March 27, 2015

HEALTHCARE/BIO AND SPECIALTY PHARMACEUTICALS

Stock Rating:

OUTPERFORM

12-18 mo. Price Target	$18.00
PRTO - NASDAQ	$10.90

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range	$12.65-$8.57
Shares Outstanding	15.0M
Float	5.5M
Market Capitalization	$179.3M
Avg. Daily Trading Volume	14,276
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
Prior (E)	--	--	*(0.30)*	*(0.21)*	*(1.51)*	*NM*
2015E	(0.28)	(0.32)	(0.35)	(0.39)	(1.35)	NM
Prior (E)	*(0.23)*	*(0.27)*	*(0.31)*	*(0.35)*	*(1.16)*	*NM*
2016E	--	--	--	--	(2.42)	NM

Proteon Therapeutics

Long-term Phase 2 PRT-201 Data Presented at NKF; Reiterate Outperform

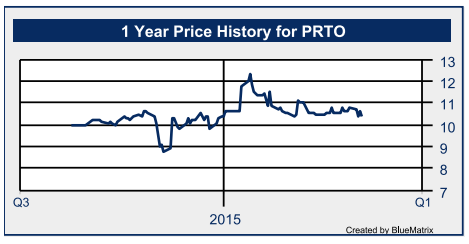
SUMMARY

Proteon is presenting a poster this weekend at the National Kidney Foundation (NKF) annual conference in Dallas. The poster highlights new 3-year follow-up data from PRTO's Phase 2 study of PRT-201 (aka vonapanitase) in arteriovenous fistulas (AVF), which previously reported 1-year follow-up data in patency loss (primary endpoint) and maturation, which showed significant benefits for PRT-201 in post-hoc analysis of radiocephalic AVF. At the 30 mcg dose, 3-year results showed continued benefits in radiocephalic AVF primary (p=0.02) and secondary (p=0.046) patency. PRT-201 patients also required fewer procedures to maintain or restore patency over the 3-year follow-up period. The results should also translate to meaningful cost savings for AVF maintenance.

KEY POINTS

- The durability of PRT-201's effects on radiocephalic AVF patency appears solid based on the 3-year follow-up data presented at NFK. While the Phase 3 trial will measure patency at one year, the longer-term data add confidence that the benefits seen in prior Phase 2 results are maintainable.
- Importantly, the poster presentation notes no meaningful difference in adverse events related to the AVF between PRT-201 and placebo patients during the 3+ year follw-up period.
- We are also updating our model for PRTO following reported 4Q14 earnings last week. Our estimates for 2015 operating expenses are unchanged but our EPS estimate moves to ($1.35) on slightly higher operating expense assumptions. We continue to model cash runway through 2018.
- **Reiterate Outperform and $18 PT.** We continue to believe PRT-201 has a strong risk/reward setup in radiocephalic AVF, with the first Phase 3 trial expected to complete enrollment later this year and read out top-line data in 1H17.

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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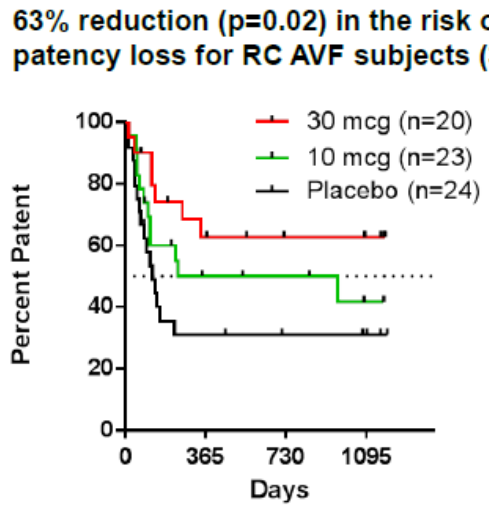
New Data Highlights Long-Term PRT-201 Efficacy

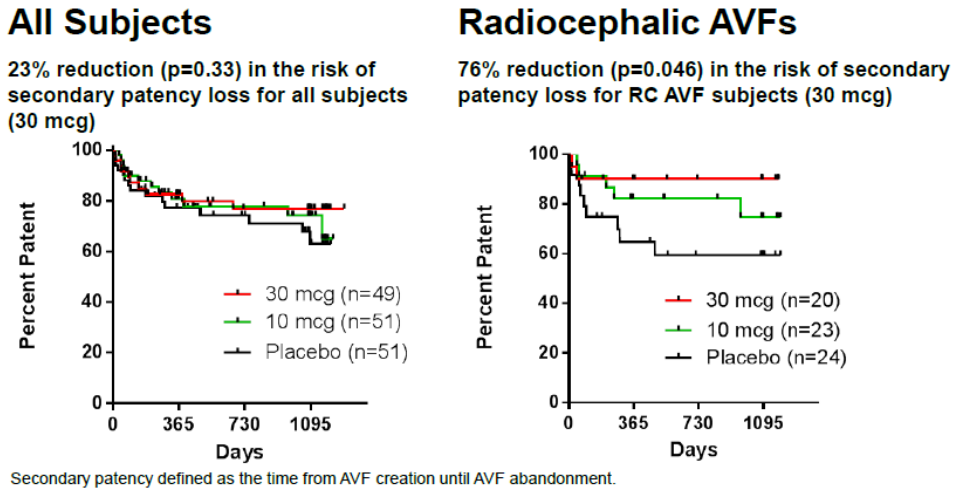
As evidenced by the long-term follow-up data presented at the NKF conference, PRT-201 demonstrated continued durability on AVF patency beyond 3 years. Speficifically, as seen in **Exhibit 1** below, 30mg of PRT-201 (study dose in Phase 3 program) was able to demonstrate a statistically signficant difference in reducing the risk of primary patency loss in radiocephalic (RC) AVF patients, the target population for the ongoing Phase 3 program. Of note, primary unassisted patency is defined as the time from AVF creation until the first occurrence of either access thrombosis or intervention (surgical) to maintain/restore patency.

Exhibit 1: Primary Unassisted Patency (3+ Years – Radiocephalic AVFs)



Source: Company Documents

Exhibit 2: Secondary Patency Over 3+ Years



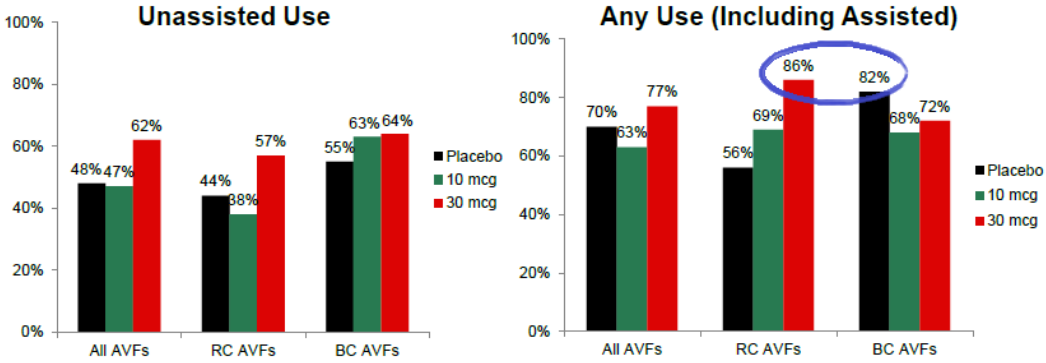
Secondary patency defined as the time from AVF creation until AVF abandonment.

Source: Company Documents

As seen in **Exhibit 2** on the previous page, PRT-201(30mg dose) was also able to demonstrate a statistically signficant reduction of 76% vs. placebo in the risk of secondary patency loss for RC AVF patients in the three-year follow-up.

Importantly, as seen in **Exhibit 3** below, 86% of PRT-201 (30mg) dosed patients were able to maintain AVF use for hemodialysis over three years vs. only 56% of placebo patients.

Exhibit 3: AVF Use for Hemodialysis Over 3+ Years



Unassisted Use defined as ≥90 days of consecutive use of the AVF without prior procedure to restore or maintain AVF patency. Any Use defined as ≥90 days of consecutive use of the AVF or ≥30 days of consecutive use in the event that the use began between the last and second to last study visits, independent of the need for procedures to restore or maintain patency. None of these differences were statistically significant.

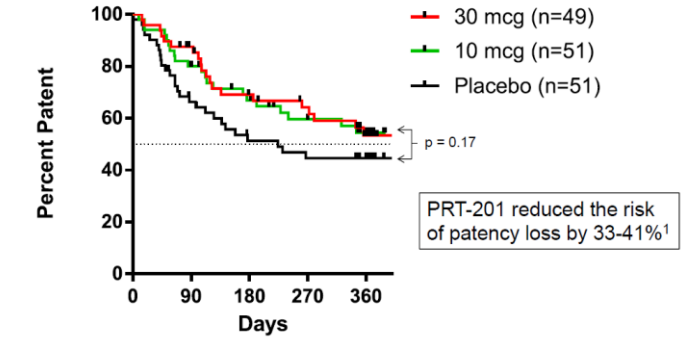
Source: Company Documents

Additionally, we highlight that this degree of durability in the 30mg PRT-201 in radiocephalic AVF exceeded the durability demonstrated in the placebo population in the patients that underwent the placement of a brachiocephalic AVF (**Exhibit 3**, circled). Although we don't ascribe any degree of superiority here due to the small numbers involved, if PRT-201 is able to generate functional radiocephalic AVFs comparable to standard bracheocephalic AVF, PRT-201 would represent a significant clinical enhancement over current standard of care.

Recap of Previously Reported PRT-201 One-Year Phase 2 Data

PRT-201 is a recombinant human elastase that has been evaluated in a Phase 2 study in 151 patients with CKD undergoing the creation of radiocephalic and brachiocephalic AVFs. Specifically, 67 patients underwent the creation of a radiocephalic AVF while 84 patients underwent the creation of a brachiocephalic AVF. These patients were treated with a single administration of either 10 or 30 micrograms of PRT-201 (or placebo) at the time of AVF placement and were followed for up to 12 months subsequent to the procedure.

Exhibit 4: Phase 2 Primary Endpoint – Patency Loss – One Year



[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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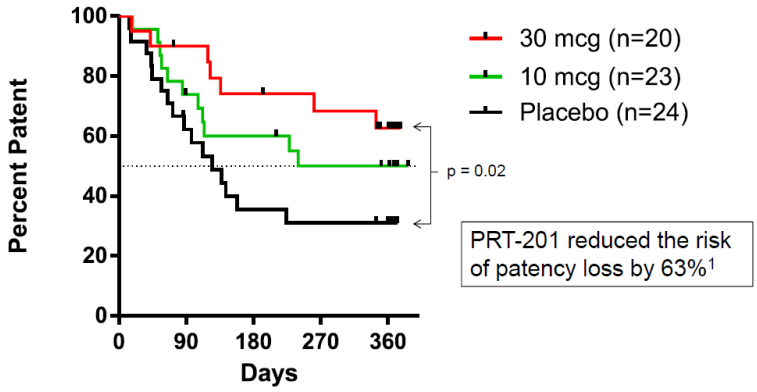
Source: Company Documents

The primary endpoint for the study was unassisted patency over 12 months defined as the time from access creation until the first occurrence of either AVF thrombosis or a corrective procedure, such as a balloon angioplasty, to maintain patency. While neither of the treatment arms demonstrated a statistically significant improvement in unassisted patency vs. placebo (as seen above in **Exhibit 5**), we note that there was a modest trend toward efficacy. Specifically, treatment with 10mcg and 30 mcg of PRT-201 was associated with a reduction of 31% and 33% of unassisted patency loss.

Exhibit 5: Patency Loss – (Radiocephalic AVF Patients Only) – One Year



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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Source: Company Documents

Efficacy of PRT-201 was more prominent in the subset of patients who underwent the placement of a radiocephalic AVF vs. those that underwent the placement of a brachiocephalic AVF. Specifically, patients who underwent the placement of a radiocephalic AVF at doses of 10mcg and 30mcg saw a 41% and 63% reduction, respectively, in the risk of primary unassisted patency loss. The median patency for the 30mcg subset of patients was 377 days vs. only 125 days for placebo patients, indicating a statistically significant improvement vs. placebo (as seen in **Exhibit 6**).

Exhibit 6: Phase 2 Primary Endpoint (All Patient Groups) – One Year

		PRT-201	
		10mcg	30mcg
All AVF	Number of patients	N = 51	N = 49
	Unadjusted Risk vs. Placebo	-31% (p=0.19)	-33% (p=0.17)
	Adjusted Risk vs. Placebo	-24% (p=0.35)	-41% (p=0.10)
Radiocephalic AVF	Number of patients	N = 23	N = 20
	Unadjusted Risk vs. Placebo	-41% (p=0.18)	-63% (p=0.02)
	Adjusted Risk vs. Placebo	-40% (p=0.20)	-61% (p=0.04)
Brachiocephalic AVF	Number of patients	N = 28	N = 29
	Unadjusted Risk vs. Placebo	-14% (p=0.72)	+10% (p=0.82)
	Adjusted Risk vs. Placebo	-12% (p=0.76)	-26% (p=0.46)

Source: Company Documents

Per the Phase 2 protocol, patients were also evaluated based on multiple secondary efficacy endpoints: unassisted maturation, secondary patency, use for hemodialysis and hemodynamically significant lumen stenosis.

Unassisted maturation of the fistula at three months was evaluated using an ultrasound to measure blood flow and lumen diameter. The 30mcg dose showed a statistically significant improvement in maturation at three months, with incremental benefits being seen in the patient population that underwent the placement of a radiocephalic AVF vs. brachiocephalic AVF. Please see **Exhibits 7 and 8** for additional information.

Exhibit 7: Ph2 Secondary Endpoint - Unassisted Maturation - (All Patient Groups) – One Year

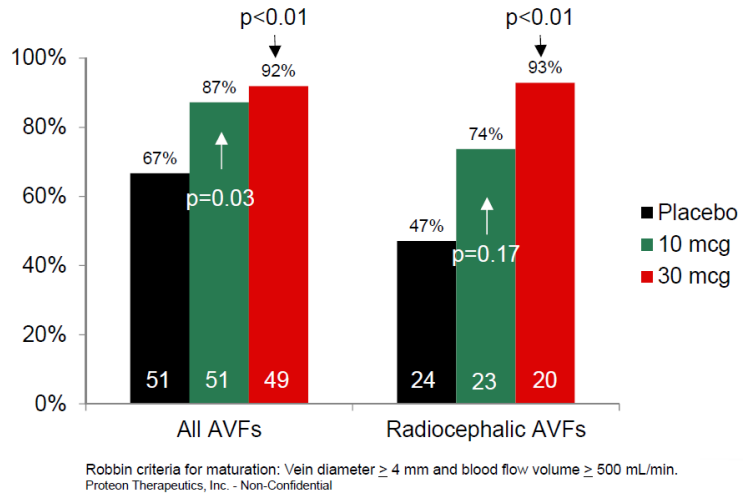
		Placebo	PRT-201	
			10mcg	30mcg
All AVF	Number of patients	N = 39	N = 39	N = 37
	Percent Mature NFK-KDOQI (1)	46%	64% (p=0.11)	70% (p=0.03)
	Percent Mature Robbin (2)	67%	87% (p=0.03)	92% (p<0.01)
Radiocephalic AVF	Number of patients	N = 17	N = 19	N = 14
	Percent Mature NFK-KDOQI (1)	24%	37% (p=0.48)	57% (p=0.08)
	Percent Mature Robbin (2)	47%	74% (p=0.17)	93% (p<0.01)
Brachiocephalic AVF	Number of patients	N = 22	N = 20	N = 23
	Percent Mature NFK-KDOQI (1)	64%	90% (p=0.07)	78% (p=0.34)
	Percent Mature Robbin (2)	82%	100% (p=0.11)	91% (p=0.41)

1) NKF-KDOQI maturation is defined as average vein lumen diameter > 6 millimeters and an outflow vein blood flow rate > 600 milliliters / minute

2) Robbin maturatino is defined as average vein lumen diameter > 4 millimeters and an outflow vein blood flow rate > 500 milliliters / minute

Source: Company Documents

Exhibit 8: Phase 2 Maturation Endpoint – One Year



Source: Company Documents

As previously mentioned, patients that have undergone vascular access procedures often require additional procedures (thrombectomy, angioplasty, stent deployment, and surgical revision) to restore blood flow. The procedure rate is calculated based on the number of days in which a procedure was performed to restore or maintain patency divided by the patient's time on the trial. As seen in **Exhibit 13**, there was a 56% reduction in the rate of procedures in the 30 mcg group versus the placebo group. In the subset of patients undergoing the placement of a radiocephalic AVF, there was a 69% reduction in the average rate of procedures in the same dose group. Moreover, in the subset of patients who underwent the placement of a brachiocephalic AVF, there was a 43% reduction in the average rate of procedures for the patients that received the 30mcg dose. We note that there was an 86% reduction in the average rate of procedures in brachiocephalic AVFs excluding central stenosis.

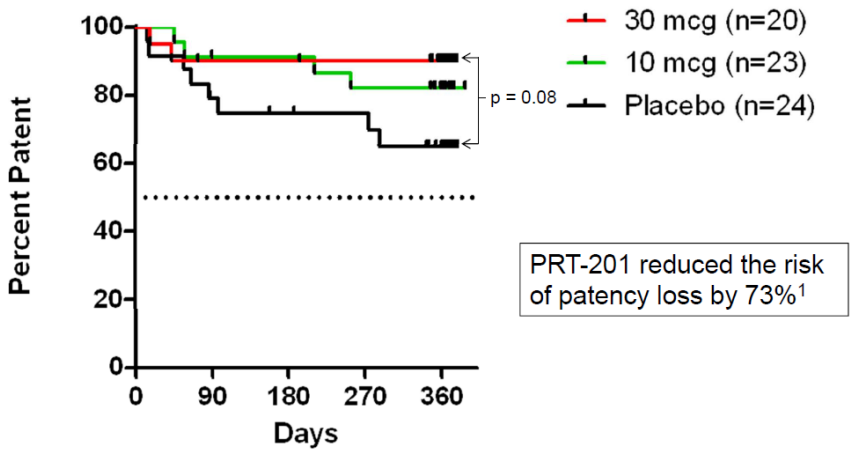
Exhibit 9: Ph2 Secondary Endpoint – Avg. Procedure Rate To Restore/ Maturation Patency - (All Patient Groups) – One Year

		Placebo	PRT-201	
			10mcg	30mcg
All AVFs (Prespecified)	Number of patients	N = 51	N = 50	N = 48
	Procedures per Year	0.9	0.8 (p=0.53)	0.4 (p=0.07)
All AVFs Excluding Central Stenosis	Number of patients	N = 51	N = 50	N = 48
	Procedures per Year	0.8	0.7 (p=0.44)	0.2 (p<0.01)
Radiocephalic AVFs	Number of patients	N = 24	N = 23	N = 20
	Procedures per Year	1.0	0.8 (p=0.63)	0.3 (p=0.06)
Brachiocephalic AVFs	Number of patients	N = 27	N = 27	N = 28
	Procedures per Year	0.7	0.7 (p=0.72)	0.4 (p=0.50)
Brachiocephalic AVFs Excluding Central	Number of patients	N = 27	N = 27	N = 28
	Procedures per Year	0.7	0.7 (p=0.54)	0.1 (p=0.07)

Source: Company Documents

follow-on procedure to restore patency), while there was no statistically significant difference there was a trend toward prolonged secondary patency in patients who received radiocephalic AVFs.

Exhibit 10: Phase 2 Secondary Endpoint – Secondary Patency – (AVF)



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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Source: Company Documents

As it relates to the last two secondary endpoints, use for hemodialysis and hemodynamically significant lumen stenosis, there were not any statistically significant differences in either dose groups vs. placebo. However, there were positive trends observed favoring PRT-201. Specifically, hemodialysis use in the 30mcg arm was 69% vs. 53% in the placebo group. Separately, there was a trend to fewer patients in the active arm with a hemodynamically significant stenosis (30% for 10mcg group and 39% for 30mcg group) compared to placebo (51%) at 6 weeks.

Exhibit 11: Phase 2 Safety and Tolerability Overview

		PRT-201	
	Placebo	10mcg	30mcg
N (%)	N = 51	N = 51	N = 49
Any adverse event	42 (82)	39 (77)	43 (88)
AVF thrombosis	13 (26)	8 (16)	7 (14)
Venous stenosis	10 (20)	7 (14)	8 (16)
Steal syndrome	7 (14)	2 (4)	6 (12)
Hypoesthesia	7 (14)	6 (12)	6 (12)
AVF incisional pain	5 (10)	9 (18)	9 (18)
AVF site complication	5 (10)	4 (8)	4 (8)
Nausea	5 (10)	1 (2)	2 (4)
Peripheral edema	5 (10)	0 (0)	2 (4)
Arterial stenosis	4 (8)	5 (10)	0 (0)
Paresthesia	1 (2)	1 (2)	5 (10)
Pain in extremity	0 (0)	1 (2)	5 (10)

Source: Company Documents

As demonstrated by the robust Phase 2 data in the radiocephalic AVF arm in the 30mcg dose cohort, PRT-201 is able to significantly improve upon many aspects of vascular access while being relatively safe and tolerable. We believe that Proteon's decision to move forward with a Phase 3 program in only radiocephalic AVF patients makes sense given the longer patency inherent in brachiocephalic AVFs that make demonstrating an effect size with PRT-201 more difficult for one-year follow-up.

Phase 3 Trial Design and Data Expectation Discussion

Proteon held an end of Phase 2 meeting with the FDA in April 2013. Following these discussions, Proteon is conducting two randomized, double-blind placebo-controlled trials involving 300 patients in each Phase 3 trial. Proteon will be evaluating the 30 microgram dose of PRT-201 in patients undergoing surgical procedures to create a radiocephalic AVF. Patients will be randomized 2:1 to receive either 30mcg PRT-201 or placebo, respectively. The primary endpoint for the study will be unassisted patency and the secondary endpoint is secondary patency, similar to the Phase 2 study. Additional secondary endpoints include unassisted maturation, rate of "rescue" procedures, and successful use for hemodialysis.

Currently, the company is enrolling patients in the first Phase 3 trial (enrollment commenced during 3Q14) and also expects to initiate the second Phase 3 trial during 2015. We expect the company to release top-line data from the first pivotal study in 1H17. Of note, Proteon's current expectation is to report the data in 1Q17, but we allow for additional time in case patient enrollment is slower than expected.

Although Proteon is planning to conduct two Phase 3 trials of PRT-201 in radiocephalic AVF, we assume that if the drug is successful, the company will file for approval based on the first study. Our reasoning that if the benefits seen at the 30 mcg dose in radiocephalic patients in Phase 2 are reproducible in a larger study (and not due to statistical chance), the resulting p-values would be well below (i.e. better than) the threshold needed for the company to file on a single study.

That said, Proteon will begin enrollment of a second, parallel Phase 3 trial in 2015 in order to generate sufficient data in the event that the company is unable to file on the first pivotal trial. We expect Proteon to prioritize putting the quicker enrolling centers in the first pivotal trial, leading to a slower enrollment curve in the second study. We currently estimate that data from the second Phase 3 trial will be available in the first half of 2018, roughly one year after the company reports data from the first Phase 3 trial.

Proteon Therapeutics (PRTO)

Oppenheimer & Co.

($000's) [FY - DEC]

	2012A	2013A	2014A					2015E					2016E
	FY:12A	FY:13A	Q1A	Q2A	Q3A	Q4A	FY:14A	Q1E	Q2E	Q3E	Q4E	FY:15E	FY:16E
Revenues from Product Sales	-	-	-	-	-	-	-	-	-	-	-	-	-
PRT-201 AVF Hemodialysis (US)	-	-	-	-	-	-	-	-	-	-	-	-	-
PRT-201 AVF Hemodialysis (EU)	-	-	-	-	-	-	-	-	-	-	-	-	-
Licensing revenue and Milestones	-	-	-	-	-	-	-	-	-	-	-	-	-
Total revenues	$ -	$ -	$ -	$ -	$ 2,948	$ -	$ 2,948	$ -	$ -	$ -	$ -	$ -	$ -
Cost of Goods	-	-	-	-	-	-	-	-	-	-	-	-	-
Gross profit	-	-	-	-	2,948	-	2,948	-	-	-	-	-	-
Operating expenses													
Research and development	5,907	3,994	1,393	1,393	1,773	1,874	6,432	2,345	2,931	3,517	4,221	13,014	32,534
Selling, general and administrative	2,089	3,128	828	828	1,041	1,399	4,096	2,356	2,380	2,403	2,428	9,567	10,524
Other		-											
Total expenses	7,996	7,122	2,221	2,221	2,814	3,273	10,528	4,701	5,311	5,921	6,648	22,580	43,058
Operating income	(7,996)	(7,122)	(2,221)	(2,221)	134	(3,273)	(7,580)	(4,701)	(5,311)	(5,921)	(6,648)	(22,580)	(43,058)
Financial expense, net	-	(861)	(429)	(429)	10	14	(833)	-	-	-	-	-	-
Other income (expense)	(6,107)	(6,048)	(48)	(48)	(5,325)	10,495	5,071	-	-	-	-	-	-
Pre-tax income	(14,103)	(14,031)	(2,697)	(2,697)	(5,181)	7,236	(3,342)	(4,701)	(5,311)	(5,921)	(6,648)	(22,580)	(43,058)
Income tax expense (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(14,103)	(14,031)	($2,697)	($2,697)	($5,181)	$7,236	(3,342)	($4,701)	($5,311)	($5,921)	($6,648)	($22,580)	($43,058)
Accretion of redeemable convert			(1,705)	(1,705)	(2,277)	(656)	(6,342)						
Basic shares outstanding	231	4,566	6,763	6,763	240	11,445	3,065	16,540	16,690	16,840	16,990	16,765	17,590
Diluted shares outstanding	231	4,566	6,763	6,763	240	12,295	3,065	16,540	16,690	16,840	16,990	16,765	17,590
GAAP EPS (basic and diluted)	($61.16)	($3.07)	($0.65)	($0.65)	($31.03)	$0.59	($3.16)	($0.28)	($0.32)	($0.35)	($0.39)	($1.35)	($2.45)
Cash and Equivalents	$ 7,471	$ 5,152	$ -	$ 25,416	$ 21,686	$ 83,595	$ 83,595	$ 148,819	$ 143,533	$ 137,638	$ 131,015	$ 131,015	$ 90,684

Source: Oppenheimer & Co. Inc., Company Reports

Investment Thesis

Our bullish investment thesis stems from our belief that 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 PRTO 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 PRTO is derived from a sum-of-the-parts analysis of the company's development pipeline drugs, namely PRT-201. We value PRTO 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 PRTO shares in the event of unsuccessful US phase 3 programs for PRT-201. Our estimates assume the drug launching in 2H18 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, PRTO 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.

Important Disclosures and Certifications

Analyst Certification - The author certifies that this research report accurately states his/her personal views about the subject securities, which are reflected in the ratings as well as in the substance of this report. The author certifies that no part of his/her compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this research report.

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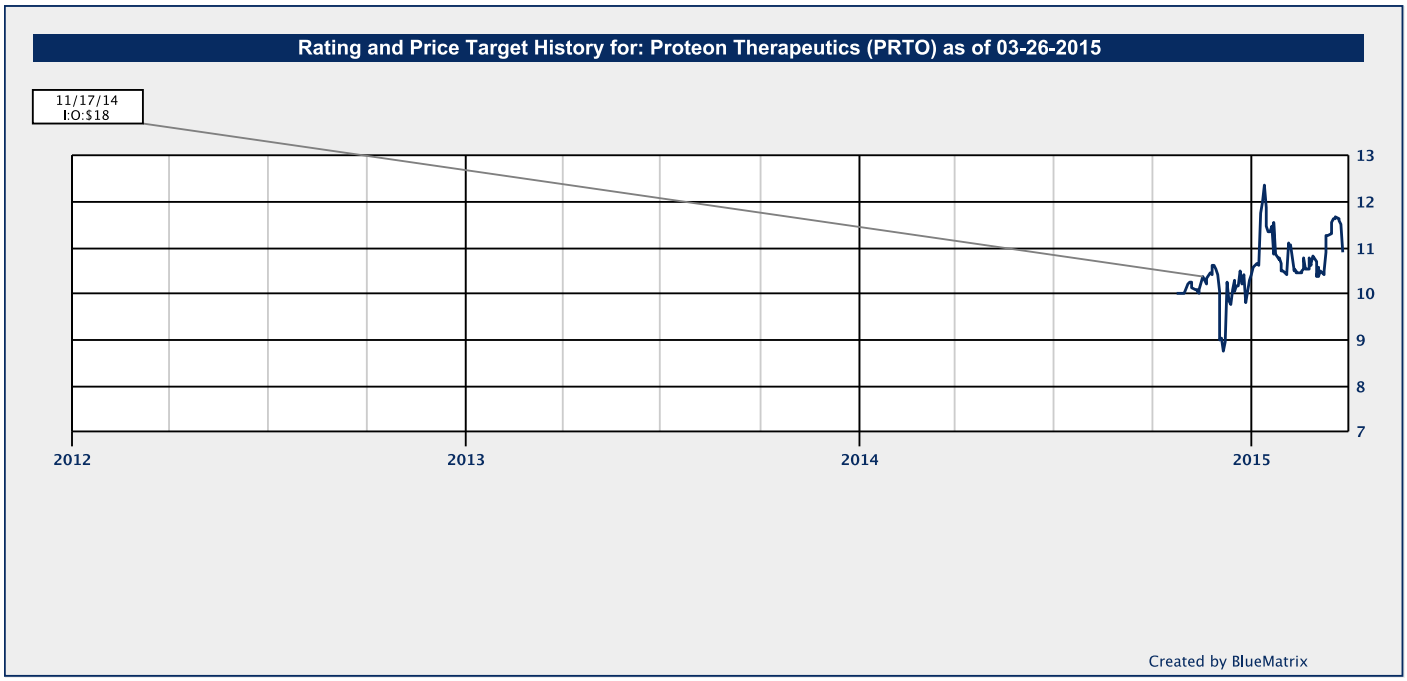

All price targets displayed in the chart above are for a 12- to- 18-month period. Prior to March 30, 2004, Oppenheimer & Co. Inc. used 6-, 12-, 12- to 18-, and 12- to 24-month price targets and ranges. For more information about target price histories, please write to Oppenheimer & Co. Inc., 85 Broad Street, New York, NY 10004, Attention: Equity Research Department, Business Manager.

Oppenheimer & Co. Inc. Rating System as of January 14th, 2008:

Outperform(O) - Stock expected to outperform the S&P 500 within the next 12-18 months.

Perform (P) - Stock expected to perform in line with the S&P 500 within the next 12-18 months.

Underperform (U) - Stock expected to underperform the S&P 500 within the next 12-18 months.

Not Rated (NR) - Oppenheimer & Co. Inc. does not maintain coverage of the stock or is restricted from doing so due to a potential conflict of interest.

Oppenheimer & Co. Inc. Rating System prior to January 14th, 2008:

Buy - anticipates appreciation of 10% or more within the next 12 months, and/or a total return of 10% including dividend payments, and/or the ability of the shares to perform better than the leading stock market averages or stocks within its particular industry sector.

Neutral - anticipates that the shares will trade at or near their current price and generally in line with the leading market averages due to a perceived absence of strong dynamics that would cause volatility either to the upside or downside, and/or will perform less well than higher rated companies within its peer group. Our readers should be aware that when a rating change occurs to Neutral from Buy, aggressive trading accounts might decide to liquidate their positions to employ the funds elsewhere.

Sell - anticipates that the shares will depreciate 10% or more in price within the next 12 months, due to fundamental weakness perceived in the company or for valuation reasons, or are expected to perform significantly worse than equities within the peer group.

Distribution of Ratings/IB Services Firmwide

			IB Serv/Past 12 Mos.	
Rating	Count	Percent	Count	Percent
OUTPERFORM [O]	327	55.71	147	44.95
PERFORM [P]	250	42.59	93	37.20
UNDERPERFORM [U]	10	1.70	2	20.00

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