patency and use for hemodialysis, although it did not meet the primary endpoint of improving primary patency.

"We believe the decision by the FDA to grant vonapanitase a Breakthrough Therapy designation speaks to the clinical importance of fistula survival and use for hemodialysis to patients with chronic kidney disease," said Timothy Noyes, President and Chief Executive Officer of Proteon Therapeutics. "Our productive ongoing dialogue with the FDA has helped to create a clear path forward for vonapanitase, and we look forward to continuing to work closely with the FDA to expedite our development efforts for this important program."

Enrollment in the PATENCY-2 trial is expected to complete in the first quarter of 2018 and Proteon expects to report top-line data in the first quarter of 2019. Proteon also expects to submit a BLA to the FDA in 2019.

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 forearm, resulting in a substantial increase in blood flow and vein dilation.

About Vonapanitase

Vonapanitase is an investigational drug intended to improve hemodialysis vascular access outcomes. Vonapanitase is applied in a single administration and is currently being studied in a Phase 3 program in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Vonapanitase has received Breakthrough Therapy, Fast Track and Orphan Drug designations from the 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 a Phase 1 clinical trial 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 hemodialysis vascular access outcomes. Proteon is currently enrolling patients in PATENCY-2, a Phase 3 clinical trial evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. Proteon is also evaluating vonapanitase in a Phase 1 clinical trial of vonapanitase in patients with 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 timing of enrollment in the PATENCY-2 trial, when the Company expects to report top-line data from the PATENCY-2 trial, whether and when we may submit a BLA, whether additional studies will be necessary to support a BLA submission as a single pivotal trial, the potential treatment of renal and vascular diseases with vonapanitase, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves secondary patency or fistula use for hemodialysis and the clinical importance of these endpoints,

the potential surgical and endovascular applications for vonapanitase, including PAD, 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, 2016, as filed with the Securities and Exchange Commission ("SEC") on March 16, 2017, 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.

Investor Relations Contact
George Eldridge, Proteon Therapeutics, Senior Vice President and Chief Financial Officer
781-890-0102
geldridge@proteontherapeutics.com

Media Contact
Ann Stanesa, Ten Bridge Communications
617-230-0347
proteon@tenbridgecommunications.com