

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): **March 21, 2017**

Proteon Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36694
(Commission
File Number)

20-4580525
(IRS Employer
Identification No.)

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 (see General Instruction A.2. below):

- 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))
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Item 7.01 Regulation FD Disclosure

Beginning March 22, 2017, Proteon Therapeutics, Inc. will share the presentation materials attached as Exhibit 99.1 to this report and furnished under this Item 7.01 in meetings with investors and in presentations.

The information in this report (including Exhibit 99.1) 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 Proteon Therapeutics, Inc. 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.

Dated: March 21, 2017

Proteon Therapeutics, Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Proteon Therapeutics, Inc. Presentation Materials



March 2017

NASDAQ: PRTO

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 ability to fund operations into the third quarter of 2018, the number of patients to be enrolled in our ongoing and planned clinical trials, the timing of completing enrollment or releasing results for PATENCY-2, our interpretation of data from PATENCY-1 and the clinical and regulatory path forward, whether and when we may submit a Biologics License Application 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, 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 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: Positioned for Success

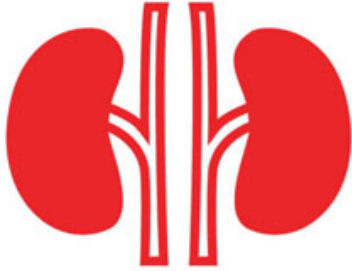
- **PATENCY-1 (first Phase 3 trial) results provide clear path forward**
 - Trial was well executed and instructive
 - Pre-specified endpoints demonstrated a positive drug effect; primary endpoint not statistically significant
 - Adverse events comparable for vonapanitase and placebo
- **PATENCY-2 endpoints re-ordered; FDA agreement on filing strategy with co-primary endpoints**
 - Endpoint definitions same as PATENCY-1
 - If each successful at $p \leq 0.05$, BLA can be filed without additional trials; PATENCY-1 would be considered supportive
 - Improvement in co-primary endpoints in PATENCY-1: use for HD ($p=0.006$), secondary patency ($p=0.048$)
 - Fast Track and orphan designations for hemodialysis vascular access
- **PATENCY-2 data expected Q4 2018; BLA filing possible in 2019**
 - Enrollment increased from 300 to 500; $>90\%$ power in each co-primary endpoint for $p \leq 0.05$
- **Significant unmet medical need to improve radiocephalic fistula outcomes**
 - Reduce catheter exposure, the worst form of access, associated with increased risk of sepsis, thrombosis, hospitalization and mortality
 - If successful, vonapanitase would represent the most significant innovation in vascular access in decades
- **Improving radiocephalic fistula outcomes is a \$1 billion market opportunity in the US**

Experienced Management Team

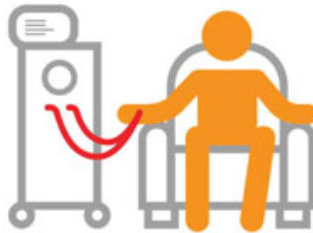
	Position	Prior Experience
Timothy Noyes	President and CEO	Trine Pharmaceuticals (COO) Genzyme Renal (President), GelTex Pharmaceuticals and Merck & Co.
Steven Burke, M.D.	SVP and CMO	Genzyme (SVP, Medical & Regulatory Affairs,) GelTex Pharmaceuticals (VP Clinical Research), Glaxo
George Eldridge	SVP and CFO	Targanta Therapeutics (CFO), Therion Biologics, Curis, Kidder Peabody
Scott Toner	SVP, Marketing	OPKO Health's Renal Division (VP US Marketing & Sales), Reata Pharmaceuticals, AMAG Pharmaceuticals, Abbott Laboratories
Daniel Gottlieb	Vice President, Corporate Development	Abbott Vascular (Strategic Marketing) Guidant (Corporate Venture Capital and Business Development)
Pam Gustafson	Vice President, Clinical Research	Trine Pharmaceuticals (Director of Clinical Operations) AAI International
Matthew Kowalsky	Vice President, Legal	Sanofi Genzyme (Senior Corporate Counsel), Cubist, Lantheus Medical
John Najim	Vice President, Manufacturing	Dyax Corp. (Associate Director of Manufacturing) GTC Biotherapeutics (Process Development Manager)

Fistula Background

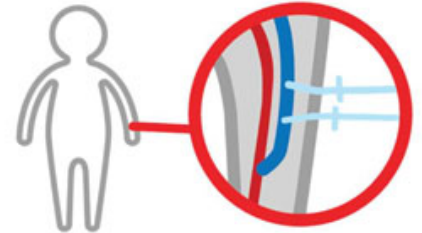
Vascular Access: A Hemodialysis Patient's Lifeline



Healthy kidneys remove waste and excess fluid continuously, 24 hours per day



Patients with kidney failure typically undergo hemodialysis three times per week (3-4 hours/session)



Hemodialysis requires a high flow vascular access, preferably an arteriovenous fistula

Less Desirable Forms of Vascular Access

Arteriovenous Graft

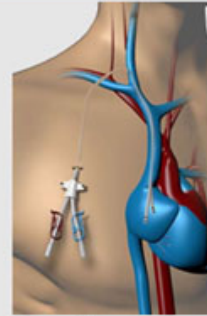
For Patients Unsuitable for Fistula



- For patients experiencing fistula failure or lacking suitable vessels
- Higher rates of failure, interventions and infection compared to fistulas
- ~20% use long term

Catheter

Least Desirable



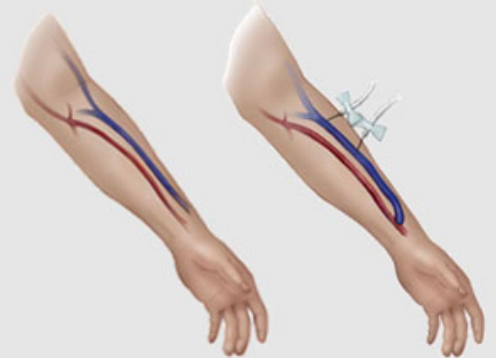
- Required when fistula or graft is not yet usable or is abandoned
- Highest rates of infection, hospitalization and mortality
- ~80% start dialysis on a catheter
- ~15% use long term

Radiocephalic (Forearm) Fistula Is Preferred Form of Vascular Access

- Fistulas used by 2/3 of US hemodialysis patients
- Lowest rates of infection, thrombosis, intervention and related hospitalization
- Lowest cost of care
- Recommended by key stakeholders
 - National Kidney Foundation (NKF) KDOQI Guidelines
 - CMS' Fistula First/Catheter Last Initiative
- Radiocephalic (forearm) fistula optimal
 - Reduced risk of hand ischemia (steal syndrome), central stenosis and heart failure
 - Preserves additional access sites in arm if needed

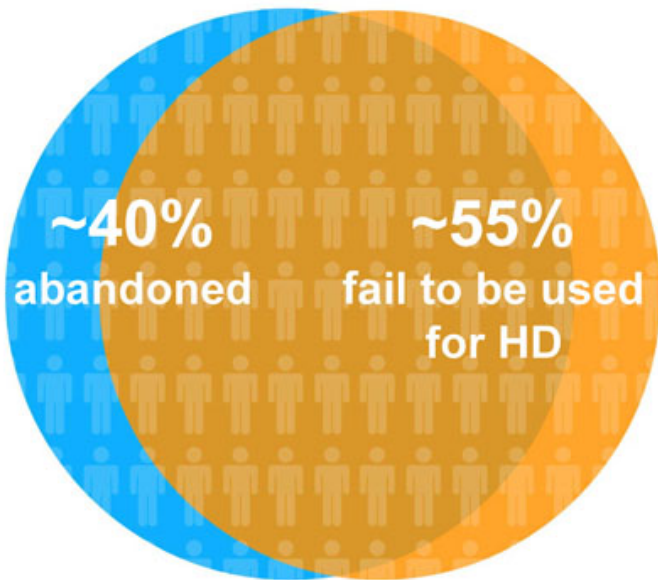
Radiocephalic Fistula

Preferred Form of Access



- Surgical connection of artery and vein
- To become usable, vein must experience increase in blood flow and diameter (~3 month process)

Gold Standard Radiocephalic Fistula Frequently Fail in First Year, With Grave Consequences



- Patient must dialyze with a catheter
 - Time on catheter twice as long if fistula fails to become usable (264 vs. 123 days)¹
 - Up to 29% of patients refuse a new fistula/graft and become chronic catheter dependent²
- New access surgery for possible upper arm fistula or graft
- Risk of exhausting all access sites in arms

“The use of hemodialysis catheters is associated with poor quality of life, increased risk of sepsis, stenosis and thrombosis, low blood flow rates, and increased hospitalizations and mortality.”³

Failure data from PATENCY-1. ¹Al-Balas 2016. HD patients undergoing AVF creation. ²Asif 2005. ³Chaudhry 2011.

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Clinical Implications of Catheter Use Are Severe

Reduced dialysis adequacy (patients with Kt/V < 1.20: 25% for catheter vs. 10% for fistula/graft)¹
Reduced quality of life²

Initiate HD on a catheter

- 2x mortality risk in first year³
- 3x mortality risk in first three months (overall 47/100 py)⁴
- 2x rate hospitalization in first six months (1.9 vs. 0.9 ppy)⁵
- 3x rate hospitalization for infection in first year (21% vs. 7%)⁶

Fistula fails to be used

- 2x rate catheter infections in first year (2.2 vs. 1.0/year)⁷
- 4x rate sepsis hospitalizations in first year (1.4 vs 0.3/year)⁷

Fistula/graft abandoned

- 2x mortality risk^{3,8}
- 3x infection-related mortality risk⁸
- 22% increase in risk of hospitalization⁹

¹Lee 2005, ²Wasse 2007, ³Lacson 2009, ⁴Lukowsky 2012, ⁵Ng 2011, ⁶Kazakova 2016 (septicemia or bacteremia), ⁷Al-Balas 2016, ⁸Allon 2006, ⁹Lacson2010.

Substantial Benefits if Fistula Can Be Used

Initiate HD on a catheter	Fistula fails to be used	Fistula/graft abandoned
Convert from catheter to fistula <ul style="list-style-type: none">• 20% reduction in risk of mortality^{1,2}• 37% reduction in hospitalizations in 1st 90 days (3.0 vs. 1.9 ppy)³• 62% reduction in positive blood cultures in 1st 90 days (0.5 vs. 0.2 ppy)³		

¹Lacson 2009. ²Ko 2016. ³Taylor 2014.

Vonapanitase

Vonapanitase Overview

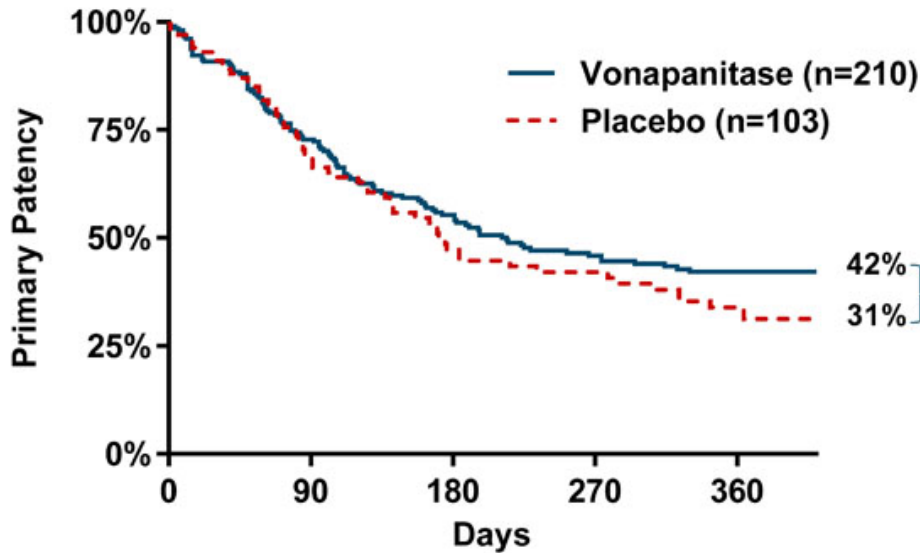
- Investigational recombinant human elastase
- 25 kilodalton serine protease that cleaves peptide bonds in the protein elastin
- Elastin is the principal component of elastic fibers in blood vessels that impart elasticity
- Single, local application (10 min) to the external surface of the fistula immediately after creation
- Active at site of application with no systemic effects observed since inactivated by blood



Phase 3 PATENCY-1 Trial

Design	Multicenter, randomized, double-blind, placebo-controlled
N	313 patients in U.S.
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)
Primary Endpoint	Primary unassisted patency (time from fistula surgical creation until first thrombosis or procedure to restore or maintain patency)
Secondary Endpoint	Secondary patency (time from fistula surgical creation until fistula abandonment)
Tertiary Endpoints	Use for hemodialysis Fistula maturation by ultrasound criteria Rate of procedures

Vonapanitase Increased Primary Unassisted Patency – Not Statistically Significant



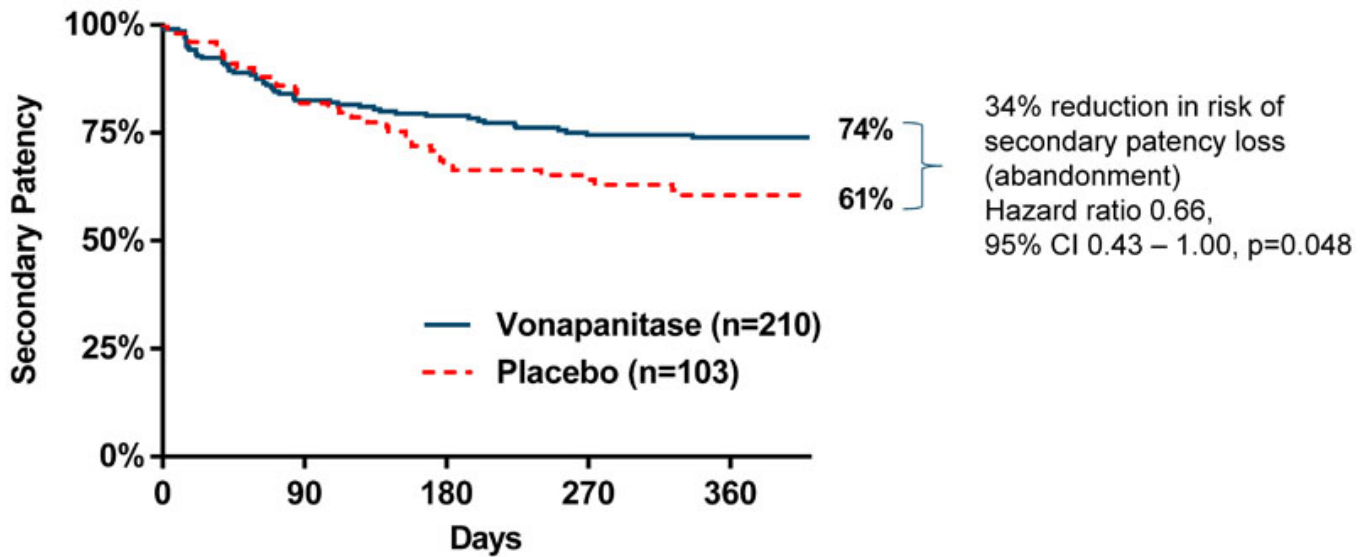
17% reduction in risk of primary unassisted patency loss (thrombosis or procedure to restore or maintain patency)
Hazard ratio 0.83,
95% CI 0.61 – 1.14, p=0.254

Numbers at risk for patency loss:

Vonapanitase	210	139	96	77	40
Placebo	103	66	37	32	19

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Vonapanitase Increased Secondary Patency

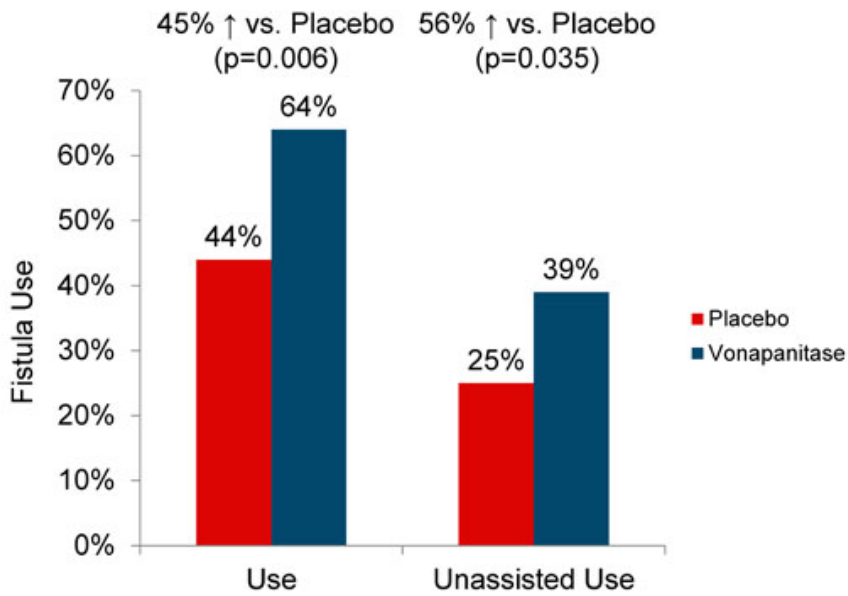


Number at risk for patency loss:

Vonapanitase	210	163	147	135	82
Placebo	103	80	60	55	39

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Vonapanitase Increased Use of the Fistula for Hemodialysis



Definition of fistula use

- Use of fistula for hemodialysis for ≥ 90 days
- For patients who did not initiate hemodialysis ≥ 90 days prior to last study visit, defined as ≥ 30 days of use including the last visit
- Unassisted use defined as use for hemodialysis without a prior corrective procedure to restore or maintain patency (e.g., angioplasty or surgical revision)

Vonapanitase Phase 3 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	Placebo (n=102)	Vonapanitase (n=209)
Vascular stenosis	40.2%	38.3%
Fistula thrombosis	26.5%	19.6%
Hypoaesthesia (numbness)	4.9%	5.3%
Procedural pain	5.9%	4.8%

Includes any adverse event that occurred in at least 5% of patients in either treatment group
Analysis excludes 2 patients who were randomized but not treated

Summary of PATENCY-1 Results

- Pre-specified endpoints demonstrated a positive drug effect
- Improvement in clinically important endpoints
 - Secondary patency (p=0.048)
 - Use for hemodialysis (p=0.006)
- Adverse events comparable for vonapanitase and placebo
- Results supported amendment to PATENCY-2, and potential to file without additional clinical trials

Ongoing Phase 3 PATENCY-2 Trial

Design	Multicenter, randomized, double-blind, placebo-controlled
N	500 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	Secondary patency (time from fistula surgical creation until fistula abandonment) Fistula use for hemodialysis
Other Efficacy Endpoints	Primary unassisted patency Procedure rate Fistula maturation

Endpoint definitions same as PATENCY-1

PATENCY-2 Co-Primary Endpoints Powered at > 90% Based on PATENCY-1 Results

Secondary Patency

- >90% power for $p \leq 0.05$ if observed improvement in PATENCY-1 is true (61% to 74%)
- ~80% power for $p \leq 0.05$ if true improvement is 61% to 72%

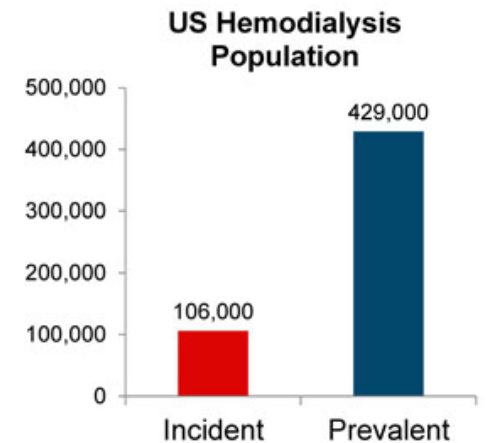
Use for Hemodialysis

- 96% power for $p \leq 0.05$ if observed improvement in PATENCY-1 is true (44% to 64%)
- ~80% power for $p \leq 0.05$ if true improvement is 44% to 59%

Endpoints were closely related in PATENCY-1: of the fistulas that were not used for hemodialysis, 92% were abandoned

Improving Radiocephalic Fistula Outcomes Is a \$1 Billion Market Opportunity in the US

- Patient population continues growing
- Market research indicates vonapanitase likely to become standard of care
- Compelling risk/reward demonstrated in PATENCY-1
 - Clear understanding of medical need by all stakeholders
 - Surgeons are anxious to improve results; receptive to innovation
 - No competitive therapies available; few in development
 - Fistulas that fail to become usable are estimated to result in incremental costs of \$30,000 in the first year after surgical creation
- Expect attractive coverage and reimbursement environment
 - Excluded from ESRD payment bundle
 - Primarily Medicare outpatient → Part B reimbursement
- Specialty pharma sales force
 - Expect 75-100 US representatives to cover ~2,800 surgeons



- Recurring flow of patients undergoing fistula creation
- 130,000 fistulas created annually
- ~35%-40% radiocephalic

Strong IP Estate

Family	Description	Status / Commentary
1	<ul style="list-style-type: none"> • Uses of elastases for increasing diameter of biological conduits (including arteries and veins) and reduction of intimal hyperplasia or stenosis. • Uses of elastases to treat vascular access sites to prolong hemodialysis access 	<ul style="list-style-type: none"> • First nonprovisional filing in 2000 • 8 patents issued in US • 3 EP patent issuances • 2 patents issued in JP
2	<ul style="list-style-type: none"> • Use of elastases for compliance matching at vascular anastomoses 	<ul style="list-style-type: none"> • First nonprovisional filing in 2004 • Issued in US, JP, AU
4	<ul style="list-style-type: none"> • Low trypsin and trypsin-free compositions of mature human type I elastases, and related therapeutic uses • Methods of manufacturing mature elastases • Engineered pro-elastase proteins and related DNA molecules and host cells 	<ul style="list-style-type: none"> • First nonprovisional filing in 2008 • Issuances in US, EP, JP, NZ, IL, CN, AU, MX • Recent allowances in RU, EP, JP and TW • Encouraging search reports and office actions in other geographies • Project patent term extension into 2033

**Patent protection into 2030 in US; through 2028 in EU
(2033 US/EU with expected extensions)**

Vonapanitase for Peripheral Artery Disease (PAD)

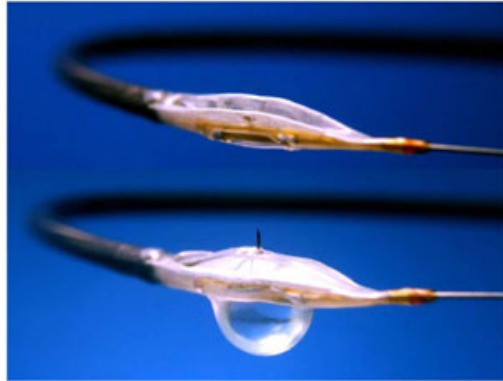
- Compelling near-term follow-on clinical area after fistulas
 - Significant unmet medical needs globally
 - Strategic fit with vascular access program (physician, patient, site of service)
- Nonclinical program evaluated safety and biologic effect
 - Vonapanitase treatment dilated diseased tibial arteries ex vivo
 - Potential therapy as complement to angioplasty or alone (“monotherapy”)
- Completed a successful Phase 1 study
 - Encouraging safety and technical feasibility of treatment via drug delivery catheter
- Conducting an additional Phase 1 study in clinical area not addressed by current therapies
 - Vonapanitase as adjunct to angioplasty below the knee

Potential PAD Applications



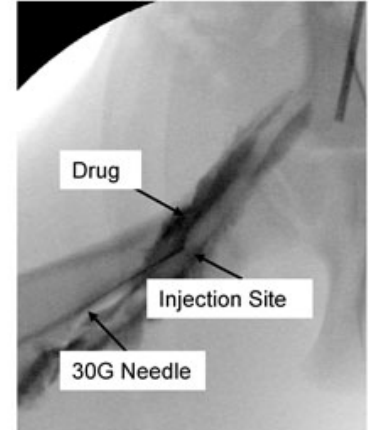
Surgical

- Patients undergoing peripheral bypass
- Similar concept to Phase 3 fistula program



Endovascular

- Active Phase 1 study in patients undergoing angioplasty of an artery below the knee
- Builds on prior Phase 1 PAD study



Percutaneous

- Active Phase 1 study (not enrolling) in patients with disease of the superficial femoral artery
- Possible alternative to angioplasty; delivery via needle

Commercial-Ready Drug Supply Chain

- Drug substance
 - Manufactured at Lonza in Switzerland; one batch generates >1 million fistula doses
 - Current cGMP stability at >5 years at -80°C; cGMP testing performed at PPD
 - Drug substance validation studies ongoing, process validation campaign scheduled
- Drug product
 - Manufacturing at Jubilant Hollister-Stier in U.S.
 - Current cGMP stability at 2 years at 2-8°C (refrigerated); cGMP testing performed at PPD
 - Drug product validation studies ongoing, process validation campaign scheduled
- Intend to use a third-party logistics provider for commercial drug distribution, storage, etc.

Strong Financial Position

- \$41.3 million of cash, cash equivalents and marketable securities at December 31, 2016
 - Existing funds sufficient to fund operations into Q3 2018
- 16.6 million shares outstanding
(an additional 2.8 million stock options outstanding)
- Ticker: PRTO (Nasdaq)

Proteon: Positioned for Success

- Clear drug effect and safety profile demonstrated in Phase 3
 - Consistent positive results in all pre-specified efficacy endpoints in PATENCY-1
- Amended PATENCY-2 design increases confidence
 - Improvement in co-primary endpoints in PATENCY-1: use for HD ($p=0.006$), secondary patency ($p=0.048$)
 - Increased sample size enhances power ($>90\%$ power in each co-primary endpoint for $p\leq 0.05$)
 - If repeat PATENCY-1 results, p-values very low
- Established regulatory path based on FDA agreement on protocol amendment and filing strategy
 - If each co-primary endpoint successful at $p\leq 0.05$, BLA can be filed without additional trials
 - PATENCY-1 would be considered supportive
 - Fast Track and orphan designations for hemodialysis vascular access
- Significant unmet medical need creates \$1 billion market opportunity in the US



PROTEON THERAPEUTICS™

March 2017

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