Zacks Small-Cap Research

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Protalex, Inc.

(PRTX-OTCQB)

PRTX: Cohort 5 data from Study PRTX-100-104 due before the end of 2014…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	09/11/2013
Current Price (11/05/2014)	$6.00
Target Price	**$10.00**

UPDATE

On October 5, 2014, Protalex reported financial results for the first quarter for FY 2015. For the three months ending August 31, 2014 the company reported no revenues, a net loss of approximately $4.2 million, equating to $0.15 per share, and total cash burn in the quarter of approximately $0.9 million. The company exited the quarter with approximately $0.8 million in cash and cash equivalents.

The company is expected to announce preliminary findings from Cohort 5 of the PRTX-100-104 study before the end of 2014. In addition, the company will likely file an IND to initiate clinical trials investigating the use of PRTX-100 for the treatment of idiopathic thrombocytopenia.

SUMMARY DATA

52-Week High	**$9.50**
52-Week Low	**$5.01**
One-Year Return (%)	**-29.77**
Beta	**5.12**
Average Daily Volume (sh)	**1,190**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$180**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**79**
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 E	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	-$0.09 E	-$0.08 E	-$0.09 E	-$0.40 E
2016					$0.92 E

WHAT'S NEW

Financial Update

On October 8, 2014, Protalex, Inc. (PRTX) filed its Form 10K for the first quarter fiscal 2015, which was the three month period that ended August 31, 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 $0.61 million in R&D, $3.5 million in G&A, and $0.07 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 $0.8 million in cash and cash equivalents, thus with a quarterly cash burn of approximately $0.9 million they will need to raise additional funds in the next 3 months. The last time Protalex raised money was in January 2014 through a private offering of 0.471 million shares of common stock at $6.00 per share, raising gross proceeds of $2.8 million. Protalex currently has a Form S/1 active with the U.S. SEC. As a reminder, the majority shareholder of Protalex is Niobe Ventures, LLC, a limited liability company controlled by Arnold P. Kling, Protalex' president and director. Protalex has an outstanding Consolidated Note with Niobe that matures September 1, 2016. The current value and accrued interest of this note as of August 31, 2015 was $9.468 million. Niobe Ventures and management own approximately 80% of the company. We have little concern about the ongoing financial needs of the company.

Business Update

Protalex took part in the Rodman & Renshaw Global Investment Conference in September 2014, with a presentation given by James W. Dowe II, who is the company's Vice Chairman of the Scientific Advisory Board. Mr. Dowe explained during his presentation the data that has been generated thus far on PRTX-100:

> *"We're going to come to market with a game changer; and this is our first public outing, so you are the first ones to hear it. For four years we've said nothing because there is a difference between what you believe and what you know. We got the data now*."

Below we review Mr. Dowe's presentation as a brief reminder of the Protalex story. In addition, the presentation contained some new information about the clinical development plan for PRTX-100.

Mr. Dowe's presentation was a refreshingly honest and straightforward examination of both Protalex's strategy and of the data that Protalex has accumulated thus far for PRTX-100 in the various clinical trials examining it as a treatment for rheumatoid arthritis (RA). He began his presentation with a brief history of the company, which he helped co-found approximately 15 years ago. Four years ago the company ceased operations. However, in Mr. Dowe's view, Protalex was working on something that was worth pursuing, so he took control of the company through Niobe Ventures, LLC, which is now the major shareholder of the company and controlled by president and director, Arnold P. Kling.

Protalex's strategy was laid out quite simply by Mr. Dowe. There are millions of individuals around the world who suffer from autoimmune diseases, such as RA. Currently, there are billions of dollars spent every year to treat these diseases, with AbbVie's Humira®, Amgen & Pfizer's Enbrel®, and J&J's Remicade® being the three major drugs. All three drugs are tumor necrosis factor alpha (TNF-α) inhibitors, which suppress the immune system. Lastly, all three drugs must be taken for the rest of a person's life. Thus, there exists a significant unmet medical need for a drug that is low cost, safe, and has a durable response.

PRTX-100 could potentially solve all of the issues listed above in the following ways:

1) The production of PRTX-100 is a very low cost, simple process. The drug is a bacterial protein cultured, purified, and vialed in a 10 mL vial, with the 10 mL vial and stopper, "costing more than the drug" according to Mr. Dowe. Thus, the cost of goods associated with PRTX-100 is going to be at least 100 times less than the currently available drugs (Humira®, Enbrel®, and Remicade®), which we believe cost around $100 per gram to make but retail for roughly $12,000 per gram in the U.S. PRTX-100 will be a drug that is significantly less expensive than the currently available treatment options, which could increase the number of people around the world who can afford to take it.

2) PRTX-100 appears to be much safer than the currently available medications. All TNF-α inhibitors are known to cause serious adverse events, such as congestive heart failure, lymphoma, and death. For this reason all TNF-α inhibitors carry a bolded "black box" warning. Thus far, PRTX-100 has been studied in five separate clinical trials with no serious adverse events reported.

3) PRTX-100 shows similar efficacy to currently available treatments with a long duration of response. The following graph shows the percentage of patients who had DAS28 scores of less than 3.2 in study PRTX-100-104 as well as in a clinical trial of Enbrel®. The DAS28 is a way to quantify disease activity in a patient with RA, with a score of less than 3.2 indicative of low disease activity.



Source: **Protalex, Inc.**

While there are obvious limitations in comparing data between different clinical trials, it is still informative in this case as both studies were examining RA patients and response to treatment was quantified using the same disease activity score. This data does not say that PRTX-100 is better than Enbrel®, but at the very least it could be stated that PRTX-100 has comparable activity to Enbrel®. In addition, the patients taking Enbrel® received approximately 30 doses, while those who took PRTX-100 only received five once-weekly treatments with the final DAS28 score recorded a full 10 to 11 weeks after the last dose. Thus, this data does show durability of response for PRTX-100 after dosing stops, something that is not achievable with drugs like Enbrel®, Humira®, or Remicade®.

Some new information to come out of the presentation by Mr. Dowe is that Protalex will be conducting a continuation study, the PRTX-100-105 study. Mr. Dowe described patients that had entered the PRTX-100-104 study with very severe RA, to the point where their mobility was limited. The patients had all been on Humira®, Enbrel®, and/or Remicade®. According to Mr. Dowe:

> *"They (the patients) took five treatments of PRTX-100 and they regained their mobility. Of course the damage that had been done had been done and you cannot repair that but they had regained their mobility and regained their life."*

That is rather powerful evidence of the efficacy of PRTX-100. The patients who responded essentially went to their doctors asking to continue using PRTX-100. In order to both help these patients and to gain long-term data on the use of PRTX-100 the company has decided to perform the continuation study.

In addition, the company is in the process of drafting a protocol for a Phase 2 study in RA. Mr. Dowe alluded to discussions with pharmaceutical companies in regards to study design and the potential for development partnerships. However, he indicated that the company would only enter into a partnership if the terms were good for Protalex, otherwise the company is prepared to perform the Phase 2 study on its own.

In closing, Mr. Dowe stated the following in regards to how he views his investment in Protalex. Clearly, he fully believes in the data surrounding PRTX-100 and the potential impact it could have on a large population of individuals with a debilitating condition.

"To many of you, Protalex is just going to be another investment. Over the years you have made a few investments here and there, won a few, lost a few. It's an investment to you, to me it's more than an investment, okay. I wouldn't have stepped into this company four years ago and resurrected it just because it was an investment. I've seen the data. I've seen the data in the people in South Africa and in the United States and it touches you when you see the difference in their lives. It just says we got to do something more with this. So for me, it is an investment and it's an opportunity to make a meaningful difference in people's lives."

PRTX-100-104 Cohort 5 data to be reported soon

The data from patients in Cohort 5 of study PRTX-100-104 are expected by the end of 2014. As a reminder, Cohort 5 consisted of individuals who received five once-weekly doses of PRTX-100 followed by once monthly maintenance doses for four months. This data will be quite important, as it will give some insight into longer-term use of PRTX-100 and how that modulates disease activity. As noted above, response to PRTX-100 in patients in cohorts 1-4 was noted at days 85 and 113, while the final treatment for those patients occurred on day 29. This is likely indicative of some type of immuno-modulatory mechanism of action, and it will be quite interesting to see how the modified dosing schedule affects disease activity.

We will have more to say in regards to the future development of PRTX-100 in RA after the Cohort 5 data is released and we get a clearer sense of what the next trial may look like. What we can say at this time is that PRTX-100 is looking more and more like a potential blockbuster drug, and we believe it is sure to attract attention from major pharmaceutical companies seeking to partner for various regions around the global in 2015, something that Mr. Dowe also alluded to during his presentation. We believe the market remains unaware of PRTX-100; we expect that to change in 2015.

Seeking Orphan Drug Designation for Idiopathic Thrombocytopenic Purpura

Protalex is currently seeking Orphan Drug Designation in the U.S. and certain foreign jurisdictions for the use of PRTX-100 in the treatment of idiopathic thrombocytopenic purpura (ITP), a rare autoimmune bleeding disorder characterized by insufficient platelets in the blood due to the patients forming autoantibodies against their own platelets. This leads to the platelet's destruction, and since platelets are an integral part of the clotting system there is abnormal bleeding.

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 in the 0.075 and 0.15 mcg/kg that were not seen with single doses in healthy volunteer trials. The company plans to file an IND for PRTX-100 in ITP before the end of 2014 and initiate a Phase 1 trial shortly thereafter.

Conclusion

We believe monthly maintenance doses of PRTX-100, as designed in the 5th cohort, may provide ACR50 and DAS28-CRP scores on par with the blockbuster anti-TNF-α drugs Humira®, Enbrel®, and Remicade®. Only these anti-TNF-alpha drugs carry significant risks. We remind investors that at the ACR annual meeting in October 2013, Protalex presented data from an infection challenge study showing a marked reduction in this risk, meaningfully differentiating PRTX-100 from the anti-TNF-α class on safety. An abstract on this infection challenge study can be found on the company's website.

Protalex currently trades with a market capitalization of approximately $180 million. The market for RA drugs is estimated to be approximately $18 billion. At this stage it remains difficult to predict potential peak sales of PRTX-100. Based on the data discussed above, sales could range between $500 million and $2.5 billion. We believe Protalex shares are fairly valued at $250 million market cap, but this number could dramatically change as the full data from Cohort 5 becomes available. We recommend investors keep Protalex on close watch over the next several quarters.

Protalex, Inc.
Income Statement

Protalex, Inc.	FY 2013 A	FY 2014 A	Aug-14 A	Nov-14 E	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	$1.0	$1.2	$1.5	$4.3	$5.0
SG&A	$1.8	$8.3	$3.5	$1.5	$1.5	$1.6	$8.1	$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)**	**($2.5)**	**($2.7)**	**($3.1)**	**($12.4)**	**$37.5**
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.7)	($0.3)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)
Pre-Tax Income	($6.3)	($11.9)	($4.2)	($2.6)	($2.8)	($3.2)	($12.8)	$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)	($2.6)	($2.8)	($3.2)	($12.8)	$37.0
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.33)**	**($0.45)**	**($0.15)**	**($0.09)**	**($0.08)**	**($0.09)**	**($0.40)**	**$0.92**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	18.9	26.2	28.8	29.5	35.0	36.0	32.3	40.0

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

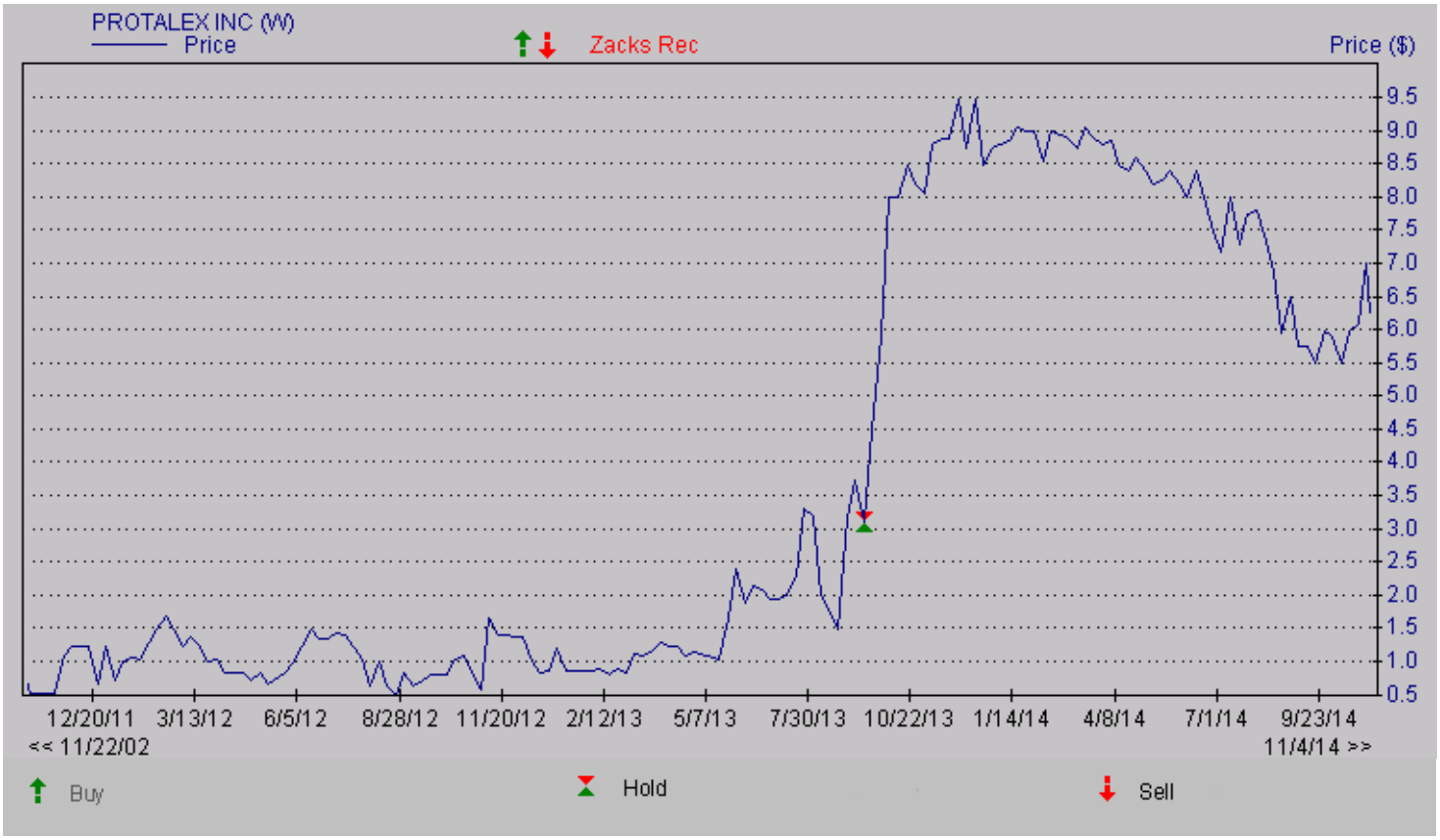
Protalex, Inc.
Balance Sheet – As of August 31, 2014

PROTALEX, INC.

CONDENSED BALANCE SHEETS

	August 31, 2014 (Unaudited)	May 31, 2014
CURRENT ASSETS:		
Cash and cash equivalents	$ 758,045	$ 1,614,758
Prepaid expenses	17,875	45,327
Total current assets	775,920	1,660,085
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $14,343 and $14,088 as of August 31, 2014 and May 31, 2014, respectively	5,192	5,,447
Total other assets	5,192	5,447
Total Assets	$ 781,112	$ 1,665,532
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 395,437	$ 412,718
Accrued expenses	7,150	40,135
Total current liabilities	402,587	452,853
LONG TERM LIABILITIES:		
Senior Secured Note – related party	9,219,366	9,219,366
Senior Secured Note Accrued Interest – related party	249,064	177,802
Total liabilities	9,871,017	9,850,021
STOCKHOLDERS' EQUITY (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	68,671,775	65,402,505
Accumulated deficit	(77,761,968)	(73,587,282)
Total stockholders' deficit	(9,089,905)	(8,184,489)
Total liabilities and stockholders' deficit	$ 781,112	$ 1,665,532

HISTORICAL ZACKS RECOMMENDATIONS



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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
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.

The current distribution is as follows: Buy/Outperform- 16.5%, Hold/Neutral- 75.4%, Sell/Underperform – 7.0%. Data is as of midnight on the business day immediately prior to this publication.