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): **December 8, 2014**

PROTEON THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36694**	**20-4580525**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 West Street **Waltham, MA**	**02451**
(Address of principal executive offices)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

Beginning December 9, 2014, 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: December 8, 2014

Proteon Therapeutics, Inc.

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

EXHIBIT INDEX

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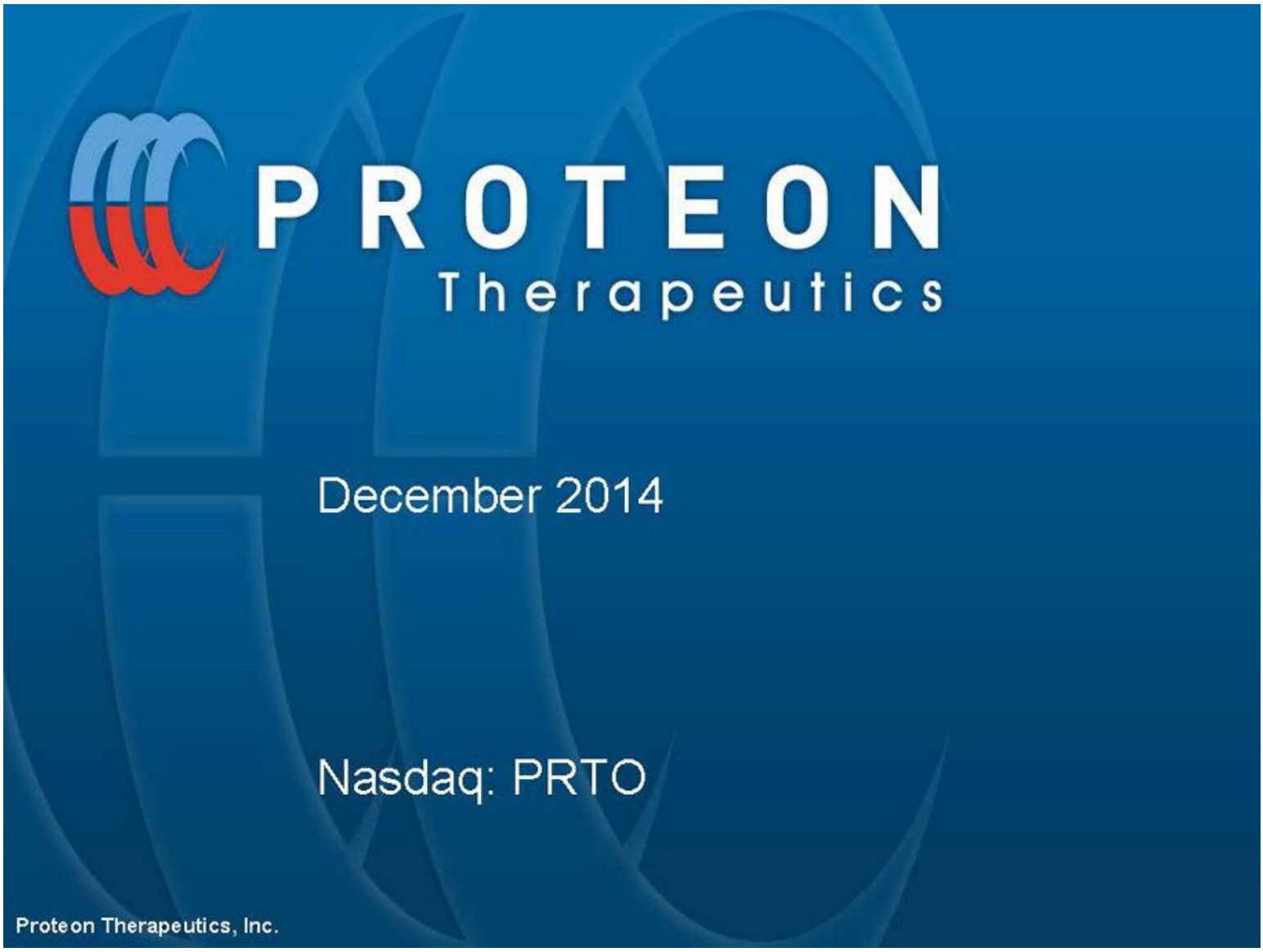
PROTEON
Therapeutics
December 2014
Nasdaq: PRTO
Proteon Therapeutics, Inc.

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 ability to fund operations into 2018, 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 PRT-201 will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether we can successfully commercialize and market our product candidates, are described more fully in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 as filed with the Securities and Exchange Commission on November 25, 2014, 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

- Developing PRT-201, a locally-acting recombinant elastase, to reduce vascular access failure in hemodialysis patients
- Ongoing Phase 3 program builds on compelling Phase 2 data
  - Trends toward efficacy across multiple endpoints and strong safety profile
  - Phase 3 studying same endpoints as in Phase 2
  - Preclinical program complete
  - FDA fast track and orphan drug designations
- Attractive commercial opportunity
  - No approved therapies – approximately $2.9 billion is spent annually in the U.S. managing vascular access dysfunction
  - Favorable reimbursement expected: primarily Medicare Part B outside ESRD payment bundle
  - IP protection into 2029 in US (2032 expected with extensions)
- Raised $70 million in Q4 IPO to fund 2nd Phase 3 trial and CMC work
- Experienced management with renal expertise

PROTEON Therapeutics

Experienced Management Team

	Position	Prior Experience
Timothy Noyes	President and CEO	Trine Pharmaceuticals (COO) Genzyme Renal (President) and GelTex Pharmaceuticals Merck & Co.
Steven Burke, M.D.	SVP and CMO	Medical & Regulatory Affairs, Genzyme (SVP) GelTex Pharmaceuticals (VP Clinical Research), Glaxo
George Eldridge	SVP and CFO	Targanta Therapeutics (CFO), Therion Biologics, Curis, Kidder Peabody
Daniel Gottlieb	Vice President, Strategic Marketing	Strategic Marketing, Abbott Vascular Corporate Venture Capital and Business Development, Guidant
John Najim	Senior Director, Manufacturing	Dyax Corp. (Assoc. Director of Manufacturing) GTC Biotherapeutics (Process Development Manager)
Marco Wong, M.D. Ph.D.	Medical Director	Stowers Institute for Medical Research General Surgery Resident, Wayne State University School of Medicine

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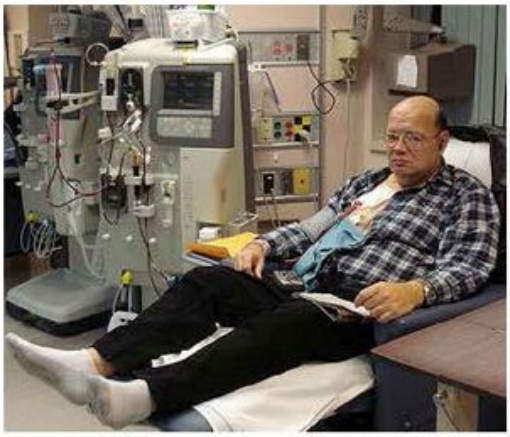
Hemodialysis Vascular Access in CKD Patients

Hemodialysis is a Life Saving Treatment for CKD Patients

- Dialysis replaces kidney function
- Significant disease burden
  - Dialysis 3x/week, 4 hours/session
  - Multiple co-morbidities (e.g. diabetes, cardiovascular disease)
  - Average 12 hospital days/year

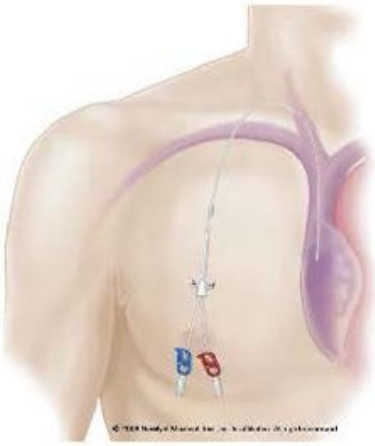


- Need to transfer large volumes of blood (400 mL/min) through dialysis machine for purification
- Requires a functioning vascular access to provide adequate blood flow

PROTEON Therapeutics

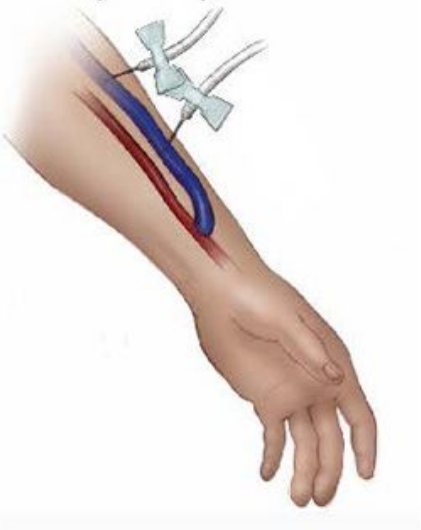
Vascular Access:
A Hemodialysis Patient's Lifeline

Catheter



Arteriovenous Graft (AVG)

Arteriovenous Fistula (AVF)

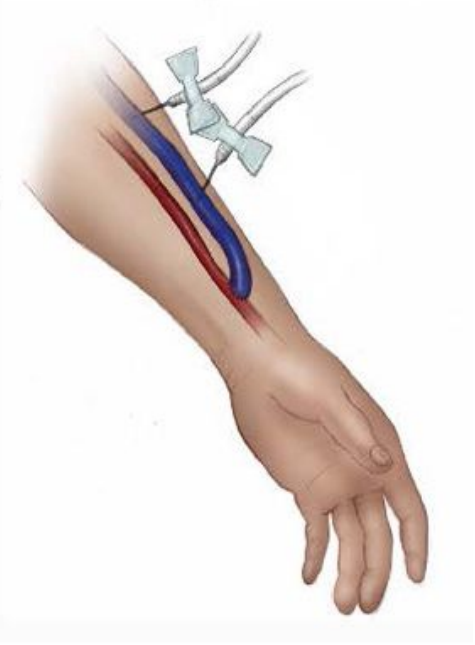


PROTEON Therapeutics

AVF Is Gold Standard of Vascular Access

- Direct surgical connection of artery and vein results in increased blood flow
  - Increase in vein diameter and blood flow required for dialysis (3 month maturation process)
- Lower rates of infection, thrombosis, intervention and related hospitalization
- For 10+ years, CMS has supported AVF use through its Fistula First Initiative
- AVFs suffer from high failure rates due to stenosis formation and reduced blood flow in response to surgical injury
- Radiocephalic (wrist) AVF preferred

Radiocephalic AVF



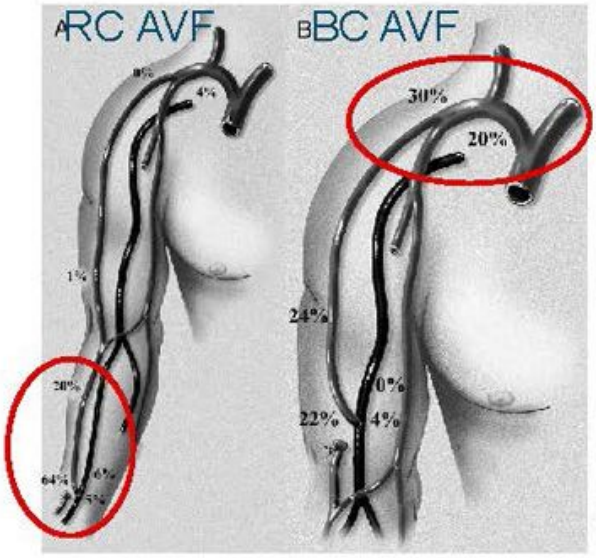
PROTEON Therapeutics

Radiocephalic AVF Preferred

- Radiocephalic (RC) AVF
  - Recommended 1st choice
    - Maximizes number of AVF sites on arm
    - Lower incidence of "steal" and heart failure
  - But, suffer from high failure rate
    - Smaller vessels and lower blood flow
    - 75-95% of stenoses at or near AVF (PRT-201 treatment zone)
- Brachiocephalic (BC) AVF
  - 2nd choice
    - Eliminates AVF sites in forearm
    - High flow can lead to steal, heart failure and central stenosis
  - Lower failure rate than RC AVFs
    - Larger vessels and higher blood flow
    - Only 26-50% of stenoses at or near AVF

"It is a tragedy for patients and caretakers alike to exhaust anatomic sites prematurely by initially bypassing more distal sites."

- Kidney Disease Outcomes Quality Initiative



Most Radiocephalic AVFs Will Fail Within One Year of Surgical Placement

- Approximately 50% fail to increase in diameter and blood flow (maturation failure)
- Approximately 70% thrombose or require an intervention (primary unassisted patency loss)
- Approximately 35% are abandoned (secondary patency loss)
- Patients frequently endure repeated procedures and/or surgeries that also have negative impact on payers and providers
- Primary cause of AVF failure is neointimal hyperplasia, primarily at or near AVF site

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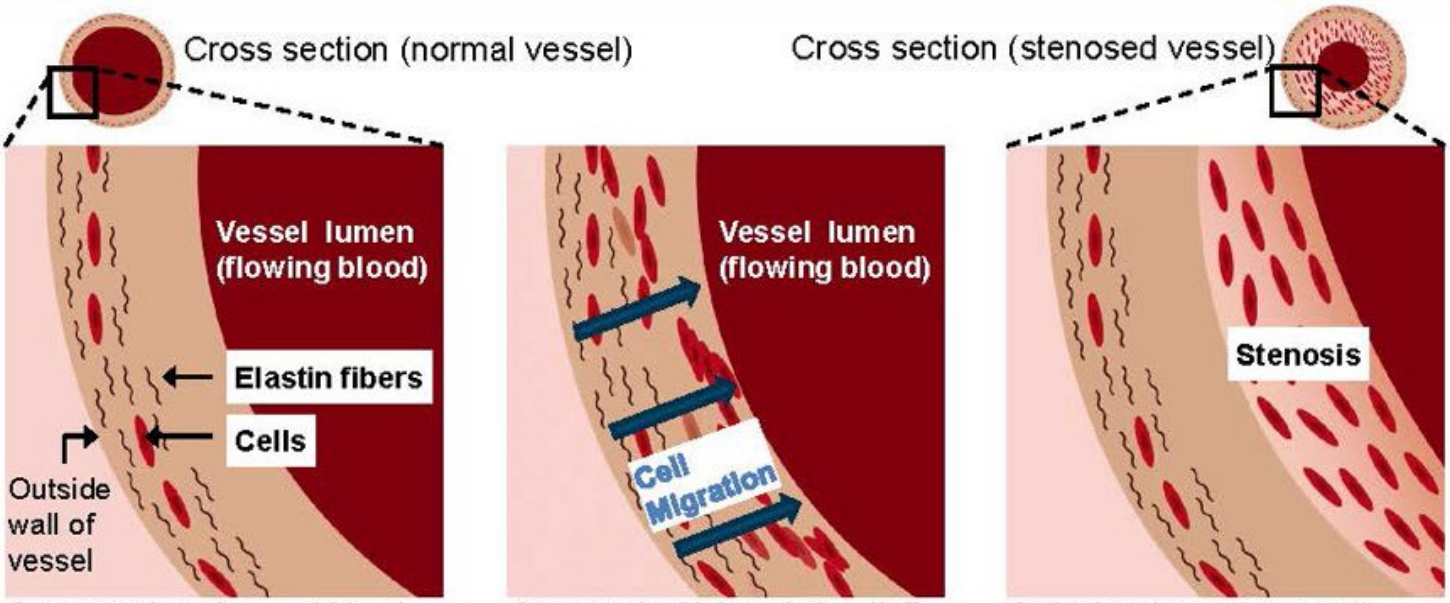
Neointimal Hyperplasia Causes Stenosis Formation



Cross section of normal blood vessel

As a result of injury during AVF surgical placement, cells multiply and migrate to the vessel lumen

Cell migration to the vessel lumen results in stenosis formation, reducing blood flow

We believe that PRT-201, a recombinant elastase, generates elastin fragments in the vessel wall and may inhibit cell migration and stenosis formation.

PROTEON Therapeutics

Single Treatment of PRT-201 Improved AVF Outcomes

- A single, local application of PRT-201, a recombinant elastase, indicated improvement in key measures of AVF function in Phase 2
  - Prolonged primary and secondary patency
  - Increased maturation
  - Reduced rate of procedures to restore/maintain patency
- **Only active at site of application with no systemic effects observed**

AVF Phase 2 Results

Successful Phase 2 Trial of PRT-201 in AVF

Design

Randomized, double-blind, placebo-controlled

Patients

151 treated pre-dialysis or hemodialysis receiving radiocephalic or brachiocephalic AVF

Doses

Placebo, 10, and 30 mcg (1:1:1)

Endpoints

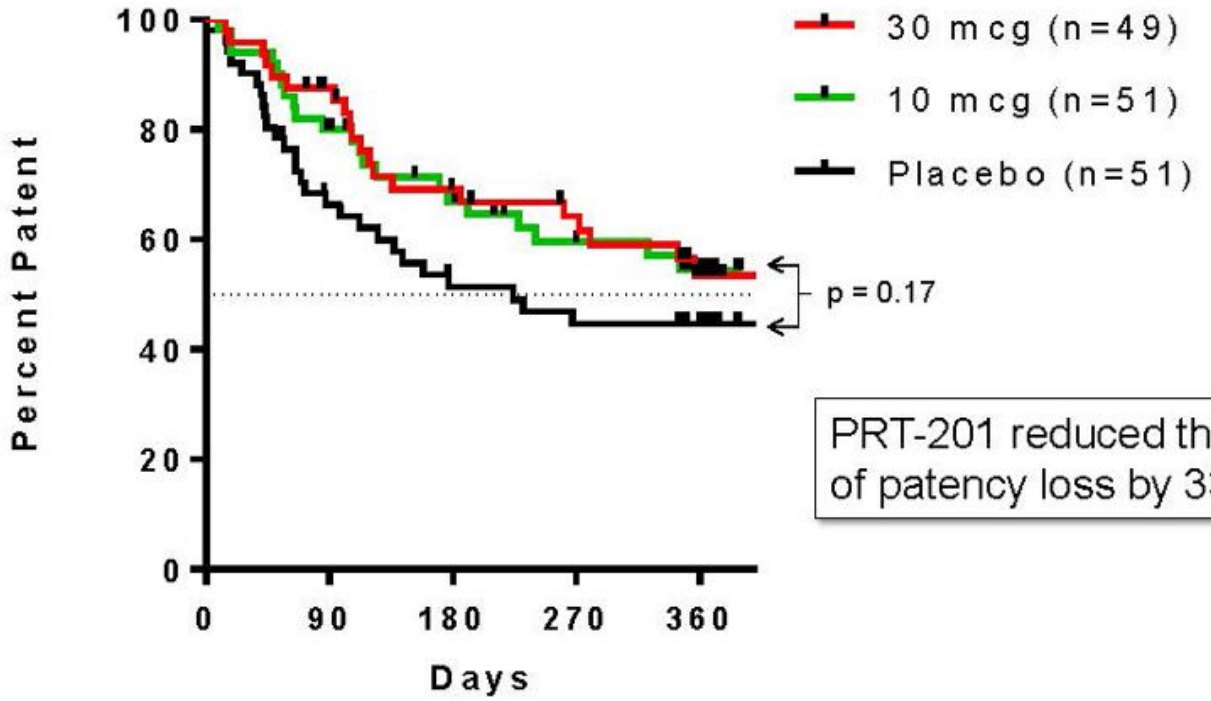
Primary: Primary Unassisted Patency (time to thrombosis or first intervention)

Secondary: Unassisted Maturation, Secondary Patency, Usability and AVF Stenosis

Timing

Enrollment: April 2011 to November 2011 with each patient followed for 12 months

PRT-201 Prolonged Primary Unassisted Patency



PRT-201 reduced the risk of patency loss by 33-41%[1]

[1] 30 mcg group - All AVFs. Hazard ratio 0.67 (Log-rank, p=0.170) and 0.59 (Cox, p=0.098) Primary unassisted patency is time from AVF surgery to first failure event (thrombosis or procedure to restore or maintain patency).

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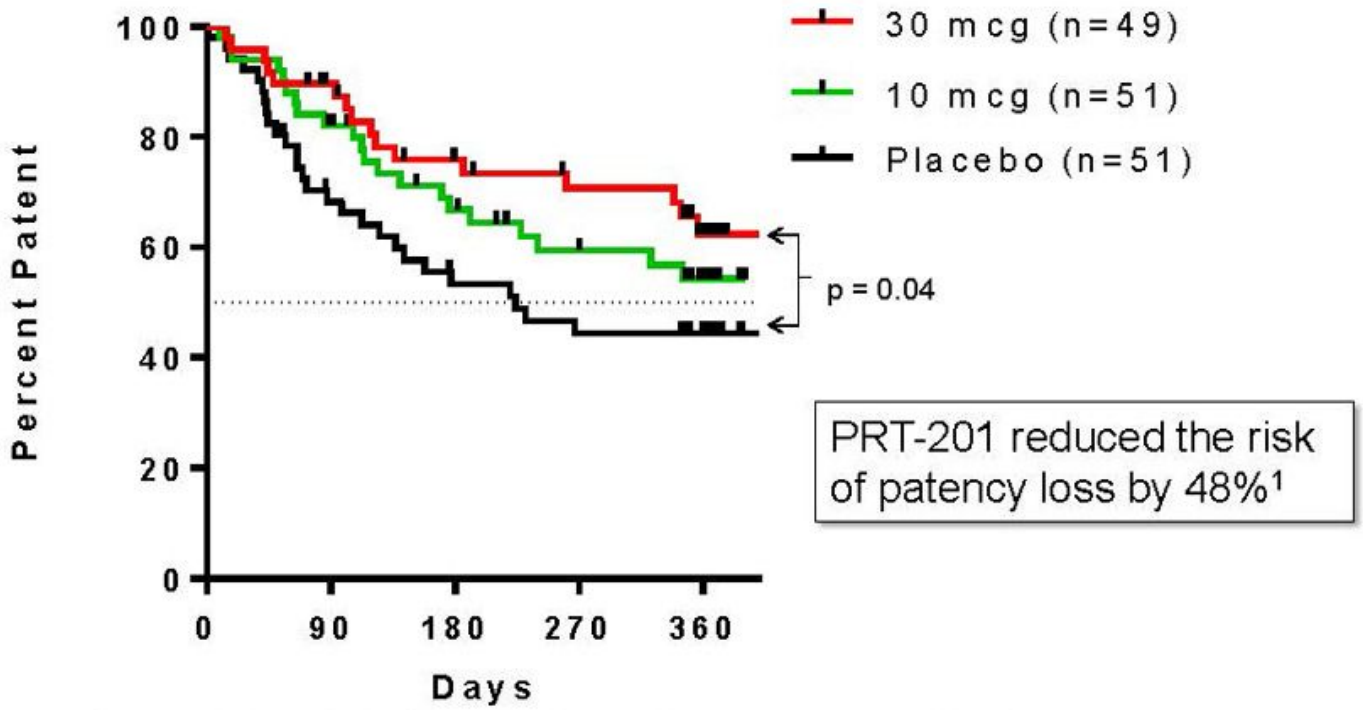
Excluding Central Stenosis Further Highlights PRT-201 Dose Effect



PRT-201 reduced the risk of patency loss by 48%[1]

Non-prespecified analysis excludes 7 events of central stenosis as a cause of patency loss (1 in placebo, 1 in 10 mcg, 5 in 30 mcg) but keeps the patients in the analysis.

[1]30 mcg group. Hazard ratio 0.52 (Log-rank, p=0.04). Dose trend p=0.03 (Log-rank).

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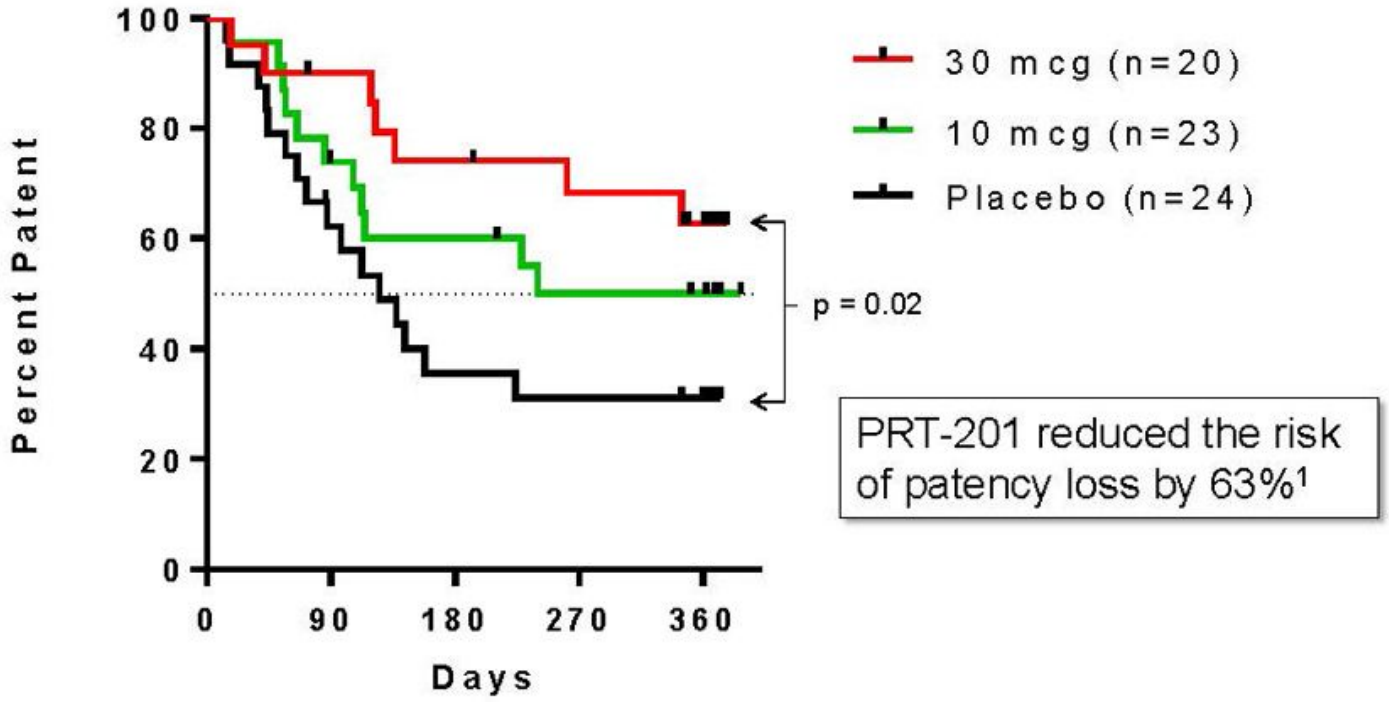
PRT-201 Increased >3x Median Days of Primary Patency in Radiocephalic AVFs



PRT-201 reduced the risk of patency loss by 63%[1]

Non-prespecified

[1] 30 mcg group. Hazard ratio 0.37 (Log-rank, p=0.02). Dose trend p=0.02 (Log-rank).

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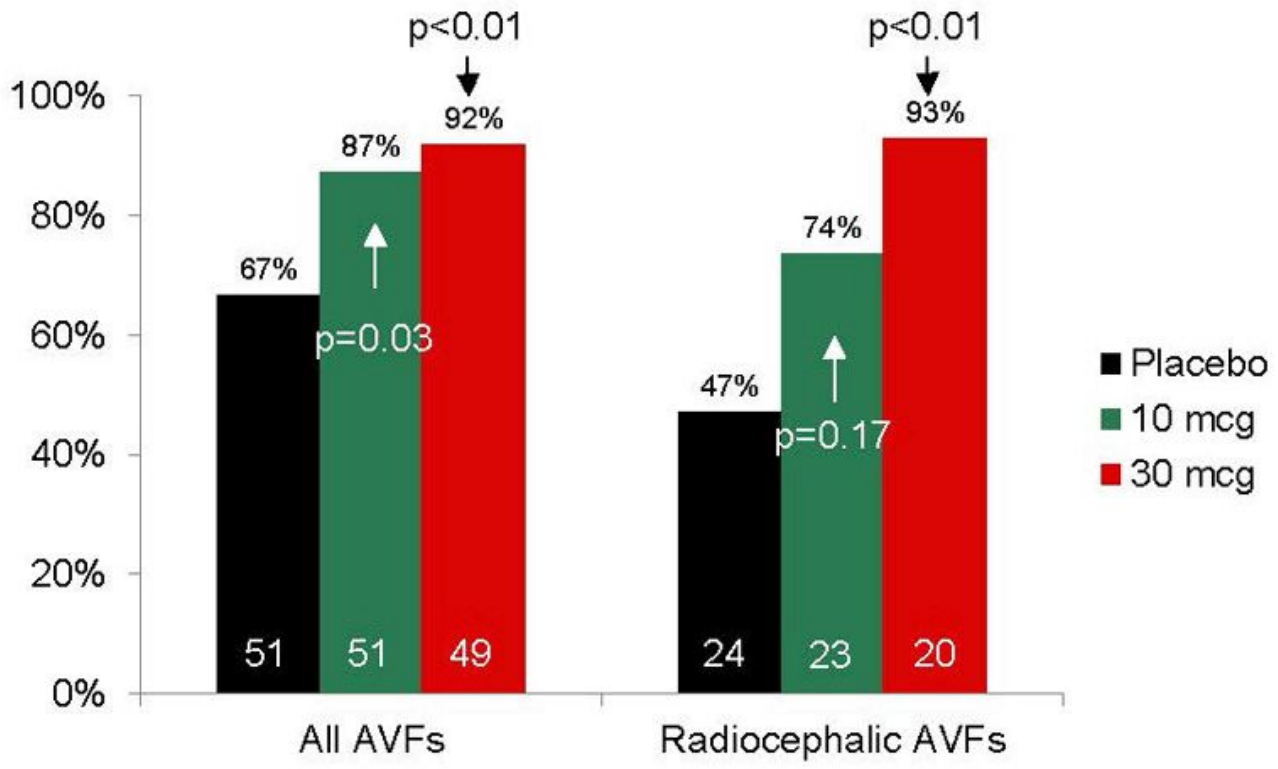
PRT-201 Increased Unassisted Maturation at 3 Months



Robbin criteria for maturation: Vein diameter ≥ 4 mm and blood flow volume ≥ 500 mL/min.

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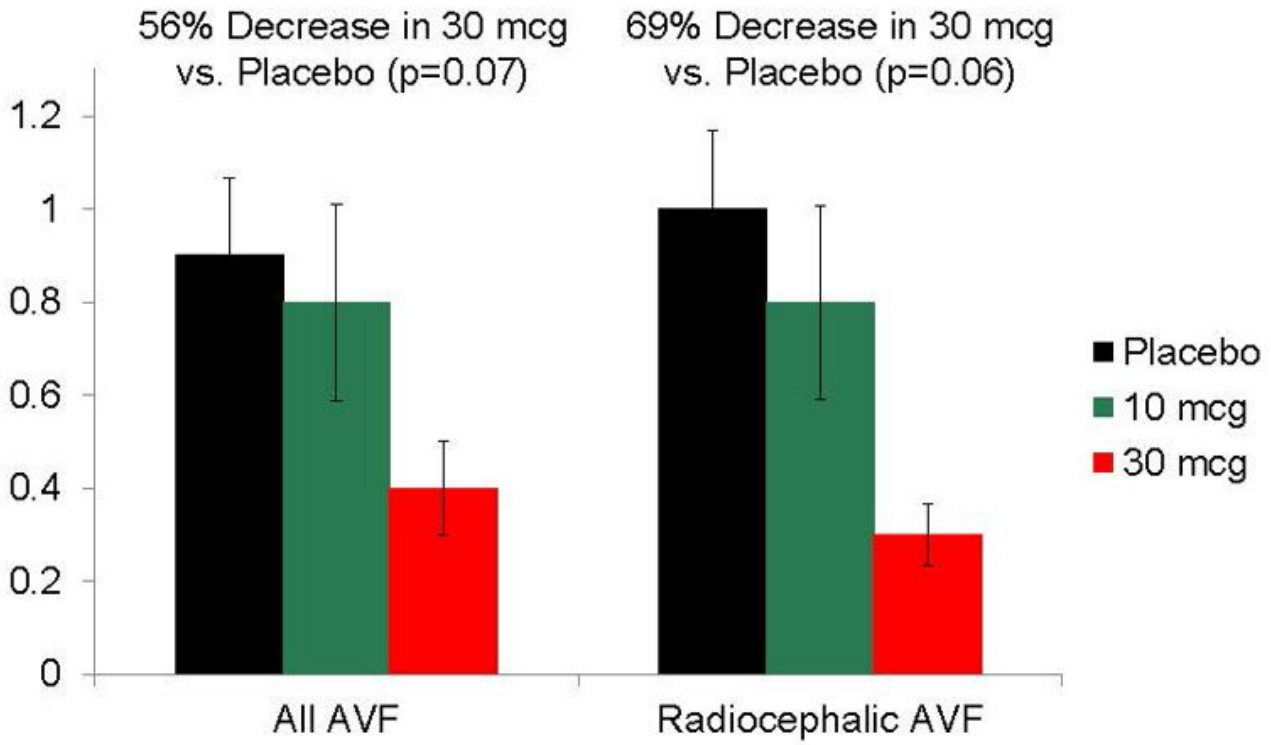
Fewer Procedures to Restore or Maintain Patency



Mean rate of procedure days per patient per year ± Standard Error
Procedure includes angioplasty, surgical patch angioplasty, stent, thrombectomy and thrombolysis.

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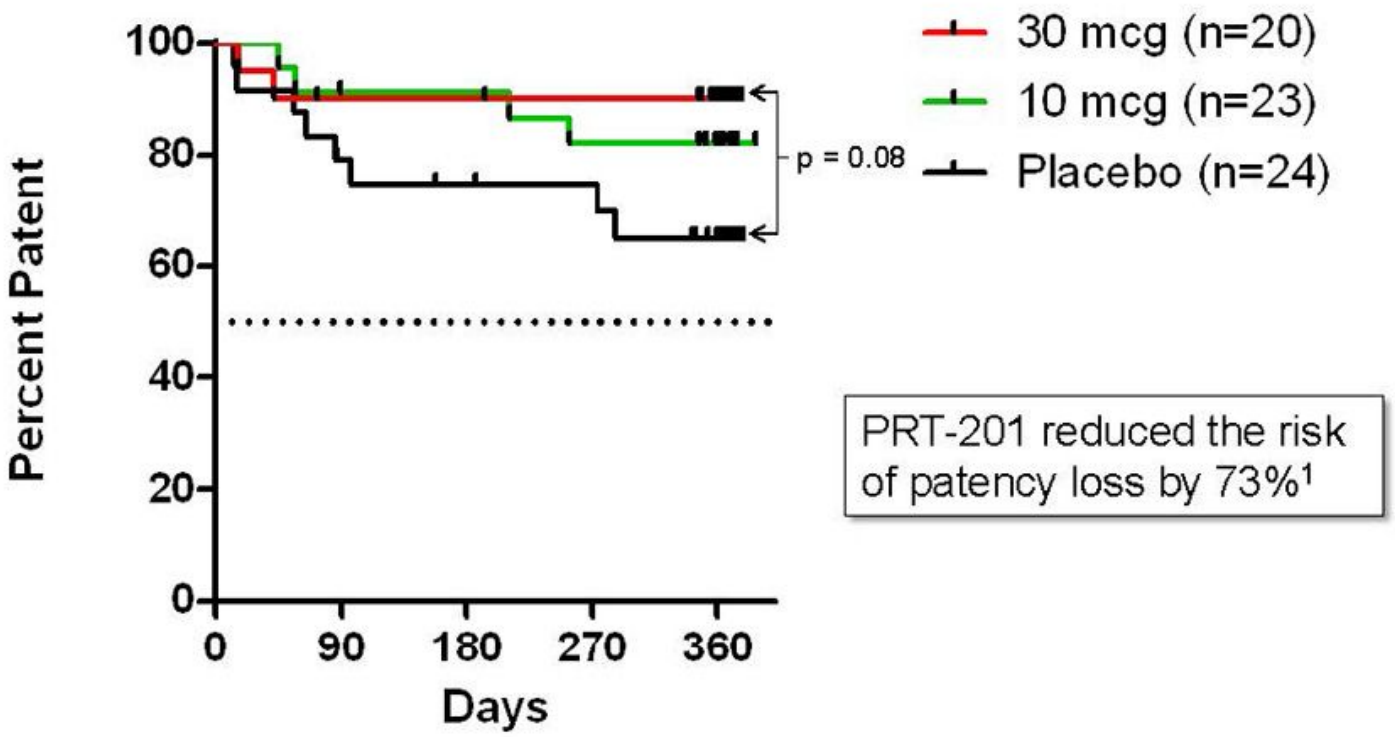
PRT-201 Prolonged Secondary Patency in Radiocephalic AVFs



PRT-201 reduced the risk of patency loss by 73%[1]

Non-prespecified. Secondary patency is time from the AVF surgery to AVF abandonment

[1] 30 mcg group. Hazard ratio 0.27 (Log-rank, p= 0.08). Dose trend p=0.06 (Log-rank).

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PRT-201 Phase 2 Safety Profile

- No meaningful physical examination findings
- No meaningful changes on safety laboratories (chemistry, hematology, coagulation)
- No evidence of immunogenicity
- Adverse events consistent with medical conditions experienced by kidney disease patients undergoing AVF surgery
- Adverse events comparable for PRT-201 and placebo

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Phase 3 Plan

End of Phase 2 Meeting with FDA: Confirmed Phase 3 Program

- Confirmed that Phase 3 primary and secondary endpoints are same as Phase 2 trial
  - Primary efficacy endpoint: primary unassisted patency
  - Secondary efficacy endpoint: secondary patency (i.e. AVF abandonment)
- Phase 3 trials studying 30 mcg dose in radiocephalic AVFs
- Patient numbers sufficient to establish safety profile for BLA
- Preclinical program complete

Phase 3 Trial Design: Endpoints Same as Phase 2

Design	Randomized, double-blind, placebo-controlled
Patients	300 patients in U.S. undergoing placement of a radiocephalic AVF and each patient followed for 12 months
Doses	PRT-201 30 mcg vs. placebo (2:1)
Endpoints	Primary: Primary Unassisted Patency Secondary: Secondary Patency Tertiary: Unassisted Maturation, Rate of Procedures, Use for Hemodialysis

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Strong Power for Phase 3 Trial

- Primary endpoint (primary unassisted patency)
  - 96% power assuming 2x improvement in median patency
  - If 2x improvement observed, p=0.0001
  - Observed >3x improvement in Phase 2 in radiocephalic AVFs[1]
- Secondary endpoint (secondary patency)
  - 97% power assuming a 20% increase in secondary patency at one year (i.e. 65% to 85%)
  - Observed 25% increase in Phase 2 in radiocephalic AVFs[1]

[1] Non-prespecified.

Commercial / Finance / Milestones

The Majority of Radiocephalic AVFs Suffer Patency Loss in the First Year

- Within 1 year of surgical creation of a radiocephalic AVF
  - Approximately 70% will lose primary unassisted patency
  - Approximately 35% will lose secondary patency (abandonment)
- The rate of patency loss is steadily worsening
  - AVFs being placed in higher risk patients to avoid alternatives
  - Determined effort to keep AVFs functioning to avoid catheter exposure (CMS Fistula First Initiative)
- Patency loss must be addressed urgently
  - Patients are either unable to dialyze or at risk of reduced dialysis adequacy
  - Risk of thrombosis, abandonment and catheter exposure
- Impact on patients, providers and payers is severe

PROTEON Therapeutics

Commercial Opportunity

- Easily identified, growing patient population globally
  - ~130,000 new AVF placements annually in US, of which approximately 40% are radiocephalic
- Unmet medical need
  - No current therapeutic drugs; few in development
  - Radiocephalic AVFs can cost on average $17,000 to maintain in year 1
- Expect compelling safety and efficacy data in Phase 3
  - Clinically important endpoints
  - Locally administered protein, excellent safety profile with AEs comparable to placebo
- Expect attractive reimbursement and coverage environment
  - Excluded from ESRD payment bundle
  - Primarily Medicare outpatient ➔ Part B reimbursement coverage at launch
- Expect 75-100 US representatives to cover ~2,800 surgeons

"Loss of patency limits hemodialysis delivery, extends treatment times and, in too many cases, results in underdialysis that leads to increased morbidity and mortality."

- Kidney Disease Outcomes Quality Initiative

PROTEON Therapeutics

Strong IP Estate

Family	Description	Status / Commentary
1	• Uses of elastases for increasing diameter of biological conduits (including arteries and veins obstructed by intimal hyperplasia or stenosis). • Uses of elastases to treat vascular access sites to prolong hemodialysis access	• First nonprovisional filing in 2000 • 7 patents issued in US • 2 issued EP patents • Pending in Japan
2	• Use of elastases for compliance matching at vascular anastomoses	• First nonprovisional filing in 2004 • Issued in US, JP, AU
4	• 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	• First nonprovisional filing in 2008 • Issued in US, EP, NZ, IL, MX; encouraging search reports and office actions in other geographies • Project patent term extension into 2032

Patent protection into 2029 in US; through 2028 in EU
(2032 US/EU with expected extensions)

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Commercial-Ready Drug Supply Chain

- Drug substance
  - Manufactured at Lonza, Switzerland; one batch generates >1 million doses
  - Current stability at >4 years and going
- Drug product
  - Using new formulation. Expect manufacturing at Jubilant Hollister-Stier in U.S.
  - Release testing at PPD
  - Current cGMP stability at >6 months and ongoing
- Intend to use 3PL solution (e.g., McKesson, AmerisourceBergen, etc.) for drug distribution, storage, etc.

PROTEON Therapeutics

Strong Financial Position

- $85.3 million of cash, cash equivalents and marketable securities at November 30, 2014
  - Includes $62.5 million of IPO net proceeds
  - Existing funds sufficient to fund operations into 2018
  - In Q2 2014, closed on $25 million led by Abingworth, Deerfield and Pharmstandard with all existing VC investors participating
- 16.4 million shares outstanding immediately after IPO (an additional 1.2 million stock options outstanding)
- Ticker: PRTO (Nasdaq)

PROTEON Therapeutics

Major Timeline Assumptions

- Clinical trial and CMC timing
  - First Phase 3 trial started and anticipate data in Q1 2017
  - Second Phase 3 trial start expected H1 2015
  - Initiate CMC work expected Q4 2014
- If first Phase 3 trial has sufficiently low p-value, may meet with FDA to discuss filing for FDA approval prior to completion of second Phase 3

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