

# Proteon Therapeutics, Inc. (PRT0)

Presents Encouraging Results from Long-Term Study

## MARKET DATA

Price	\$10.90
52-Week Range:	\$8.57 - \$12.65
Shares Out. (M):	0.2
Market Cap (\$M):	\$2.2
Average Daily Vol. (000):	14.0
Cash (M):	\$22
Cash/Share:	\$91.03
Enterprise Value (M):	\$290
Float (M):	15.0
LT Debt (M):	\$0
Short Interest:	0.6%

Source: Thomson Reuters and JMP Securities LLC

**MARKET OUTPERFORM** | Price: \$10.90 | Target Price: \$22.00

## INVESTMENT HIGHLIGHTS

**Proteon Therapeutics presents positive results from a long-term analysis of vonapanitase; we reiterate our Market Outperform rating and \$22 price target, based on a synthesis of discounted cash flow and compound annual growth valuation methodologies.** In a poster presented at the National Kidney Foundation's 2015 Spring Clinical Meeting, PRT0 presented results from the long-term follow-up of patients treated from the Phase II randomized, double-blind placebo controlled study of vonapanitase in patients with chronic kidney disease undergoing the surgical creation of an arteriovenous fistula for hemodialysis. The results of this three-year study are in line with the previous results, and demonstrated increases in specific outcomes, including a 76% reduction in the risk of secondary patency loss in the high dose cohort ( $p=0.046$ ) for patients receiving a radiocephalic arteriovenous fistula. We are also encouraged by the significant decrease in the number of procedures to restore or maintain patency, where radiocephalic patients showed an 80% decrease in procedures ( $p=0.05$ ). These results support the potential for success in the ongoing Phase III trial, with data expected in 2017.

**Highlights of the data.** As we detailed in our initiation report (11/17/14), initial results from the one-year study were encouraging and laid the foundation for advancement into Phase III studies in patients undergoing the creation of radiocephalic arteriovenous fistula (RC AVF) for hemodialysis. The current data follows the 150 trial participants out to three years and examines parameters including Phase III primary endpoint of primary unassisted patency (PP) and secondary patency (SP). Encouragingly, as shown in Figures 3 and 4, PP in the RC AVF cohort showed a 63% reduction in risk ( $p=0.02$ ) in subjects on high dose treatment. Loss of SP in RCF patients also became significant over the course of the study, initially reported as a 67% reduction in loss of secondary patency ( $p=0.08$ ), but now has matured to  $p=0.046$ , suggesting that patients in the placebo group continue to have greater abandonment of their fistulas, as compared to those in the 30 mcg treatment group (Figure 4). We are also encouraged by the compelling value proposition presented to the healthcare system. The study demonstrated an 80% decrease in procedures to restore patency in the RC AVF group (Figure 2), reflecting the potential long-term savings that can result from vonapanitase use. Studies have shown that procedures to maintain RC AVF's can cost payers more than \$43,000 over the course of two years. Taken in its totality, the long-term follow up data for vonapanitase suggest meaningful clinical and economic benefits.

FY DEC		2014A	2015E	2016E
Revenue (\$M)	1Q	--	\$0.0	--
	2Q	\$0.0	\$0.0	--
	3Q	\$2.9	\$0.0	--
	4Q	\$0.0	\$0.0	--
	FY	\$2.9	\$0.0	\$0.0
EPS	1Q	--	(\$0.52)	--
	2Q	(\$1.30)	(\$0.56)	--
	3Q	(\$31.03)	(\$0.59)	--
	4Q	\$1.38	(\$0.62)	--
	FY	(\$3.16)	(\$2.29)	(\$4.18)

Source: Company reports and JMP Securities LLC

## STOCK PRICE PERFORMANCE



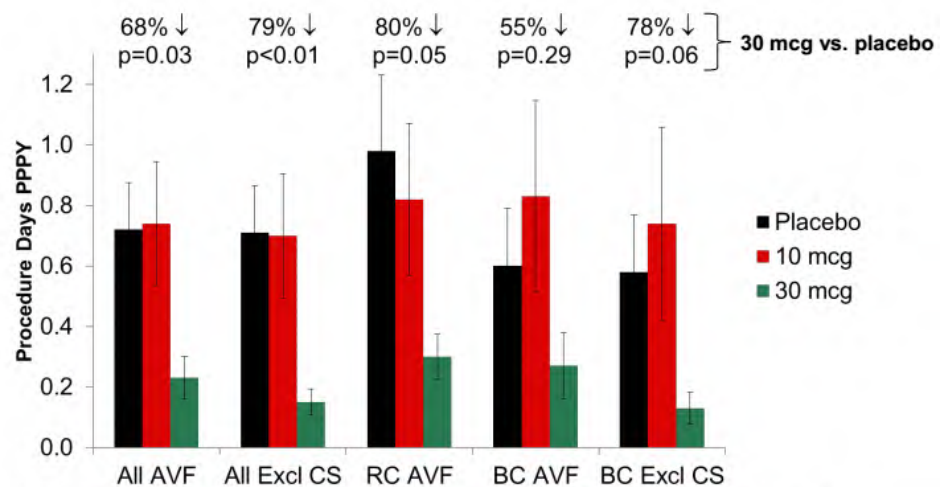
**Proteon Therapeutics is focused on the development of vonapanitase (PRT-201) for the improvement of vascular access outcomes in patients undergoing radiocephalic surgery in preparation for hemodialysis.** Current guidelines set forth by KDOQI, CMS, and the Fistula First Initiative state that arteriovenous fistulas (AVF) is the preferred method of vascular access, with significantly reduced infections and morbidity commonly associated with arteriovenous grafts or temporary catheter use. According to Proteon and JMP estimates, currently over 130,000 AVF surgeries are performed each year in the U.S., with over half of the procedures failing due to neointimal hyperplasia. There are no current therapies to improve AVF success rates, which, in our view, is supportive of a >\$1 billion market opportunity.

**FIGURE 1. Upcoming Potential Catalysts**

Timing	Program	Catalyst
1H15E	PRT-201	Initiate second Phase III clinical trial in U.S.
2H15E	PRT-201	Phase I data in PAD
1Q17E	PRT-201	.Top-line Data from Phase III

Source: Company Presentations

**FIGURE 2. Procedures to Restore/Maintain Patency Over 3+ Years**

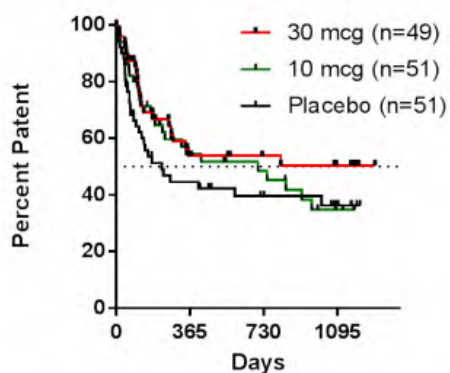


Mean number of days with a procedure to restore or maintain patency (thrombectomy, thrombolysis, percutaneous transluminal angioplasty, stent placement, or surgical revision). PPPY = per patient per year. +/- Standard Error.

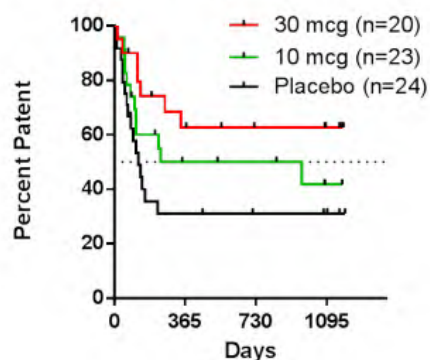
Source: JMP Securities LLC, Company Reports

**FIGURE 3. Primary Unassisted Patency 3+ Years****All Subjects**

37% reduction ( $p=0.10$ ) in the risk of primary patency loss for all subjects (30 mcg)

**Radiocephalic AVFs**

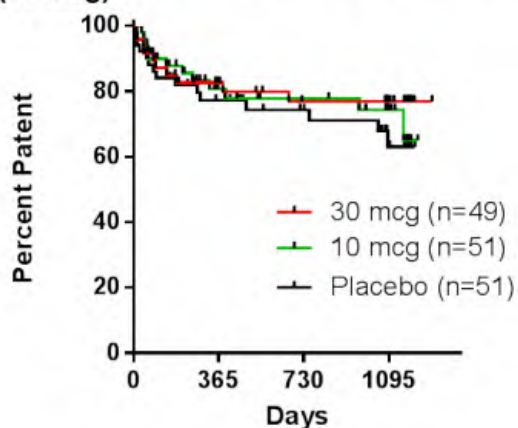
63% reduction ( $p=0.02$ ) in the risk of primary patency loss for RC AVF subjects (30 mcg)



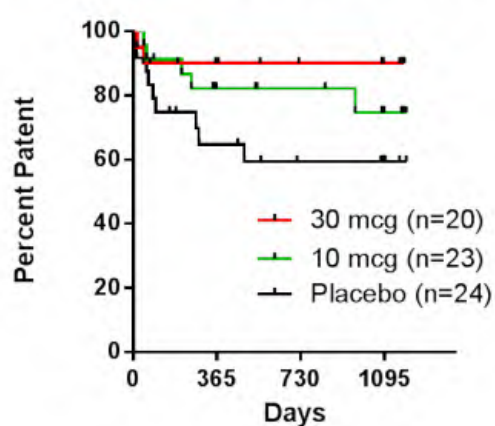
Source: JMP Securities LLC, Company Reports

**FIGURE 4. Secondary Patency 3+ Years****All Subjects**

23% reduction ( $p=0.33$ ) in the risk of secondary patency loss for all subjects (30 mcg)

**Radiocephalic AVFs**

76% reduction ( $p=0.046$ ) in the risk of secondary patency loss for RC AVF subjects (30 mcg)



Source: JMP Securities LLC, Company Reports

FIGURE 5. Income Statement

Proteon Income Statement	2013A	1Q15	2Q15	3Q15	4Q15	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
<b>Product Sales and Royalties</b>																
PRT201 - US Sales		\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 91.2	\$ 141.6	\$ 127.0	\$ 202.2	\$ 376.7	\$ 498.1	\$ 560.4	\$ 580.0
PRT201 - EU Sales									-	89.2	133.2	192.8	259.8	445.6	593.3	658.4
<b>Total Sales</b>	-	-	-	-	-	-	-	-	<b>91.2</b>	<b>230.8</b>	<b>260.2</b>	<b>395.0</b>	<b>636.5</b>	<b>943.7</b>	<b>1,153.7</b>	<b>1,238.4</b>
PRT201 - JPN Royalties									-	-	3.4	4.1	6.1	8.1	14.3	18.1
Deferred Revenue Realized																
<b>Total Revenues</b>	-	-	-	-	-	-	-	-	<b>91.2</b>	<b>230.8</b>	<b>263.5</b>	<b>399.1</b>	<b>642.6</b>	<b>951.8</b>	<b>1,168.0</b>	<b>1,256.4</b>
% change																
<b>COGS</b>	-	-	-	-	-	-	-	-	10.9	27.69	31.2	43.4	63.6	94.4	115.4	123.8
% of PRT201 Total sales		0.0%	0.0%	0.0%	0.0%				12.0%	12.0%	12.0%	11.0%	10.0%	10.0%	10.0%	10.0%
<b>Gross Profit</b>	-	-	-	-	-	-	-	-	80.3	203.1	232.3	355.7	579.0	857.4	1,052.6	1,132.6
<b>Research and development</b>	4.0	5.0	5.5	5.8	6.0	22.3	43.5	86.97	120.02	144.02	158.42	177.44	195.18	214.70	234.02	252.74
% change							95.0%	100.0%	38.0%	20.0%	10.0%	12.0%	10.0%	10.0%	9.0%	8.0%
% of Total revenues									131.5%	62.4%	60.1%	44.5%	30.4%	22.6%	20.0%	20.1%
<b>Selling, general and administrative</b>	3.1	1.7	1.8	1.8	2.0	7.2	11.6	15.6	21.1	34.8	38.3	49.7	67.2	90.7	108.8	125.1
% change	49.7%					330.4%	60.0%	35.0%	35.0%	65.0%	10.0%	30.0%	35.0%	35.0%	20.0%	15.0%
% of Total revenues									23.1%	15.1%	14.5%	12.5%	10.5%	9.5%	9.3%	10.0%
<b>Total operating expenses</b>	7.1	6.7	7.3	7.6	8.0	29.5	55.1	102.6	141.1	178.8	196.7	227.2	262.3	305.4	342.8	377.9
% net revenue									155%	77%	75%	57%	41%	32%	29%	30%
<b>Operating Profit (Loss)</b>	(7.1)	(6.7)	(7.3)	(7.6)	(8.0)	(29.5)	(55.1)	(102.6)	(60.8)	24.3	35.6	128.5	316.6	552.1	709.8	754.8
Margin(%)									-66.7%	10.5%	13.5%	32.2%	49.3%	58.0%	60.8%	60.1%
Investment Income	0.0	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	0.3	0.5
Interest Expense	(0.9)	(0.9)	(0.9)	(0.9)	(0.9)	(3.4)										
Other income (expense)	0.1					-										
<b>Total other income</b>	(0.8)	-	-	-	-	(3.39)	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	0.3	0.5
<b>Pretax income</b>	(7.9)	(6.7)	(7.3)	(7.6)	(8.0)	(29.5)	(55.0)	(102.5)	(60.8)	24.3	35.6	128.5	316.7	552.2	710.1	755.3
Provision for income taxes						-	-	-	-	3.6	8.9	45.0	110.8	193.3	248.5	264.4
% Tax Rate						0.0%	0.0%	0.0%	0.0%	15.0%	25.0%	35.0%	35.0%	35.0%	35.0%	35.0%
<b>Net profit (loss) and comprehensive income</b>	(7.9)	(6.7)	(7.3)	(7.6)	(8.0)	(29.5)	(55.0)	(102.5)	(60.8)	20.6	26.7	83.6	205.9	359.0	461.6	490.9
After Tax Margin(%)									-66.6%	8.9%	10.1%	20.9%	32.0%	37.7%	39.5%	39.1%
Accretion of redeemable convertible preferred stock to redemption value	(6.1)															
<b>Net profit (loss) attributable to common shareholders</b>	(14.0)	(6.7)	(7.3)	(7.6)	(8.0)	(29.5)	(55.0)	(102.5)	(60.8)	20.6	26.7	83.6	205.9	359.0	461.6	490.9
Basic shares outstanding	4.6	12.9	12.9	12.9	12.9	12.9	13.2	13.4	20.1	20.5	21.0	21.4	21.8	22.2	22.7	23.1
Diluted shares outstanding	4.6	12.9	12.9	12.9	12.9	12.9	13.2	13.4	20.1	21.6	22.0	22.4	22.9	23.3	23.8	24.3
<b>Basic GAAP EPS</b>	\$ (1.73)	\$ (0.52)	\$ (0.56)	\$ (0.59)	\$ (0.62)	\$ (2.29)	\$ (4.18)	\$ (7.64)	\$ (3.02)	\$ 1.01	\$ 1.28	\$ 3.91	\$ 9.44	\$ 16.14	\$ 20.35	\$ 21.22
<b>Diluted GAAP EPS</b>	\$ (1.73)	\$ (0.52)	\$ (0.56)	\$ (0.59)	\$ (0.62)	\$ (2.29)	\$ (4.18)	\$ (7.64)	\$ (3.02)	\$ 0.96	\$ 1.21	\$ 3.72	\$ 8.99	\$ 15.37	\$ 19.38	\$ 20.21

Source: JMP Securities LLC, Company Reports

## Company Description

Proteon is a late-stage biopharmaceutical company engaged in the development of novel therapeutics to treat patients with vascular and renal disease. The company is developing a novel therapy to improve the outcomes of vascular access surgeries for dialysis patients. The company's lead product, PRT-201, is a recombinant human elastase solution applied to the exposed blood vessel during a surgical procedure to prevent remodeling of the blood vessel that can reduce vascular diameter and blood flow, resulting in high failure rates and fallback to ineffective and high-risk access methods, such as catheters. PRT-201 has completed Phase II clinical development, and demonstrated clinical efficacy in a subset of vascular access procedures known as radiocephalic arteriovenous fistulas (AVF). We estimate greater than 137,000 AVF procedures will be performed in the U.S. in 2014. The company plans to initiate the first of two Phase III trials by the end of 2014, and a second Phase III trial by 1H2015.

## Investment Risks

Potential risks to our price target include, but are not limited to, clinical, regulatory, commercial and competitive factors.

**Clinical and regulatory.** If PRT-201 were to fail to show adequate efficacy in its Phase III trials, the FDA may not provide marketing approval in the U.S. If PRT-201 were to demonstrate unexpected serious adverse effects, this would also prevent market approval or potentially limit the scope of the intended market. Additionally, if the FDA and EMEA do not approve PRT-201, Proteon's stock price would likely suffer.

**Partnering.** Proteon plans to commercialize PRT-201. If it becomes necessary for it to develop and market any of its programs due to the inability to garner a partner, it may be difficult to develop an internal commercial structure. Management has limited experience in commercialization and marketing activities. In early 2014, Novartis declined its option to buy PRT0 for \$550MM.

**Financial.** PRT0 currently derives revenue capital raised through financing. The company sold ~6,110,000 shares in October 2014, raising gross proceeds of ~\$61.1MM. As a result, it is projected to finish 4Q14 with ~\$60.3MM in cash, equivalents, and marketable securities. We expect this funding to be able to carry the company to 2017. Like most non-profitable biotechnology companies, PRT0 will likely need to seek additional financing, exposing current investors to dilutive risk.

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JMP Securities expects to receive OR intends to seek compensation for investment banking services from Proteon Therapeutics, Inc. in the next 3 months.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

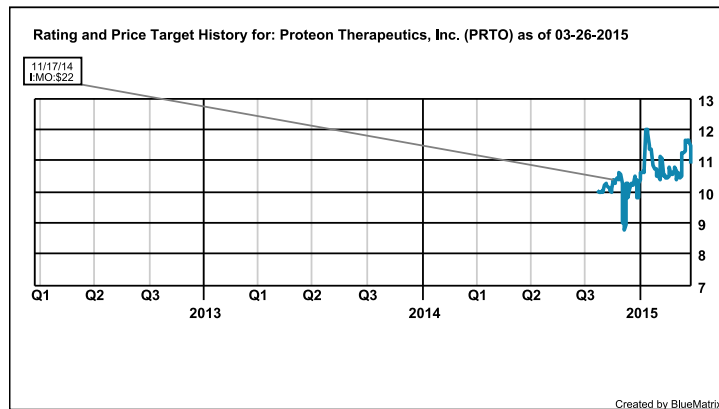
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months				
				Regulatory Equivalent	# Co's Under Coverage	% of Total	% of Co's With This Rating	
MARKET OUTPERFORM	Buy	285	63.62%	Buy	285	63.62%	89	31.23%
MARKET PERFORM	Hold	153	34.15%	Hold	153	34.15%	21	13.73%
MARKET UNDERPERFORM	Sell	8	1.79%	Sell	8	1.79%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL:		448	100%		448	100%	110	24.55%

### Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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