# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

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# FORM 8-K

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## CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): March 28, 2019

## 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 8.01. Other Events.**

On March 28, 2019, the Company issued a press release announcing the release of data from its second Phase 3 clinical trial with investigational vonapanitase, PATENCY-2. The press release is attached to this Current Report as Exhibit 99.1 hereto and is incorporated herein by reference.

Further, beginning March 28, 2019, officers and representatives of the Company will use the presentation materials attached to this Current Report as Exhibit 99.2 hereto in presentations regarding the data from PATENCY-2. These presentation materials are incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated March 28, 2019, issued by Proteon Therapeutics, Inc. |
| 99.2 | Management Presentation Materials |

**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: March 28, 2019

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release, dated March 28, 2019, issued by Proteon Therapeutics, Inc. |
| 99.2 | Management Presentation Materials |

**EXHIBIT 99.1**

# Proteon Therapeutics Announces Top-Line Results From Phase 3 PATENCY-2 Clinical Trial of Vonapanitase in Radiocephalic Arteriovenous Fistulas

**- Investigational Vonapanitase Did Not Meet Co-Primary Endpoints -**

WALTHAM, Mass., March 28, 2019 (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 results from PATENCY-2, its Phase 3 clinical trial of investigational vonapanitase in patients with chronic kidney disease (CKD) undergoing creation of a radiocephalic fistula for hemodialysis. This study did not meet its co-primary endpoints of fistula use for hemodialysis (p=0.328) and secondary patency (p=0.932). The adverse events with vonapanitase were similar to placebo and consistent with previous clinical trials.

PATENCY-2 evaluated the safety and efficacy of a single dose of investigational vonapanitase in patients with CKD undergoing creation of a radiocephalic arteriovenous fistula for hemodialysis. The multicenter, randomized, double-blind, placebo-controlled PATENCY-2 trial treated 603 patients at 39 medical centers in the United States and Canada. Patients were followed for up to one year.

The PATENCY-2 clinical trial had two co-primary endpoints:

- Fistula use for hemodialysis. 69.7 % of vonapanitase-treated patients achieved use of the fistula for hemodialysis, compared to 65.1% of placebo-treated patients (p=0.328), a result that is not statistically significant. Fistula use is defined as use of the fistula for two-needle hemodialysis for at least 90 days or, if hemodialysis was not initiated at least 90 days prior to the last study visit, for at least 30 days and including the patient's last study visit.
- Secondary patency. A comparison of the Kaplan-Meier curves did not demonstrate a statistically significant difference in favor of vonapanitase (p=0.932). At the end of one year, 78% of vonapanitase-treated patients maintained secondary patency, compared to 76% of placebo-treated patients. Secondary patency is a measure of the length of time from surgical creation of the fistula until the fistula experiences final failure and must be abandoned.

The Kaplan-Meier curves for secondary patency can be accessed **here**.

Top-line results also included data relating to primary unassisted patency, one of PATENCY-2's other efficacy endpoints. 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). Vonapanitase-treated patients had a 15% reduction in the risk of primary unassisted patency loss over one year, compared to placebo (p=0.178), a result that is not statistically significant. At the end of one year, 50% of patients who received vonapanitase retained primary unassisted patency, compared to 43% of placebo-treated patients.

The Kaplan-Meier curves for primary unassisted patency can be accessed **here**.

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

Proportions of Patients Experiencing Common Adverse Events

| | Vonapanitase N=399 | Placebo N=204 |
|---|---|---|
| Vascular Stenosis | 35.1% | 41.7% |
| Fistula Thrombosis | 16.8% | 18.6% |
| Local swelling | 5.0% | 2.0% |
| Hematoma | 5.0% | 3.9% |

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

PATENCY-2 is the fourth multicenter, randomized, double-blind, placebo-controlled clinical trial Proteon has conducted evaluating investigational vonapanitase in patients undergoing creation of an arteriovenous fistula for hemodialysis. In each of the four trials, patients have been followed for up to one year, plus up to an additional two years of follow-up in a registry. Combined, these trials have enrolled more than 1,100 patients at more than 60 centers in the U.S. and Canada.

"We believe this trial was well conducted and are surprised and disappointed by these results," said Timothy Noyes, President and Chief Executive Officer of Proteon. "We want to thank the clinical investigators and patients who volunteered to participate in this important clinical program. In the coming weeks and months, the Company intends to review the full data set from PATENCY-2 and evaluate our strategic options."

We estimate that Proteon will have at March 31, 2019 cash, cash equivalents and available-for-sale investments of $16.5 million.

**About PATENCY-1 and PATENCY-2**
PATENCY-1 and PATENCY-2 are Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trials that evaluated vonapanitase in patients with chronic kidney disease (CKD) undergoing surgical creation of a radiocephalic arteriovenous fistula for hemodialysis. The studies were designed to evaluate, over one year, whether a single administration of vonapanitase can improve fistula outcomes. The results of PATENCY-1, which treated 311 patients at 31 centers in the United States, have been published in the *Journal of Vascular Surgery*.

**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. Approximately 130,000 fistulas are created in the United States annually, 35-40% of which are radiocephalic. A patient whose fistula fails to become usable or is abandoned is often subjected to interrupted and missed dialysis sessions, additional invasive procedures, and less desirable forms of vascular access, including prolonged exposure to catheters, the worst form of vascular access because of the increased risk of serious infection, hospitalization and death.

**About Vonapanitase**
Vonapanitase is an investigational drug applied in a single administration that is intended to improve hemodialysis vascular access outcomes. Vonapanitase has been evaluated in PATENCY-1 and PATENCY-2, 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 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. 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 has completed two Phase 3 clinical studies, PATENCY-1 and PATENCY-2, which evaluated 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" as defined in the Private Securities Litigation Reform Act of 1995. 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 estimate of the amount of cash, cash equivalents and available-for-sale investments that we will have at March 31, 2019, the effect or benefit of vonapanitase in patients with CKD, whether vonapanitase improves hemodialysis vascular access failure, including fistula use for hemodialysis or secondary 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 the Company’s 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 the Company can successfully commercialize and market its product candidates, are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (“SEC”) on March 13, 2019, and the Company’s 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 the Company’s forward-looking statements, no person should place undue reliance on these statements or regard these statements as a representation or warranty by the Company or any other person that the Company will achieve its objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this press release represent the Company’s estimates and assumptions only as of the date of this press release and, except as required by law, the Company undertakes 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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**Exhibit 99.2**


PROTEON
THERAPEUTICS™
PATENCY-2 Top-Line Results
March 28, 2019
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# Cautionary Note Regarding Forward-Looking Statements

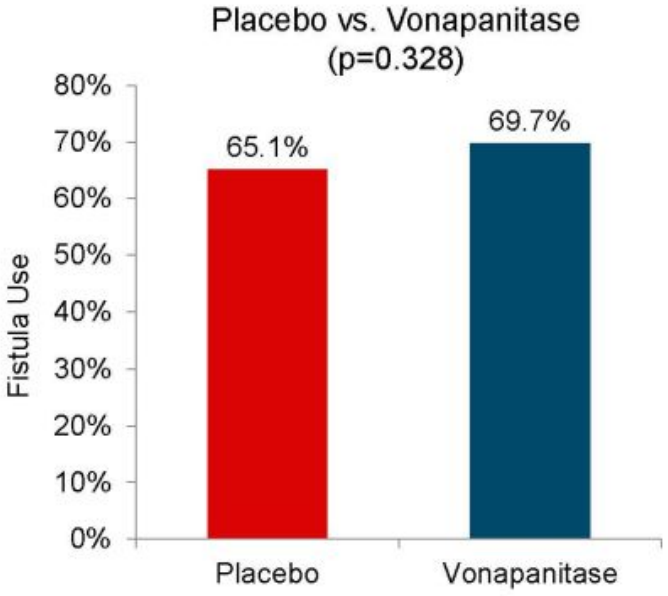
This presentation contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "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 our interpretation of data from PATENCY-2 and other clinical and pre-clinical studies, the clinical and regulatory path forward for vonapanitase and whether additional studies will be necessary to support a Biologics License Application (BLA), whether and when we may submit a BLA or commercially launch in the United States, our ability to establish a commercially-ready supply chain, our intellectual property position, the significance or clinical utility of any approved product, the market opportunity, standard of care and reimbursement for improving fistula outcomes, and those relating to future events or our future financial performance or condition, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, product approvals, research and development costs, current and prospective collaborations, 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, 2018, as filed with the Securities and Exchange Commission ("SEC") on March 13, 2019, 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.

# Phase 3 PATENCY-2 Trial Design

| | |
|---|---|
| **Design** | Multicenter, randomized, double-blind, placebo-controlled |
| **N** | 603 treated patients in U.S. and Canada |
| **Patients** | Patients with CKD on or expecting to initiate hemodialysis and undergoing surgical creation of a radiocephalic fistula |
| **Dose** | Vonapanitase 30 mcg vs. placebo (2:1 randomization) |
| **Co-Primary Endpoints** | Fistula use for hemodialysis<br>Secondary patency (time from fistula surgical creation until fistula abandonment) |
| **Other Efficacy Endpoints** | Primary patency<br>Procedure rate<br>Fistula maturation |

# Co-Primary Endpoint: Fistula Use for Hemodialysis




- Defined as use of the fistula for two-needle hemodialysis for at least 90 days or, if hemodialysis was not initiated at least 90 days prior to the last study visit, for at least 30 days and including the patient's last study visit
- Results
  - No statistically significant difference between the arms (p=0.328)



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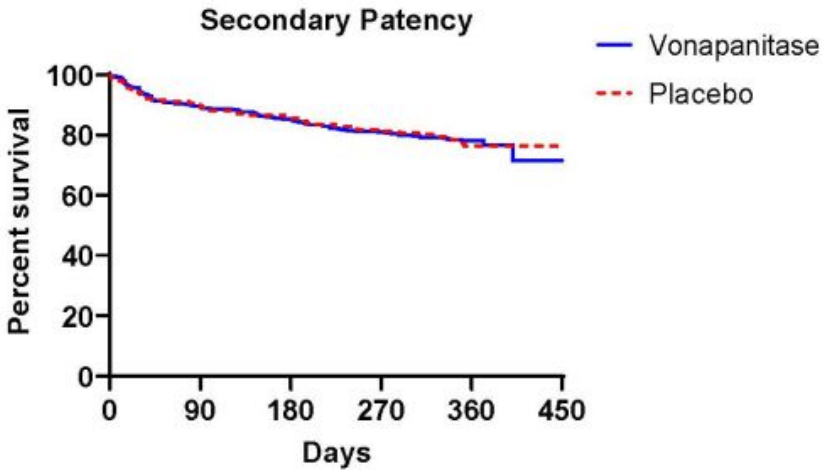
# Co-Primary Endpoint: Secondary Patency




Defined as time from fistula creation to abandonment

Results

- No statistically significant difference between the arms (p=0.932)



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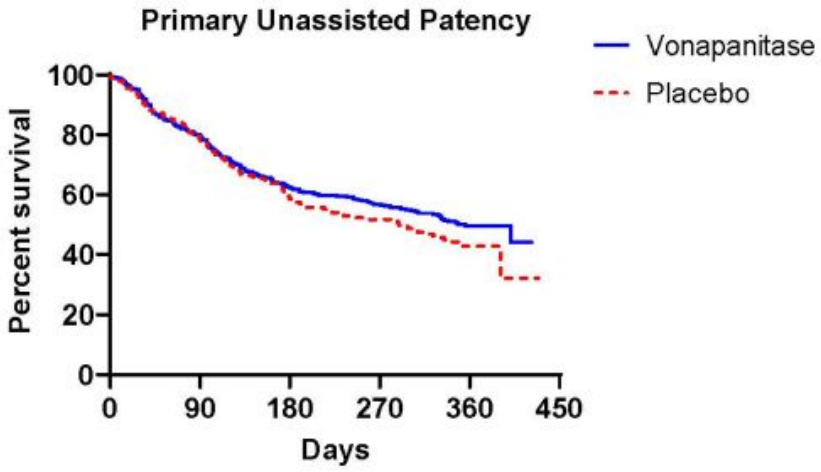
# Other Endpoint: Primary Unassisted Patency




Defined as time from fistula creation to first occurrence of a fistula thrombosis or corrective procedure to restore or maintain patency

Results

- No statistically significant difference between the arms (p=0.178)



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# PATENCY-2 Safety Profile

- No evidence of immunogenicity
- Adverse events consistent with medical conditions experienced by kidney disease patients undergoing fistula surgery
- Adverse events comparable for vonapanitase and placebo

| Adverse Events | Vonapanitase (n=399) | Placebo (n=204) |
|---|---|---|
| Vascular stenosis | 35.1% | 41.7% |
| Fistula thrombosis | 16.8% | 18.6% |
| Local swelling | 5.0% | 2.0% |
| Hematoma | 5.0% | 3.9% |

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



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# PATENCY-2 Top-Line Results

March 28, 2019