Zacks Small-Cap Research

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Protalex, Inc.

(PRTX-OTCQB)

PRTX: Moving Forward With PRTX-100!

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	12/1/2014
Current Price (1/20/2015)	$6.25
Target Price	**$10.00**

UPDATE

On January 9, 2015, Protalex reported financial results for the second quarter for FY 2015. For the three months ending November 30, 2014, the company reported no revenues, a net loss of approximately $4.2 million, or $0.15 per share, and burned through approximately $0.9 million. The company exited the quarter with approximately $0.7 million and cash and cash equivalents.

Having reported the final data from study PRTX-100-104, the company is looking ahead to initiating a Phase 2 study in RA with PRTX-100 in 2015. In addition, in 2015 the company also plans to initiate a clinical trial of PRTX-100 in idiopathic thrombocytopenic purpura (ITP), a rare autoimmune bleeding disorder.

SUMMARY DATA

52-Week High	**$9.50**
52-Week Low	**$5.00**
One-Year Return (%)	**-27.89**
Beta	**4.95**
Average Daily Volume (sh)	**1,701**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$187**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**81**
Annual Cash Dividend	**$9.50**
Dividend Yield (%)	**$1.30**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 E	0 E	0 E
2016					50 E

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

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2013	-$0.07 A	-$0.08 A	-$0.09 A	-$0.10 A	-$0.33 A
2014	-$0.08 A	-$0.05 A	-$0.18 A	-$0.13 A	-$0.45 A
2015	-$0.15 A	-$0.15 A	-$0.08 E	-$0.09 E	-$0.45 E
2016					$0.92 E

WHAT'S NEW

Financial Update

On January 9, 2015, Protalex, Inc. (PRTX) filed its form 10-Q for the second quarter of fiscal 2015, which was the three months ending November 30, 2014. As expected, Protalex did not report any revenues in the quarter. Net loss for the fourth quarter totaled $4.2 million, and was comprised of $0.9 million in R&D, $3.2 million in G&A, and $0.1 million in D&A and other expenses. Net loss for the quarter equated to $0.15 per share based on 28.8 million shares outstanding. Total cash burn for the fourth quarter was $0.9 million.

The company exited the quarter with approximately $0.7 million in cash and cash equivalents. On November 4, 2014, Protalex entered into a new Credit Facility Agreement with Niobe Ventures, LLC, a limited liability company controlled by Arnold P. Kling, Protalex's president and director. Under the terms of the agreement, Protalex may borrow up to $5.0 million in the form of secured loans at any time prior to December 31, 2015. Each loan made to Protalex will be represented by a senior secured promissory note with an interest rate of 3%. We remind investors that Niobe Ventures and management own approximately 80% of the company. As we've stated previously, we have little concern about the ongoing financial needs of the company.

Protalex Ready to Move PRTX-100 Ahead in the Clinic

In November 2014, Protalex announced data from Cohorts 1 through 5 of study PRTX-100-104 was presented at a poster session at the American College of Rheumatology (ACR) and the Association for Rheumatology Health Professionals (ARHP) Annual Meeting 2014. We invite investors to review our detailed analysis of the poster from December 2014.

The company is continuing to analyze the data generated during the course of the study with the help of an outside consulting firm while at the same time putting together the plan for a Phase 2 clinical trial. In addition to working with outside consultants, the company is working with various "Big Pharma" companies in order to design the Phase 2 trial such that the results will be of interest to potential partners at pharmaceutical companies. PRTX-100 is not far enough along in clinical development for a large pharmaceutical company to want to enter into a partnership yet, thus Protalex wants to be sure that whatever data is generated in the Phase 2 trial will be sufficient for a large pharmaceutical company to decide whether or not PRTX-100 is worth pursuing further.

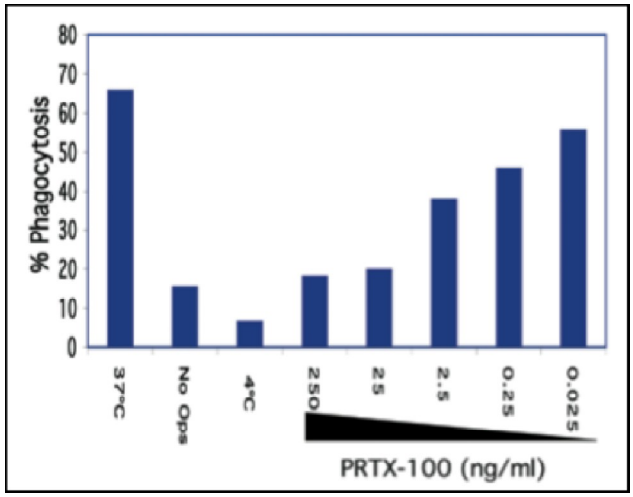
As a follow-up to the PRTX-100-104 study, Protalex is going to be conducting an open-label extension study (PRTX-100-105) with subjects who completed the -104 study. A total of 11 individuals completed the -104 study, and the goal is to enroll at least eight of these people in the continuation study. The purpose of the extension study is to allow the company to obtain long-term safety and efficacy data for PRTX-100 in these RA patients.

Clinical Trial for Idiopathic Thrombocytopenic Purpura To Commence in 2015

Protalex is set to file an IND for PRTX-100 in Idiopathic Thrombocytopenic Purpura (ITP) so that a clinical trial can commence in 2015. ITP is a rare autoimmune bleeding disorder characterized by insufficient platelets in the blood due to the patients forming autoantibodies against their own platelets. The antibody/platelet complexes are then cleared by the monocytes and macrophages of the reticuloendothelial system. This leads to the platelet's destruction, and since platelets are an integral part of the clotting system there is abnormal bleeding.

The incidence of ITP in the U.S. is estimated to be between 50-100 per one million per year. ITP affects more women than men and is also more common in children than in adults. It is not uncommon for the condition to spontaneously resolve in children (an acute condition) while remaining a chronic condition in adults, with subsequent periods of no disease (remissions) with intermittent relapses. Treatment in adults typically consists of anti-inflammatory steroids (prednisone). Patients who do not respond to steroid therapy can be treated with romisplostim (Nplate) or eltrombopag (Promacta), both of which are thrombopoietin receptor agonists that stimulate the production of new platelets. Global sales of Nplate and Promacta were $400 million and $250 million, respectively, in 2013. While successful in treating ITP patients, neither of those drugs impacts the principal pathological mechanism of ITP, namely the destruction of platelets.

rotalex believes that PRTX-100 may have a more direct impact on ITP by limiting the destruction of platelets, thus complementing or perhaps even reducing the use of thrombopoietic agents. Research presented at the 2006 Annual meeting of the American Society of Hematology showed that PRTX-100 inhibited the phagaocytosis of platelets in an *in vitro* assay in a dose dependent manner, as shown in the following chart.



***Source*: Protalex, Inc.**

The assay consisted of labeling platelets with an antibody, thus signaling for the platelets to be destroyed through phagocytosis. This is similar to what occurs in a patient with ITP. Interestingly, when monocytes were treated with either 25 or 250 ng/mL PTRX-100 prior to exposure to antibody-bound platelets, the level of platelet phagocytosis was similar to that seen when platelets were not labeled with antibody ("No Ops" group), indicating that PRTX-100 eliminated most antibody-mediated phagocytosis.

A small clinical trial in adult patients with chronic ITP was previously designed to provide safety data on repeated weekly dosing with PRTX-100 (PTRX-100b-103 Study). The study was to be performed under the Australian and New Zealand Clinical Trial Notification procedure and was initiated but not completed. After approval of the clinical protocol, the PRTX-100b-103 Study began enrolling patients in the second quarter of 2008. The study was designed to evaluate the safety and pharmacokinetics of up to four doses of PRTX-100, beginning at the lowest dose, and escalating upwards after a safety review of the prior dose.

The PRTX-100b-103 Study proved difficult to enroll due to a concurrent ITP Phase 3 study and subsequent availability of new and effective medicines for ITP. Nine patients were dosed at the first two dose levels by the end of the 1st quarter of 2009, at which point further recruitment of patients was suspended. No side effects or toxicities were noted with repeated weekly doses of PRTX-100 of 0.075 and 0.15 µg/kg.

Conclusion

Based on the proof-of-concept data that has been presented thus far showing PRTX-100 to be a safe and effective therapy in RA patients, we recently upgraded the stock to 'Buy'. In 2015, Protalex is looking to build upon the successful Phase 1 trials of PRTX-100 by: 1) performing the continuation study of PRTX-100-105 in patients who completed study PRTX-100-104, such that additional long-term efficacy and safety data can be compiled; 2) initiating a Phase 2 trial of PRTX-100 in RA; and 3) filing an IND and initiating a Phase 1 clinical trial of PRTX-100 in ITP patients.

As we recently stated in our article titled "15 Biotech Names for 2015", we think Protalex shares could double in 2015 as the company continues to advance PRTX-100 in the clinic and as more investors become familiar with the potential for PRTX-100. We are maintaining a 'Buy' rating and a $10.00 price target.

Protalex, Inc.
Income Statement

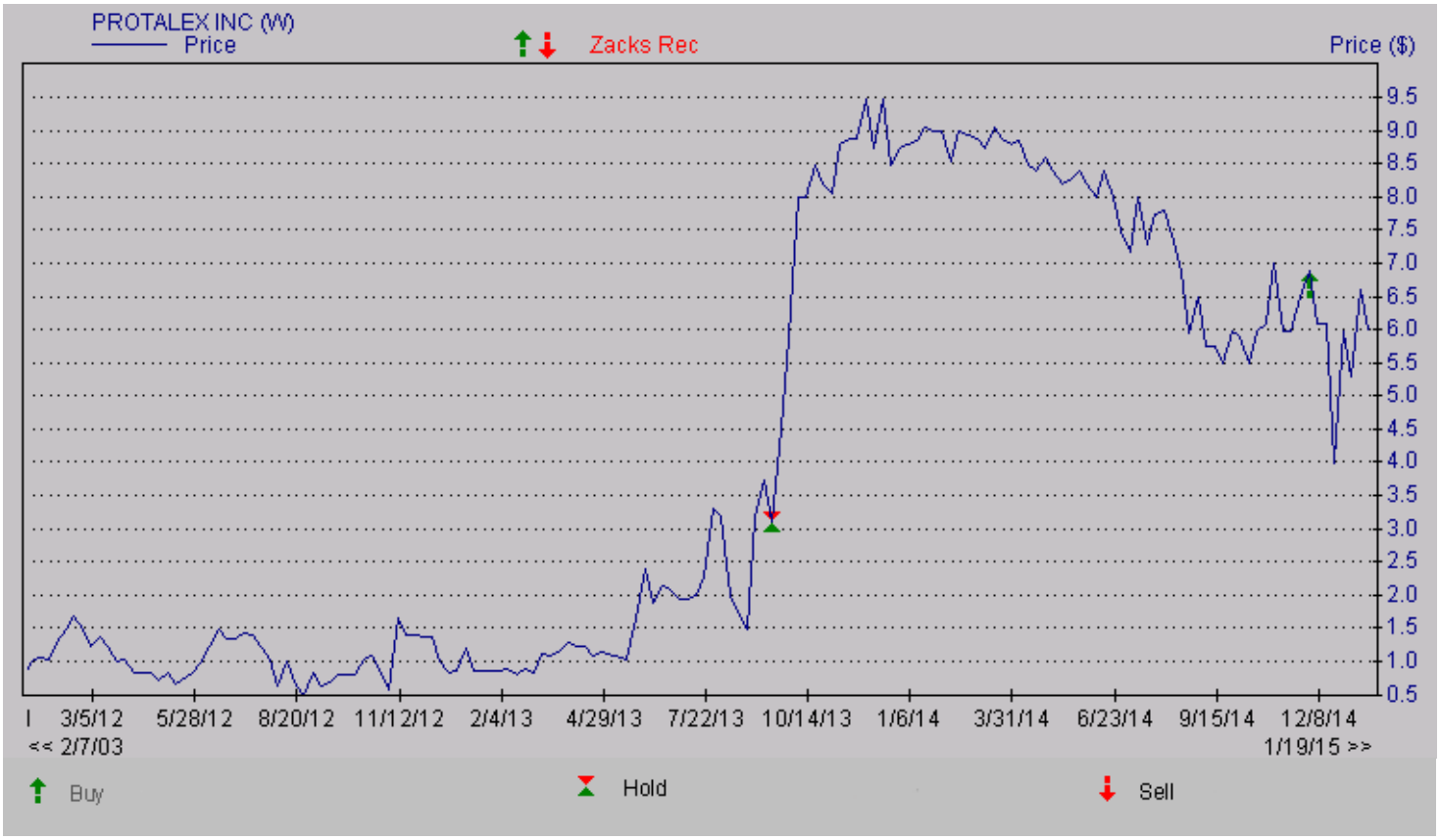
Protalex, Inc.	FY 2013 A	FY 2014 A	Aug-14 A	Nov-14 A	Feb-15 E	May-15 E	FY 2015 E	FY 2016 E
PRTX-100 Sales / Royalties	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Licensing / Collaborative	$0	$0	$0	$0	$0	$0	$0	$50.0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50.0**
YOY Growth	-	-	-	-	-	-	-	-
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$3.8	$3.2	$0.6	$0.9	$1.2	$1.5	$4.3	$5.0
SG&A	$1.8	$8.3	$3.5	$3.2	$1.5	$1.6	$9.8	$7.5
Depreciation & Amortization	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($5.6)**	**($11.6)**	**($4.1)**	**($4.1)**	**($2.7)**	**($3.1)**	**($14.0)**	**$37.5**
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.7)	($0.3)	($0.1)	($0.1)	($0.1)	($0.1)	($0.3)	($0.5)
Pre-Tax Income	($6.3)	($11.9)	($4.2)	($4.2)	($2.8)	($3.2)	($14.4)	$37.0
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($6.3)	($11.9)	($4.2)	($4.2)	($2.8)	($3.2)	($14.4)	$37.0
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.33)**	**($0.45)**	**($0.15)**	**($0.15)**	**($0.08)**	**($0.09)**	**($0.45)**	**$0.92**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	18.9	26.2	28.8	28.8	35.0	36.0	32.1	40.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

Protalex, Inc.
Balance Sheet – As of November 30, 2014

	November 30, 2014 (Unaudited)	May 31, 2014
CURRENT ASSETS:		
Cash and cash equivalents	$ 662,273	$ 1,614,758
Prepaid expenses	102,695	45,327
Total current assets	764,968	1,660,085
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $14,343 and $14,088 as of November 30, 2014 and May 31, 2014, respectively	4,937	5,447
Total other assets	4,937	5,447
Total Assets	$ 769,905	$ 1,665,532
LIABILITIES AND STOCKHOLDERS' (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 800,020	$ 412,718
Accrued expenses	7,151	40,135
Total current liabilities	807,171	452,853
LONG TERM LIABILITIES:		
Senior Secured Note – related party	9,949,367	9,219,366
Senior Secured Note Accrued Interest – related party	320,869	177,802
Total liabilities	11,077,407	9,850,021
STOCKHOLDERS' (DEFICIT)		
Preferred stock, par value $0.00001, 1,000,000 shares authorized; none issued and outstanding	0	0
Common stock, par value $0.00001, 100,000,000 shares authorized; 28,767,582 and 28,767,582 shares issued and outstanding, respectively	288	288
Additional paid in capital	71,653,962	65,402,505
Accumulated deficit	(81,961,752)	(73,587,282)
Total stockholders' deficit	(10,307,502)	(8,184,489)
Total liabilities and stockholders' deficit	$ 769,905	$ 1,665,532

HISTORICAL ZACKS RECOMMENDATIONS



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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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