Zacks Small-Cap Research

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Protalex, Inc.

(PRTX-OTCQB)

PRTX: Safety Monitoring Committee Gives Positive Interim Review of PRTX-100 in ITP Study …

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	12/1/2014
Current Price (03/01/2016)	$4.05
Target Price	**$10.00**

UPDATE

On February 29, 2016, Protalex announced that the company is continuing enrollment and increasing the dose in the ongoing Phase 1/2 clinical trial of PRTX-100 in patients with immune thrombocytopenia following a review by the independent safety monitoring committee (SMC).

We are glad to see the trial continuing and believe there is little chance of safety issues in future dosing cohorts as PRTX-100 was safe and well tolerated in five previous clinical trials involving patients with rheumatoid arthritis. We anticipate data from the ongoing trial before the end of 2016 and view that as a major catalyst for the stock, thus we recommend investors initiate or add to a position ahead of that data release.

SUMMARY DATA

52-Week High	**$6.00**
52-Week Low	**$3.00**
One-Year Return (%)	**-21.97**
Beta	**1.82**
Average Daily Volume (sh)	**811**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$117**
Short Interest Ratio (days)	**1.15**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**N/A**
Dividend Yield (%)	**N/A**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 E	0 E	0 E
2017					50 E
2018					0 E

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

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2015	-$0.15 A	-$0.15 A	-$0.06 A	-$0.05 A	-$0.40 A
2016	-$0.13 A	-$0.08 A	-$0.07 E	-$0.07 E	-$0.35 E
2017					$1.00 E
2018					-$0.20 E

WHAT'S NEW

On February 29, 2016, Protalex, Inc. (PRTX) announced that the independent safety monitoring committee (SMC) gave a positive planned interim review of the safety data for the first cohort of patients in the company's ongoing Phase 1/2 clinical trial of PRTX-100 in patients with immune thrombocytopenia (ITP). Based on this positive review, the company is continuing enrollment and increasing the dose for the next cohort of patients. For a detailed review of the preclinical data supporting the use of PRTX-100 in the treatment of ITP, please see our previous report.

Immune Thrombocytopenia

Immune thrombocytopenia (ITP) is a bleeding disorder characterized by bruising and increased bleeding as a result of immune-mediated accelerated destruction of platelets and impaired production of platelets. ITP is an autoimmune-mediated condition in which the immune system attacks and destroys platelets, which are necessary for normal blood clotting. The disease can be brought on by bacterial or viral infections. The condition can be acute (short-term) or chronic (long-lasting) in nature, with women being two to three times as likely to develop chronic ITP as men. The bleeding can be found inside the body (internal bleeding), and underneath or from the skin (external bleeding).

The diagnosis of ITP is based upon a low platelet count, usually less than 100,000 per microliter of blood, in the absence of other possible causes of reduced platelet numbers such as an underlying illness or medication. A normal platelet count is considered to be between 150,000 and 450,000 per microliter of blood. ITP is recognized by the FDA as an orphan disease, which is defined as a condition that affects fewer than 200,000 people nationwide. The incidence for ITP is approximately 9.5 per 100,000 people in the U.S., representing approximately 30,000 cases.

Treatment of ITP depends upon the severity of symptoms and whether the patient is newly diagnosed or has a chronic condition. Adult patients who have significant bleeding are almost always treated, and while there is not necessarily an absolute platelet count threshold, bleeding accompanied with a platelet count < 50,000 per microliter of blood almost always warrants treatment. Current treatment options include glucocorticoids, intravenous immunoglobulin, and the thrombopoietic agents romiplostim (Nplate®) and eltrombopag (Promacta®).

Clinical Trials of PRTX-100 in ITP

Protalex is currently testing PRTX-100 in adults with chronic/persistent ITP in two clinical trials. As these trials are both open label, we

Study PRTX-100-202 (NCT02401061): This is an open label, dose escalation trial taking place in the U.S. that is expected to enroll up to 36 patients in as many as six dosing cohorts (1, 3, 6, 12, 18, and 24 µg/kg with 3-6 patients per dosing cohort). Inclusion criteria includes patients that are refractory to treatment with a thrombopoietic agent, are not receiving another ITP treatment and have a platelet count of <30,000 per microliter, or if on an approved treatment (corticosteroids or one of the thrombopoietic agents) having a platelet count of <50,000 per microliter. The primary endpoint for the study is platelet response, which for patients not receiving another ITP treatment is defined as platelet count >30,000 per microliter and at least a doubling of baseline platelet count. For patients receiving permitted treatments for ITP with a baseline platelet count of >30,000 per microliter and <50,000 per microliter, an increased platelet count >50,000 per microliter will be considered a platelet response. As mentioned above, an independent SMC is monitoring the trial for adverse events following the dosing of each cohort before the next cohort can be enrolled.

Study PRTX-100-203 (NCT02566603): This is an open label, dose escalation trial that is taking place in France and is expected to enroll 30 adults who have received one prior ITP treatment in as many as five dosing cohorts. Similar to the 202 Study, the open-label 203 Study will dose patients with four, once-weekly doses of PRTX-100 (3, 6, 12, 18, and 24 µg/kg) and then follow them for up to a year. The primary outcome for the 203 Study is safety, with secondary outcomes including platelet response and concomitant ITP medication usage.

Conclusion and Recommendation

We are glad to see that the first safety hurdle for PRTX-100 has been cleared in ITP patients, although we never anticipated there being any issues since PRTX-100 has previously been tested in five clinical trials involving patients with rheumatoid arthritis (RA) and was found to be safe and well tolerated in all of those trials. The company had tested doses of PRTX-100 of up to 12 µg/kg in RA patients, thus the only doses for which there is no prior clinical experience are for 18 and 24 µg/kg. The paucity of adverse events in prior trials, even in the previously tested 12 µg/kg cohort, gives us confidence that there will not be any new safety issues caused by those higher doses.

While safety is certainly of interest in the -202 Study, the primary endpoint is platelet response, and we believe that we will receive some type of an indication as to the clinical effectiveness of PRTX-100 in ITP before the end of 2016. As a reminder, this trial is open label, so the patients can be tracked in real time and their results relayed to the company in an ongoing basis. It took approximately 3 months for the first cohort of patients in the -202 Study to be enrolled and dosed, and we would anticipate that future cohorts would take no longer than this or even a bit less time as new study sites are added. Thus, the 3 µg/kg cohort should be completed by the end of May and then will have approximately 7 months of follow-up by the end of 2016.

We view ITP as a meaningful opportunity for Protalex and we estimate potential peak sales of approximately $400 million (for comparison, in 2014 Amgen reported revenues of $469 million for Nplate® while GlaxoSmithKline reported revenues of approximately $340 million for Promacta®). PRTX-100 has already been granted Orphan Drug Designation by the FDA and EMA for the treatment of ITP, which both confers market exclusivity as well as making the compound more attractive to potential 'Big Pharma' partners.

Topline data from the ongoing Phase 1/2 clinical trials of PRTX-100 in ITP is a major catalyst for the stock in the second half of 2016. Based on our modeling, we believe the shares are worth approximately $10 and we are maintaining a 'Buy' rating and encourage investors to take a position now ahead of anticipated data later in 2016.

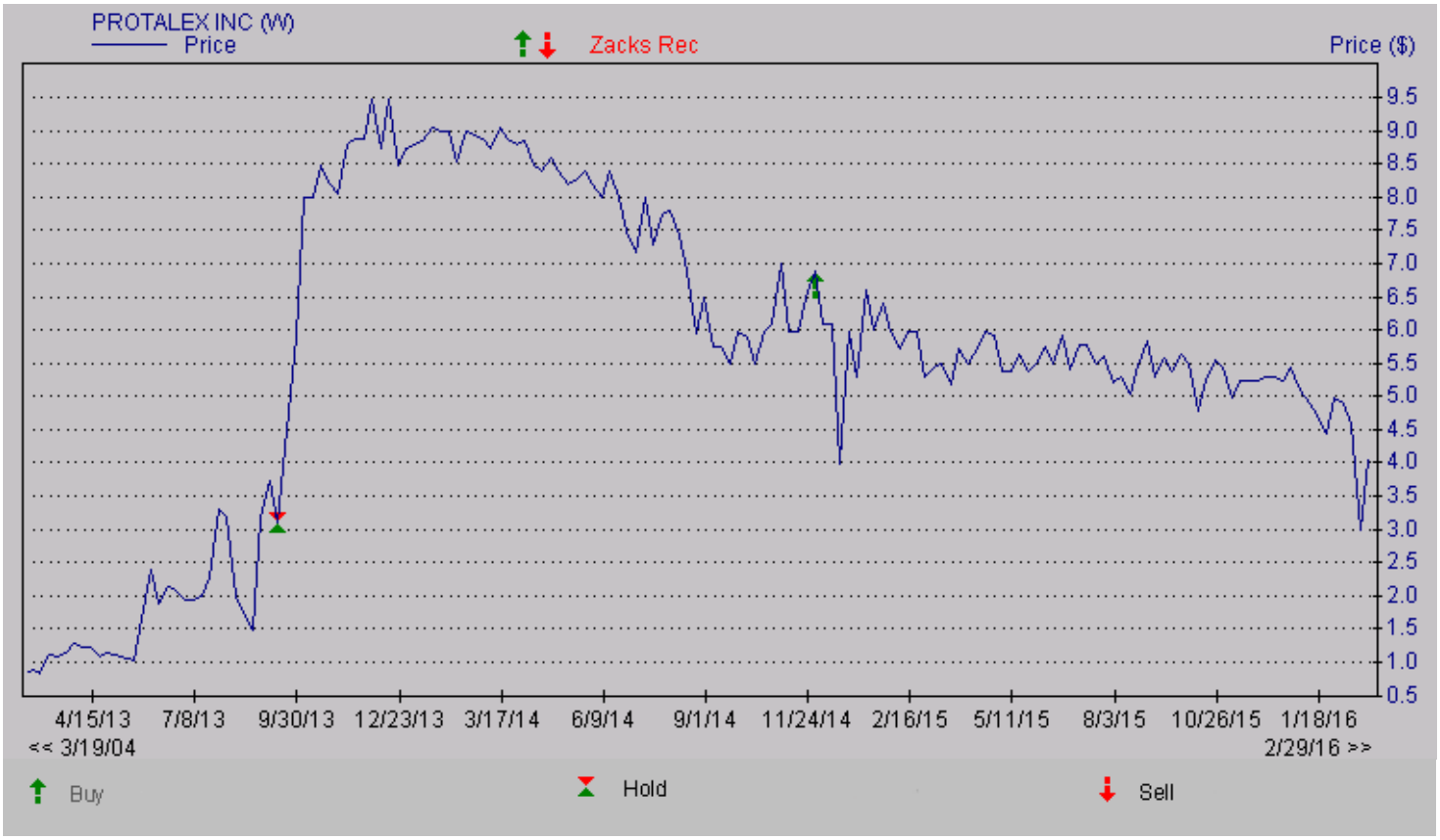
PROJECTED FINANCIALS

Protalex, Inc.
Income Statement

Protalex, Inc.	FY 2015 A	Aug-15 A	Nov-15 A	Feb-16 E	May-16 E	FY 2016 E	FY 2017 E
PRTX-100 Sales / Royalties	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Licensing / Collaborative	$0	$0	$0	$0	$0	$0	$50.0
YOY Growth	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50.0**
YOY Growth	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
R&D	$3.0	$0.5	$1.1	$1.0	$1.0	$3.6	$5.0
SG&A	$8.3	$3.0	$1.0	$1.2	$1.2	$6.4	$7.5
Depreciation & Amortization	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($11.3)**	**($3.5)**	**($2.1)**	**($2.2)**	**($2.2)**	**($10.0)**	**$37.5**
Operating Margin	-	-				-	-
Interest & Other Income	($0.3)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)
Pre-Tax Income	($11.6)	($3.6)	($2.2)	($2.3)	($2.3)	($10.4)	$37.0
Taxes & Other	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($11.6)	($3.6)	($2.2)	($2.3)	($2.3)	($10.4)	$37.0
Net Margin	-	-				-	-
Reported EPS	**($0.40)**	**($0.13)**	**($0.08)**	**($0.07)**	**($0.07)**	**($0.35)**	**$1.00**
YOY Growth	-	-				-	-
Basic Shares Outstanding	28.8	28.8	28.8	31.0	32.0	30.1	37.0

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

HISTORICAL ZACKS RECOMMENDATIONS



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