Zacks Small-Cap Research

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Pieris Pharmaceuticals, Inc. (PIRS - NASDAQ)

PIRS: Positive Phase 1 Data for PRS-080; Increasing PT to $8…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	04/08/2015
Current Price (11/05/15)	$1.88
Target Price	**$8.00**

UPDATE

On November 5, 2015, Pieris Pharmaceuticals, Inc. announced publication of an abstract at the 2015 American Society of Hematology meeting that disclosed results from the company's Phase 1 study of PRS-080 in healthy volunteers. The data showed that PRS-080 was safe and well-tolerated and led to a decrease in hepcidin levels along with an increase in serum iron concentration.

This is the second time that an anticalin has been successfully administered to humans with no serious adverse events, thus we believe this mitigates any risk associated with anticalin administration. The fact that PRS-080 showed activity in a healthy patient population is highly encouraging, and shows further validation of the anticalin platform. We are raising our price target to $8 per share and re-iterating our 'Buy' rating.

SUMMARY DATA

52-Week High	**$4.20**
52-Week Low	**$1.58**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**180,170**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$75**
Short Interest Ratio (days)	**1.70**
Institutional Ownership (%)	**43**
Insider Ownership (%)	**2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	2.1 A	0 A	5.4 A
2015	0.2 A	0.2 A	0.3 E	0.3 E	1.1 E
2016					7.0 E
2017					12.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.23 A	-$0.20 A	-$0.18 A	-$0.19 A	-$0.71 A
2015	-$0.13 A	-$0.12 A	-$0.16 E	-$0.17 E	-$0.54 E
2016					-$0.58 E
2017					-$0.59 E

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WHAT'S NEW

PRS-080 Phase 1 Data to be Presented at ASH 2015

On November 5, 2015, Pieris Pharmaceuticals, Inc. (PIRS) announced the presentation of Phase 1 clinical data for PRS-080 at the 2015 American Society of Hematology (ASH) annual meeting. The abstract, entitled "A Phase I Study Investigating Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Activity of the Hepcidin Antagonist PRS-080#022. Results from a Randomized, Placebo Controlled, Double-Blind Study Following Single Administration to Healthy Subjects" will be presented on Monday, December 7, 2015.

PRS-080 is an anticalin that targets hepcidin, a 25 amino acid peptide produced in the liver and excreted into the bloodstream where it binds to ferroportin, an iron transporter found on duodenal enterocytes, reticuloendothelial macrophages, and hepatocytes (Donovan *et al*., 2006). Binding of hepcidin to ferroportin induces its internalization and degradation, resulting in iron accumulation in enterocytes, macrophages, and the liver. Hepcidin expression is induced by inflammatory cytokines, which is hypothesized to result in the sequestration of iron from invading pathogens (Babitt *et al*., 2010). This increased hepcidin expression results in many of the hallmarks of chronic diseases, including iron sequestration, hypoferremia, and anemia.

Pieris is developing PRS-080 as a treatment for functional iron deficiency (FID) in anemic patients with chronic kidney disease (CKD), which is a progressive loss of kidney function over a period of months or years. FID in CKD patients is characterized by low circulating iron levels that limits erythropoiesis even when these patients have sufficient iron stores in their body. These patients have low serum transferrin (a measure of circulating iron) and normal or high serum ferritin (a marker of body iron stores). FID is characteristic of a chronic inflammatory state, which in CKD patients may be due to an increased incidence of infections and/or the induction of inflammatory cytokines by the hemodialysis procedure.

The data to be presented at ASH 2015 is from a placebo controlled, double blind, Phase 1 study with ascending doses of PRS-080 in six cohorts of healthy volunteers of 0.08, 0.4, 1.2, 4.0, 8.0, and 16.0 mg/kg (NCT02340572). Six patients in each cohort received drug while two patients received placebo through a two hour intravenous infusion. A total of 39 adverse events (AEs) were reported during or after treatment in 22 subjects. All AEs were mild or moderate and there were no serious AEs reported. Importantly, there were no infusion reactions or hypersensitivities noted during the study.

A decrease in free hepcidin was noted beginning one hour after administration of PRS-080 along with a transient increase in serum iron concentration and transferrin saturation. Serum iron concentrations reached approximately 50 µM in individual subjects but did not increase further with increasing dose. The normal range for serum iron concentration is approximately 11-30 µM. We believe this is a very important data point to come out of this trial, because if PRS-080 is able to increase normal iron levels to above normal, it stands to reason that it should be able to increase anemic patients iron levels to within the normal range.

The company is planning to move quickly into a Phase 1b clinical trial of PRS-080 in anemic patients with chronic kidney disease, which should commence before the end of 2015. Data from that study should be available in the second half of 2016.

Conclusion and Recommendation

The data to be presented at ASH 2015 on PRS-080 in healthy volunteers does two things: 1) it reinforces the notion that anticalins are safe, well tolerated, and do no elicit anti-drug antibodies (a Phase 2 study of PRS-050 was the first to show this); and 2) it shows that PRS-080 is biologically active and performs as anticipated in that it raised serum iron concentrations in healthy individuals to above normal levels. The second point is the most important because there is no reason to think that PRS-080 would only work in healthy volunteers and not in anemic patients. For this reason, we are increasing the probability of success for PRS-080.

In addition to the presentation at ASH 2015 next month, the company is taking part in three R&D conferences in November: Protein Engineering Summit Europe (PEGS), Society for Immunotherapy of Cancer (SITC), and AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Those conferences include

poster presentations on preclinical data for the company's lead immunooncology product PRS-343. For a detailed overview of that data please see this article.

We believe that Pieris' current market cap of $75 million vastly undervalues the company. The anticalin platform is a transformative technology that could lead to a number of novel treatments in a variety of diseases. The results from the Phase 1 study of PRS-080 have reduced many of the risks associated with the program, and as such we are increasing our target price from $6 to $8 and re-iterating our 'Buy' rating.

PROJECTED FINANCIALS

Pieris Pharmaceuticals, Inc.
Income Statement

Pieris Pharma	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E	2017 E
PRS-080	$0	$0	$0	$0	$0	$0	$0	$0
PRS-060	$0	$0	$0	$0	$0	$0	$0	$0
PRS-343	$0	$0	$0	$0	$0	$0	$0	$0
PRS-050	$0	$0	$0	$0	$0	$0	$0	$0
PRS-110	$0	$0	$0	$0	$0	$0	$0	$0
PRS-NN	$0	$0	$0	$0	$0	$0	$0	$0
PRS-SNY	$0	$0	$0	$0	$0	$0	$0	$0
Licensing & Collaborative	**$5.4**	**$0.2**	**$0.2**	**$0.3**	**$0.3**	**$1.0**	**$7.0**	**$12.0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$5.4**	**$0.2**	**$0.2**	**$0.3**	**$0.3**	**$1.0**	**$7.0**	**$12.0**
CoGS	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D Expense	$5.6	$1.5	$1.7	$2.0	$2.4	$7.7	$16.0	$19.0
SG&A Expense	$7.0	$2.4	$2.0	$3.0	$3.3	$10.7	$15.0	$20.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.2)	($3.7)	($3.5)	($4.7)	($5.4)	($17.3)	($24.0)	($27.0)
Operating Margin	*-134.2%*	*-1700.8%*	*-2205.7%*	*-1566.7%*	*-1800.0%*	*-1772.8%*	*-342.9%*	*-225.0%*
Total Other Income	($2.7)	($0.0)	$0.0	($0.4)	($0.5)	($0.9)	($2.0)	($2.5)
Pre-Tax Income	($9.8)	($3.7)	($3.5)	($5.1)	($5.9)	($18.2)	($26.0)	($29.5)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*
Net Income	($9.9)	($3.7)	($3.5)	($5.1)	($5.9)	($18.2)	($26.0)	($29.5)
Reported EPS	**($0.71)**	**($0.13)**	**($0.12)**	**($0.13)**	**($0.15)**	**($0.54)**	**($0.58)**	**($0.59)**
YOY Growth	-						-	-
Shares Outstanding	13.9	29.3	29.4	38.5	38.5	33.9	45.0	50.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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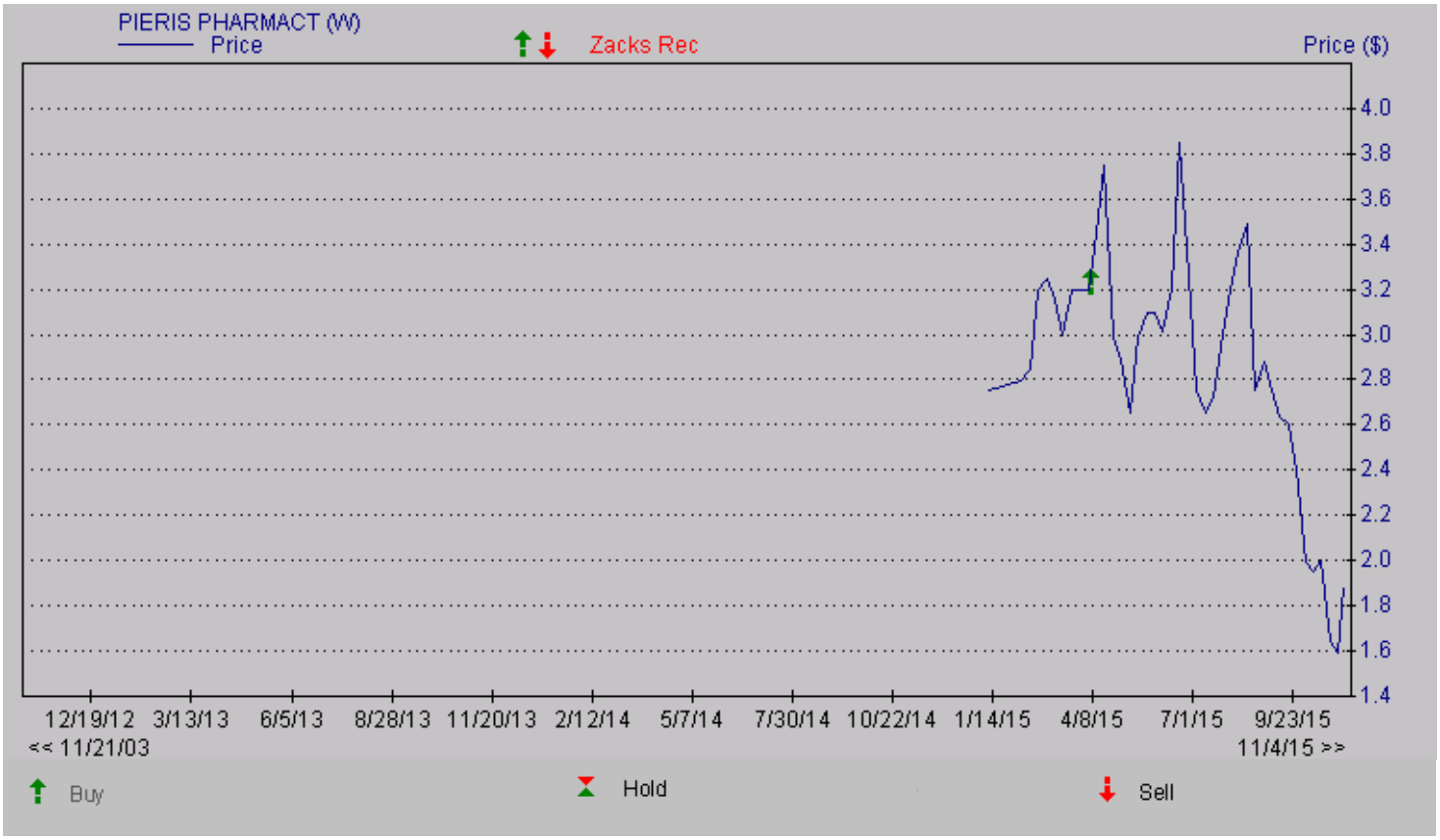

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