Zacks Small-Cap Research

April 17, 2014
Jason Napodano, CFA
David Bautz, PhD
312-265-9421 / jnapodano@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Protalex, Inc.

(PRTX-OTCQB)

PRTX: Study-104 Fully Enrolled; Top-line data to be released soon…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	09/11/2013
Current Price (4/17/2014)	$8.40
Target Price	**$10.00**

UPDATE

On April 14, 2014, Protalex reported financial results for the third quarter of FY 2014. Operating results for the three months ending February 28, 2014 were in-line with expectations, which included no reported revenues for the quarter, a net loss of roughly $5.0 million, equating to $0.18 per share, and total cash burn in the quarter of approximately $1.1 million. The sizable net loss was due to nearly $3.8 million in administrative expenses owing to a significant increase in employee stock compensation expense. In January 2014, Protalex entered a private placement with net proceeds to the company of $2.828 million in cash through the issuance of 471,334 shares of common stock at $6.00 per share. We believe this will be enough to fund the company through the fall of calendar 2014. Top-line data from Study-104 cohorts 1-4 should be released within the next few weeks with cohort 5 data available later in 2014.

SUMMARY DATA

52-Week High	**$9.50**
52-Week Low	**$1.30**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**1,740**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$242**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2013 Estimate	**N/A**
P/E using 2014 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 E	0 E	0 E
2015					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	-$0.04 E	-$0.05 E	-$0.18 E
2015					-$0.19 E
2016					$0.94 E

WHAT'S NEW

Financial Results

On April 14, 2014, Protalex, Inc. reported financial results for the third quarter of FY 2014 that ended February 28, 2014. As expected, Protalex did not report any revenues in the quarter. Net loss for the quarter totaled $5.0 million, and was comprised of $0.8 million in R&D, $4.1 million in G&A, and $0.1 million in D&A and other expenses. Net loss equated to $0.18 per share based on 28.5 million shares outstanding. The $4.1 million in G&A expenses included $3.8 million in employee stock compensation expense due to the vesting of a tranche of options triggered by dosing of the final patient in Study-104. These options had been granted with a vesting schedule based on an achievement as opposed to time, and thus vested with the final dosing achieved in Study-104. These options were granted with a strike price of less than one dollar, and with the stock currently trading at greater than eight dollars there was a large expense that the company recorded to account for the vesting of these options. Total cash burn in the quarter was only $1.15 million.

On January 23, 2014, Protalex, Inc. announced completion of a private placement with net proceeds to the company of $2.83 million in cash through the issuance of 471,334 shares of common stock at $6.00 per share. Protalex plans to use the proceeds from the offering for working capital purposes and to fund ongoing clinical trials and other related activities. The investors in the offering were granted piggy-back registration rights in connection with certain registration statements filed by the company, subject to certain exceptions, including a registration statement filed in connection with a primary offering.

During the second and third quarter of fiscal 2014, Protalex burned $0.94 and $1.15 million from operating, respectively. The company exited its fiscal third quarter 2014, ended February 28, 2014, with $2.72 million in cash and equivalents. Therefore, we believe the company has sufficient cash to fund operations into the fall of calendar 2014.

In February 2014, the company filed a registration statement on form S-1 with the U.S. SEC in connection with a prospective underwritten public offering of up to 3,000,000 shares of common stock. There is currently no commitment or understanding with any underwriter with respect to any offering.

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 proved 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 2nd 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.

PRTX-100-104 Study

In November 2012, Protalex, Inc. initiated a U.S.-based Phase 1b clinical study, dubbed Study-104. Study-104 is a multicenter, randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate and leflunomide in adult patients with active rheumatoid arthritis (RA). Back in 2012 when the study initiated, the goal was to enroll up to 40 patients into five cohorts ranging from 1.50 micrograms/kg (mcg/kg) up to 18.0 mcg/kg of PRTX-100 or placebo. The primary endpoint of the study is safety and tolerability of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate therapy. Secondary objectives include determining the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the pharmacokinetic (PK) parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety, PK and efficacy parameters.

In August 2013, following a planned interim safety review by the independent Data Safety Monitoring Committee (DSMC) and upon completion of the fourth cohort, the company expanded the 3.0 mcg, 6.0 mcg, and 12.0 mcg/kg dose cohorts of the study, and an additional nine patients were enrolled in the expansion cohort that was completed in October 2013. In total, the first four dose-escalating cohorts of the study, which included these three expanded cohorts, enrolled 41 patients with doses ranging from 1.5 mcg/kg up to 12.0 mcg/kg.

In November 2013, following completion of the Cohort 4 expansion cohorts, management initiated enrollment of the fifth and final cohort (Cohort 5) in the study. The Cohort 5 sub-study will enroll up to 20 patients and include additional monthly maintenance doses of PRTX-100 in the 3.0 mcg/kg to 6.0 mcg/kg range. Patients could receive up to nine doses of PRTX-100 over the six month study visit period, but the cumulative dose will not exceed that of Cohort 4 (12 mcg/kg). The primary objective of the Cohort 5 sub-study is to assess safety and tolerability of one of these doses administered on a modified schedule. As of March 1, 2014, all 20 patients were enrolled into Cohort 5 at six study sites in the U.S.

On Feb. 10, 2014, Protalex reported interim data analysis from the first four cohorts. The data showed that PRTX-100 was generally safe and well-tolerated. The rates of AEs among patients receiving PRTX-100 was comparable to those patients receiving placebo, and similar to the safety and tolerability seen in the company's previous Phase 1 study, P-103. Pharmacokinetic analyses indicated a roughly linear increase in plasma maximum concentrations with increasing doses of 1.5, 3.0, 6.0 and 12 mcg/kg of PRTX-100.

In the company's press release, they noted that two patients discontinued treatment during the 85-day study because of treatment-related adverse events. Our digging into this statement yielded the information that one patient with a history of cardiovascular disease experienced shortness of breath and dizziness, whereas another patient experienced an asthma exacerbation that required treatment with albuterol. Because the fifth cohort of Study-104 remains active, study investigators have not unblinded the data. Thus, the company is unsure if these two patients were on PRTX-100 or placebo. As such, we caution investors into reading too much into these events.

Initial results from the first four cohorts show effects on measures of disease activity as patients who received PRTX-100 had average Disease Activity Score / C-reactive protein (DAS28-CRP) and Clinical Disease Activity Index (CDAI) scores lower than the average scores of those who received placebo, which is consistent with the therapeutic effect in patients with this disease from the P-103 study. No additional statistics were provided by the company in the press release. In our conversations with management, the company noted results were very near statistical significance, which for a small dose-escalation trial of only 41 patients is good news. Management also told us that the results from Study-104 were consistent with P-103, and that the average of all the patients in the two highest dose cohorts, 6.0 and 12.0 mcg/kg, had DAS28 scores below 3.2 (baseline of ~5.0) at the end of the study. This was not the case with the placebo group.

The next step after Study-104 has been completed is to design a protocol for a larger Phase 2 study in RA with the U.S. FDA, and engage in discussion with the agency in regards to ITP. Depending on the data from the Phase 1b RA study, Protalex may find it more advantageous to move forward with the orphan disease indication first, and leave larger indications like RA to a development partner. We will have plenty more to say on Protalex this summer when the data from Study-104 becomes available.

PROJECTED FINANCIALS

Protalex, Inc.
Income Statement

Protalex, Inc.	FY 2012 A	FY 2013 A	Aug-13 A	Nov-13 A	Feb-14 A	May-14 E	FY 2014 E	FY 2015 E	FY 2016 E
PRTX-100 Sales / Royalties	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Licensing / Collaborative	$0	$0	$0	$0	$0	$0	$0	$0	$50.0
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50.0**
YOY Growth	*100.0%*	-	-	-	-	-	-	-	-
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-					-	-	-
R&D	$1.9	$3.8	$0.9	$0.7	$0.8	$1.1	$4.5	$5.0	$5.0
SG&A	$1.6	$1.8	$0.5	$0.7	$4.1	$0.5	$2.0	$2.2	$2.5
Depreciation & Amortization	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($3.5)**	**($5.6)**	**($1.4)**	**($1.4)**	**($5.0)**	**($1.6)**	**($6.5)**	**($7.2)**	**$42.5**
Operating Margin	-	-					-	-	-
Interest & Other Income	($0.9)	($0.7)	($0.1)	($0.1)	($0.1)	($0.1)	($0.3)	($0.3)	($0.3)
Pre-Tax Income	($4.4)	($6.3)	($1.5)	($1.5)	($5.0)	($1.7)	($6.8)	($7.5)	$42.2
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($4.4)	($6.3)	($1.5)	($1.5)	($5.0)	($1.7)	($6.8)	($7.5)	$42.2
Net Margin	-	-					-	-	-
Reported EPS	**($0.23)**	**($0.33)**	**($0.08)**	**($0.05)**	**($0.18)**	**($0.05)**	**($0.22)**	**($0.21)**	**$1.05**
YOY Growth	-	-					-	-	-
Basic Shares Outstanding	18.9	18.9	19.3	28.3	28.5	31.5	31.5	35.0	40.0

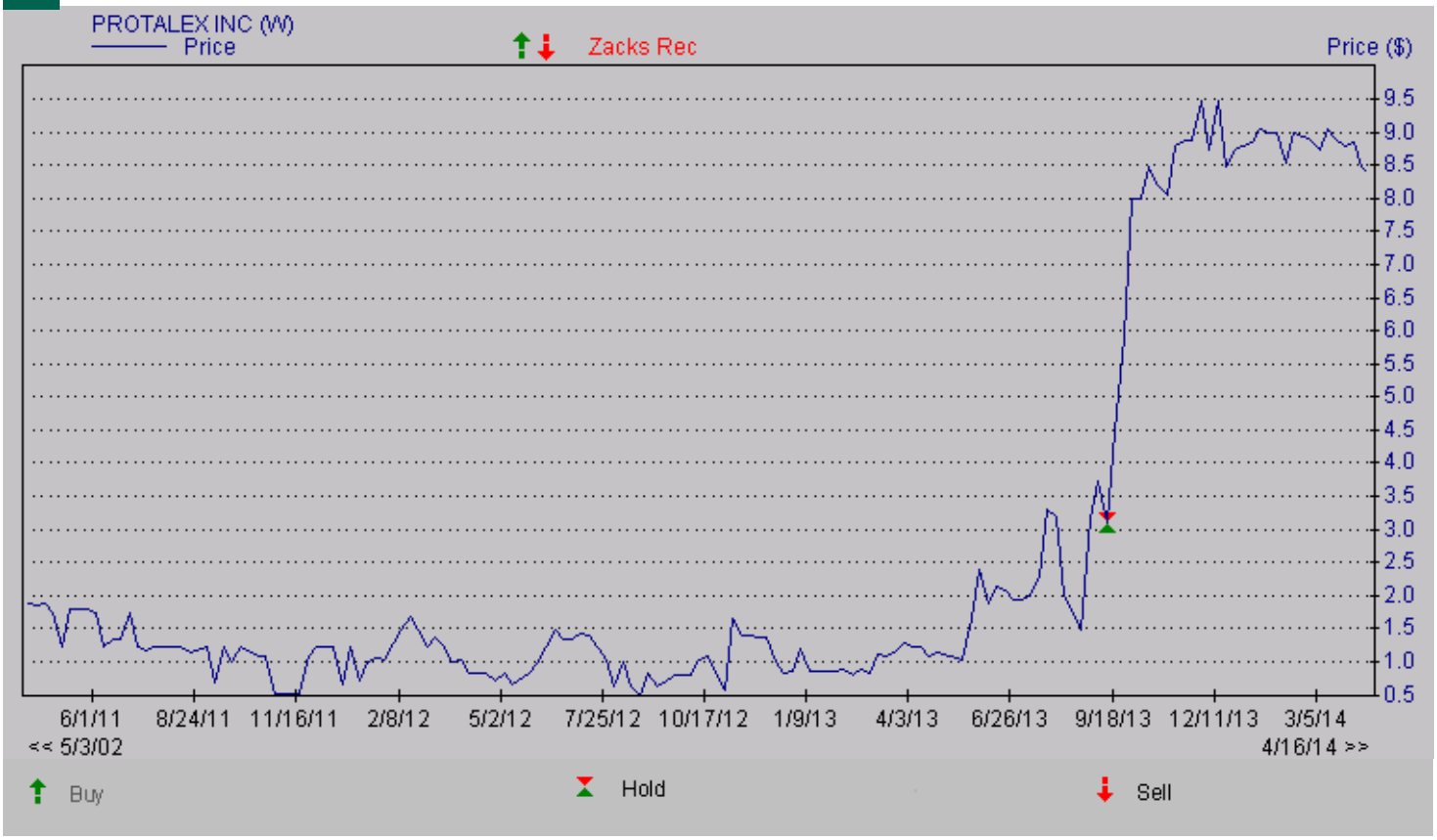
Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

Protalex, Inc.
Balance Sheet – As of February 28, 2014

PROTALEX, INC.
(A Development Stage Company)
CONDENSED BALANCE SHEETS

	February 28, 2014 (Unaudited)	May 31, 2013
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,716,459	$ 2,457,046
Prepaid expenses	67,214	42,320
Total current assets	2,783,673	2,499,366
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $13,833 and $13,068 as of February 28, 2014 and May 31, 2013, respectively	5,702	6,467
Total other assets	5,702	6,467
Total Assets	$ 2,789,375	$ 2,505,833
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 475,022	$ 671,738
Accrued expenses	32,773	62,517
Current portion – long term debt, related party,	0	4,210,833
Total current liabilities	507,795	4,945,088
LONG TERM LIABILITIES:		
Senior Secured Note – related party	9,219,366	6,000,000
Senior Secured Note Accrued Interest – related party	107,076	57,616
Total liabilities	9,834,237	11,002,704
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 18,926,615 shares issued and outstanding, respectively	288	189
Additional paid in capital	62,743,260	53,237,993
Deficit accumulated during the development stage	(69,788,410)	(61,735,053)
Total stockholders' equity (deficit)	(7,044,862)	(8,496,871)
Total liabilities and stockholders' equity (deficit)	$ 2,789,375	$ 2,505,833

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Jason Napodano, CFA, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1085 companies whose securities it covers, including securities covered by Zacks SCR:
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.