

August 12, 2015

HEALTHCARE/BIO AND SPECIALTY PHARMACEUTICALS

Stock Rating:
OUTPERFORM

12-18 mo. Price Target \$18.00
PRTO - NASDAQ \$14.33

3-5 Yr. EPS Gr. Rate NA
52-Wk Range \$20.00-\$8.57
Shares Outstanding 15.0M
Float 5.5M
Market Capitalization \$235.7M
Avg. Daily Trading Volume 42,909
Dividend/Div Yield NA/NM
Book Value \$2.42
Fiscal Year Ends Dec
2015E ROE NA
LT Debt NA
Preferred \$123.9M
Common Equity \$(109)M
Convertible Available No
Trading range is as of 10/22/14 IPO.

EPS Diluted	Q1	Q2	Q3	Q4	Year	Mult.
2013A	--	--	--	--	(3.07)	NM
2014A	(0.65)	(0.65)	(31.03)	0.59	(3.16)	NM
2015E	(0.28)A	(0.31)	(0.35)	(0.39)	(1.32)	NM
2016E	--	--	--	--	(2.45)	NM

Proteon Therapeutics

Proteon Initiates Second Phase 3 Study of PRT-201 in AVF

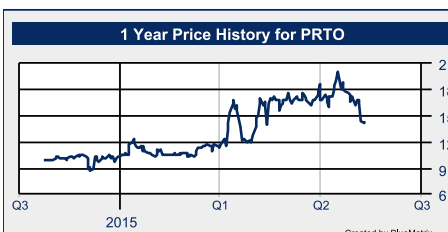
SUMMARY

Proteon has initiated the second Phase 3 trial to evaluate the safety and efficacy of PRT-201 (vonapanitase) in prolonging patency and reducing the failure of vascular access in patients with chronic kidney disease undergoing surgical creation of a radiocephalic arteriovenous fistula (AVF). While initiation of the trial is slightly after our prior 2Q15 expectation, we continue to anticipate Proteon to apply for approval in 3Q17 based on top line data from the first Phase 3 trial, whose enrollment is expected to be completed by YE2015 (data ~1Q17). Based on the clinical efficacy of PRT-201 in improving the patency and maturation of radiocephalic AVF observed in the Phase 2 studies, we remain optimistic for success in Phase 3.

KEY POINTS

- The first patient has been treated in the second Phase 3 trial testing 30µg PRT-201 in improving the patency of AVF in CKD patients. The Phase 3 trials will each enroll 300 patients in a double-blind RCT across 40 medical centers in the US and Canada.
- The primary efficacy endpoint for the trials is the time from AVF creation until thrombosis or a procedure to maintain patency through 12 months. The trial will also investigate secondary patency, i.e. the time between AVF creation and abandonment, as a secondary endpoint.
- Recall that the first Phase 3 study began in 3Q14 (data expected ~1Q17). We expect Proteon to file for US approval in 3Q17 utilizing data from the first Phase 3 study given our expectation that the trial is well powered to demonstrate robust efficacy, if successful.
- **We reiterate Outperform and \$18 PT.** Based on clinical efficacy of PRT-201 in increasing patency of radiocephalic AVF fistulas at 1 and 3 years post procedure, as well as fistula maturation, we see attractive risk/reward around the Phase 3 readout expected in early 1Q17.

Stock Price Performance



Company Description

Proteon Therapeutics is a development stage biopharmaceutical company focused on therapies for treating patients with renal and vascular diseases.

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Exhibit 1: Anticipated Upcoming Milestones for Proteon Therapeutics (PRT0)

Expected Date	Event Description
Aug-15	Initiate second Phase 3 trial for vonapanitase in radiocephalic AVF
4Q15	Follow-up data from Phase 1 PAD study of vonapanitase (PRT-201)
2H15	Complete enrollment in first Phase trial for vonapanitase in radiocephalic AVF
2016/2017	Potential business development relating to ex-US rights of vonapanitase
1Q17	Potential release of top-line data from first Phase 3 vonapanitase study
3Q17	Potential filing for U.S. approval of vonapanitase based on first Phase 3 study
1H18	Potential approval of vonapanitase in Radiocephalic AVF placements (on first study)
2Q18	Potential release of top-line data from second Phase 3 vonapanitase study
2H18	Anticipate launch of vonapanitase in U.S. if approved on results of first study
2H19	Anticipate launch of vonapanitase in U.S. if results of both Phase 3 studies are required

Source: Company Documents and Oppenheimer & Co.

Investment Thesis

Our bullish investment thesis stems from our belief that vonapanitase (PRT-201) is poised to become standard of care during hemodialysis access procedures if Phase 3 clinical studies are successful. In our view, the company's current market valuation does not fully reflect the full potential of PRT-201 to take meaningful share in the sizable hemodialysis access market. While the clinical trial risk associated with Phase 3 is appreciable, we believe PRT-201 shares represent a significantly favorable risk/reward proposition for investors with appropriate risk and time horizons.

Price Target Calculation

Our 12- to 18-month \$18 price target for PRT-201 is derived from a sum-of-the-parts analysis of the company's development pipeline drugs, namely PRT-201. We value PRT-201 using a sum-of-parts probability-adjusted net present value (pNPV) approach, calculating anticipated profits from PRT-201 discounted at 10.5% through 2031 with no terminal value. We then adjust for clinical and regulatory risk by assigning an estimated probability of success. We currently assign a 54% probability of approval for PRT-201.

Key Risks to Price Target

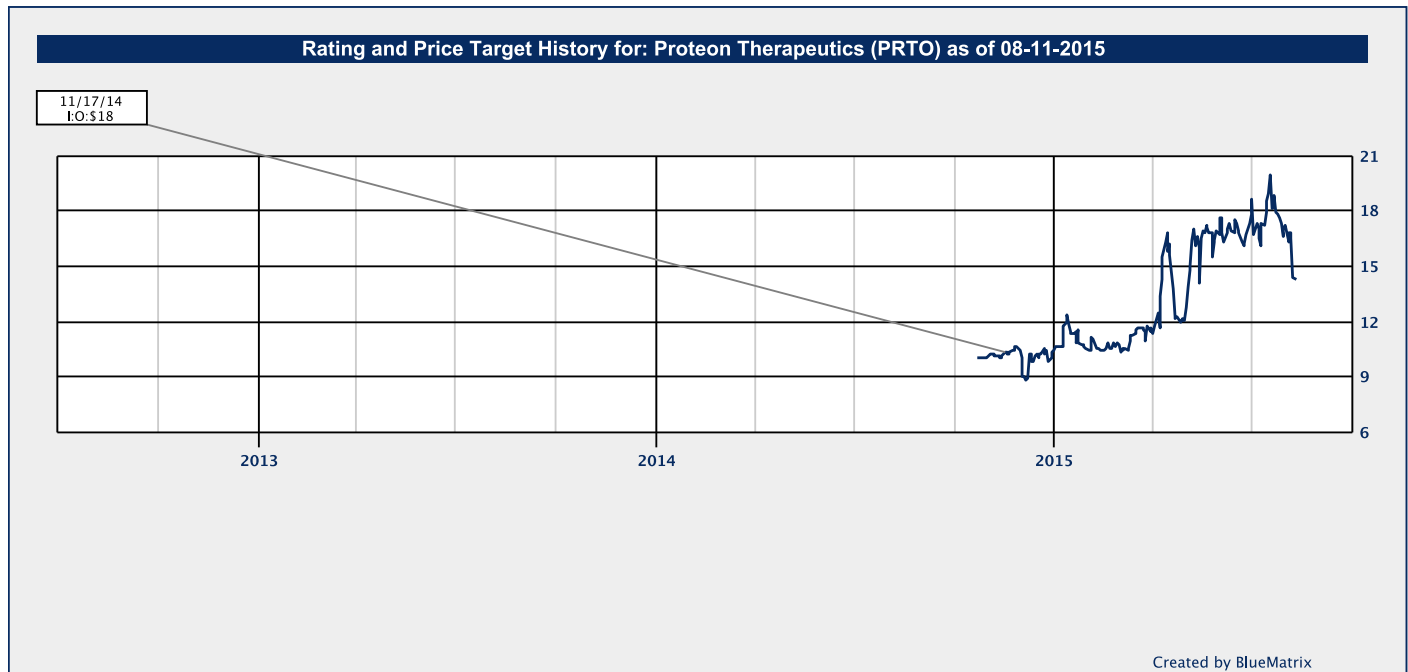
We would expect a material decline in PRT-201 shares in the event of unsuccessful US phase 3 programs for PRT-201. Our estimates assume the drug launching in 2018 based on a regulatory filing of a single pivotal study demonstrating efficacy in AVF. If the first Phase 3 study is positive, but the p-value associated with the primary endpoint isn't strong enough to support registration on a single pivotal, PRT-201 will need to wait for data from the second trial before seeking approval. In this scenario, the drug would then be launched roughly one year later than our current estimates.

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Rating	Count	IB Serv/Past 12 Mos.	
		Percent	Count
OUTPERFORM [O]	329	56.05	143
PERFORM [P]	251	42.76	90
UNDERPERFORM [U]	7	1.19	3

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