Zacks Small-Cap Research

December 2, 2014
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Protalex, Inc.

(PRTX-OTCQB)

PRTX: With sufficient proof-of-concept data in hand, we are upgrading Protalex to 'Buy'…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	12/1/2014
Current Price (12/2/2014)	$6.25
Target Price	**$10.00**

UPDATE

On November 17, 2014, Protalex reported final data from Cohorts 1 through 4 and interim data from Cohort 5 of the PRTX-100-104 study in a poster session at the 2014 ACR and ARHP annual meeting.

The data presented showed that the addition of four monthly maintenance doses of PRTX-100 did not increase the rate or type of adverse events, and that, although limited, these early results show efficacy results on par with results seen with other biologic RA treatments.

Based on the highly encouraging proof-of-concept data that has been generated thus far for PRTX-100, we are upgrading the stock to 'Buy', and feel that investors should now take a serious look at the Protalex story.

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 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

Protalex ACR 2014 Poster Analysis

On November 17, 2014, Protalex, Inc. (PRTX) announced that 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. Below we review the data presented and provide our analysis, including how the data presented by Protalex compares to data from clinical trials of Humira®, Enbrel®, and Remicade®.

…Brief Background of Study PRTX-100-104…

Study PRTX-100-104 was designed to test PRTX-100, a highly purified form of Staphylococcal A (SpA) protein, for the treatment of active rheumatoid arthritis. The primary endpoint of the study was the safety and tolerability of PRTX-100, with secondary objectives examining the effects of PRTX-100 on 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.

SpA is a 42 kilodalton bacterial membrane protein composed of five nearly identical domains. Each of the domains is capable of disrupting the activity of antibodies and B-cell receptors. SpA is capable of binding the Fc region of human IgG and the Fab framework region of antibodies from the VH3 gene family. This binding produces small complexes of SpA and IgG that are capable of inducing "alternatively activated" or "regulatory" macrophages that have an anti-inflammatory phenotype. Additionally, SpA is capable of interacting with VH3 B-cells and inducing apoptosis.

Previous Phase 1 dose-escalation studies of PRTX-100 have shown it to be safe and well tolerated at doses up to 1.5 µg/kg. Study PRTX-100-104 was designed to test weekly doses of PRTX-100 at 1.5, 3.0, 6.0, and 12.0 µg/kg in Cohorts 1 through 4. A fifth cohort of patients was dosed with weekly doses of either 420 µg PRTX-100 (12 patients), 240 µg PRTX-100 (3 patients), or placebo (5 patients) and then continued with four monthly "maintenance" doses at weeks 8, 12, 16, and 20. For comparison sakes, a 70 kg patient in Cohorts 1 through 4 would have received 105 µg, 210 µg, 420 µg, or 840 µg of PRTX-100 per dose.

Protalex had previously presented data on Cohorts 1-4 at EULARs Annual European Congress of Rheumatology in June 2014. The data showed that PRTX-100 was safe and well tolerated at the tested doses and that, while the number of patients treated was small, there appeared to be a treatment response.

The data presented for Cohort 5 included pharmacokinetic analysis, evaluation of anti-drug antibodies (ADAs), and disease activity assessed using the American College of Rheumatology (ACR) response. The ACR score is a number indicating to what degree a patient's rheumatoid arthritis has improved, based on guidelines set forth by the ACR. The ACR score represents a percentage, with an ACR50 score meaning that a patient's RA has improved by 50%. ACR20 and ACR70 scores are also typically reported in clinical studies of RA treatments.

To qualify for an ACR50 score, a person with RA must have at least 50% fewer tender joints and at least 50% fewer swollen joints at assessment vs. baseline. In addition, the person must show a 50% improvement in at least three of the following five areas: 1) the person's overall assessment of his or her own RA, 2) the physician's global assessment of the person's RA, 3) the person's assessment of his or her own pain, 4) the person's assessment of his or her own physical functioning, and 5) the results of an erythrocyte sedimentation rate or C-reactive protein blood test (both of which test for inflammation).

…Pharmacokinetic analysis of Cohort 5 PRTX-100 administration…

The following table shows a summary of the pharmacokinetic parameters for PRTX-100 after a 20-minute intravenous infusion of either 240 µg or 420 µg of PRTX-100. C_{max} is the maximum serum concentration of PRTX-100 while T_{max} is the time, in hours, which it takes to reach the maximum serum concentration. This data is quite comparable to the 3.0 µg/kg and 6.0 µg/kg data seen in Cohort's 1-4. The decrease in C_{max} between Days 1 and 22 was also seen in Cohort's 1-4.

Parameters[a]	PRTX-100 dose 240 μg	420 μg
Day 1		
C_{max}, ng/mL	77.3 ± 42.7 (3)	144 ± 44.6 (10)
T_{max}, h	0.38 (3) [0.00–0.58]	0.48 (10) [0.38–1.08]
Day 22		
C_{max}, ng/mL	47.4 ± 37.6 (3)	114 ± 41.2 (8)
T_{max}, h	0.38 (3)	0.38 (8)

Source: Protalex, Inc.

…Analysis of anti-drug antibody development…

PRTX-100 is a foreign protein, thus it is not surprising that immunization with the compound would lead to the development of anti-drug antibodies (ADA's). The following table shows the number of patients in Cohorts 1-5 that were positive for IgG ADA's. Interestingly, even though patients in Cohort 5 received four additional monthly doses of PRTX-100, the rate of ADA formation was very similar when compared to patients in Cohort's 1-4 (64.3% vs. 57.7%).

Treatment / Dose	Number of patients positive for IgG ADA: PRTX-100 240 μg	PRTX-100 420 μg	PRTX-100 240 μg and 420 μg	PRTX-100 Cohorts 1–4	PRTX-100 All	Placebo All
No. of subjects	3	12	15	31	46	15
Day 22 / 29 [1]	2 / 3 (66.7%)	7 / 8 (87.5%)	9 / 11 (81.8%)	19 / 27 (70.3%)	28 / 38 (73.7%)	0 / 13
Day 57	1 / 2 (50.0%)	5 / 7 (71.4%)	6 / 9 (66.7%)	19 / 28 (67.9%)	25 / 37 (67.6%)	0 / 13
Day 169 [2]	2 / 3 (66.7%)	7 / 11 (63.6%)	9 / 14 (64.3%)	15 / 26 (57.7%)	24 / 40 (60.0%)	0 / 12

Source: Protalex, Inc.

In addition to the development of IgG ADA's, the development of IgE ADA's was also assessed. The development of these antibodies can trigger an allergic response such as anaphylaxis. No patients in Cohort 5 developed detectable IgE ADA's while 5/30 patients in Cohorts 1-4 developed them. However, no patient who tested positive for IgE ADA's ever developed respiratory problems or anaphylaxis, and the five patients who were deemed positive for IgE ADA's had IgE levels just above the lower limit of detection for the assay.

Lastly, the relationship between the development of IgG ADA's and ACR20 response on day 57 and day 169 was examined. There did not appear to be any effect on ACR20 response due to the presence of IgG ADA's, as the following table shows that similar percentages of antibody negative and antibody positive patients experienced ACR20 responses across all cohorts on both days.

Summary	Treatment: PRTX-100 Cohorts 1–4 (n=31) Antibody Positive	PRTX-100 Cohorts 1–4 (n=31) Antibody Negative	PRTX-100 Cohort 5 (n=15) Antibody Positive	PRTX-100 Cohort 5 (n=15) Antibody Negative	PRTX-100 All Cohorts (n=46) Antibody Positive	PRTX-100 All Cohorts (n=46) Antibody Negative
ACR20						
Day 57	9 / 18 (50.0%)	4 / 9 (44.4%)	4 / 6 (66.7%)	1 / 2 (50.0%)	13 / 24 (54.2%)	5 / 11 (45.5%)
Day 169	6 / 15 (40.0%)	4 / 11 (36.4%)	3 / 5 (60.0%)	3 / 5 (60.0%)	9 / 20 (45.0%)	7 / 16 (43.8%)

Source: Protalex, Inc.

…RA disease activity…

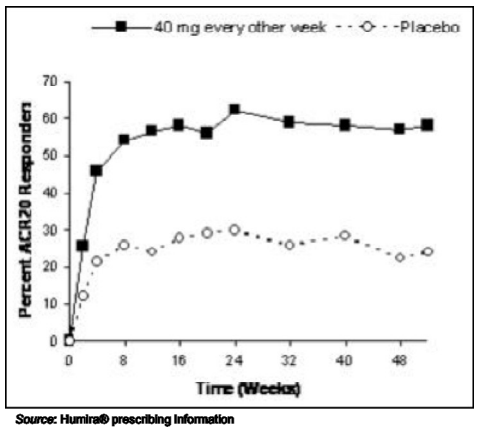
As we mentioned in our initial analysis of the Cohort 1-4 data in June 2014, it is difficult to ascertain any clear signals of efficacy, as the numbers of patients treated was quite low. However, we feel it is still useful to examine the data and compare it to results that are seen with the other biological treatments of RA (Humira®, Enbrel®, and Remicade®). We will restrict our analysis to the group of patients from Cohort 5 that were administered 420 µg per dose, as this group comprised most of the patients in Cohort 5 and they appeared to have the most interesting results.

The following table shows the two month ACR20, ACR50, and ACR70 values for Cohort's 1-5 along with the ACR20 data for up to six months.

	Treatment				
	PRTX-100				Placebo
	240 µg	420 µg	Cohorts 1–4 [2]	All	All
No. of subjects [1]	3	9	29	41	15
Day 57 ACR20	2 / 3 (66.7%)	4 / 8 (50.0%)	14 / 28 (50.0%)	20 / 39 (51.3%)	5 / 13 (38.5%)
Day 57 ACR50	0 / 3	1 / 9 (11.1%)	8 / 27 (29.6%)	9 / 39 (23.1%)	2 / 13 (15.4%)
Day 57 ACR70	0 / 3	1 / 9 (11.1%)	3 / 28 (10.7%)	4 / 40 (10.0%)	0 / 12
ACR20					
Day 15	1 / 3 (33.3%)	3 / 8 (37.5%)	6 / 28 (21.4%)	10 / 39 (25.6%)	4 / 13 (30.8%)
Day 29	2 / 3 (66.7%)	4 / 8 (50.0%)	8 / 28 (28.6%)	14 / 39 (35.9%)	4 / 13 (30.8%)
Day 57	2 / 3 (66.7%)	4 / 8 (50.0%)	14 / 28 (50.0%)	20 / 39 (51.3%)	5 / 13 (38.5%)
Day 85	1 / 1 (100%)	5 / 9 (55.6%)	14 / 29 (48.3%)	20 / 39 (51.3%)	4 / 10 (40.0%)
Day 113	2 / 3 (66.7%)	5 / 7 (71.4%)	10 / 25 (40%)	17 / 35 (48.6%)	4 / 11 (36.4%)
Day 169	1 / 2 (50.0%)	5 / 6 (83.3%)	7 / 22 (31.8%)	13 / 30 (43.3%)	5 / 8 (62.5%)

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

Approximately 50% of patients from Cohorts 1-5 achieved ACR20 two months after treatment began (Day 57). This is quite comparable to ACR20 response rates seen in patients treated with Humira®, as shown in the following graph.



***Source*: Humira® prescribing information**

In addition to comparing quite favorably to the Humira® ACR20 response rates at two months, the six month ACR20 response rate for Cohort 5 patients dosed with 420 µg PRTX-100 is quite similar to the ACR20 response rates seen with Humira®, Enbrel®, and Remicade®.

ACR20 at 6 months

	Humira®	Enbrel®	Remicade®	Cohort 5 420 µg
No. Patients	207	59	86	6
Dose	40 mg	50 mg	3 mg/kg	0.42 mg
Frequency	Bi-weekly	Weekly	0, 2, 6 wks then bi-monthly	Weekly
Duration	Continuous	Continuous	Continuous	5 weeks + 1x/mo. 4 mo.
ACR20	63%	71%	50%	83%

Sources: **Protalex, Inc.; Humira®, Enbrel®, Remicade® prescribing information**

There are a couple of points to keep in mind when comparing the data between PRTX-100 and the leading biologic treatments for RA:

1) The number of patients treated with PRTX-100 was very small (n=6). This is in comparison to the Phase 3 trials for Humira®, Enbrel®, and Remicade® that contained 207, 59, and 86 patients, respectively. In addition, each of the biologics was tested in at least one other Phase 3 trial that showed very similar results for each of those products.
2) Keeping in mind that it was a very small number of patients, it is still quite encouraging to see such a high ACR20 response rate in the PRTX-100 Cohort 5 group.
3) The amount of drug needed to achieve the ACR20 response rate at six months in the PRTX-100 treated patients is at least two orders of magnitude less than the amount of drug needed for ACR20 responses when treating with Humira®, Enbrel®, or Remicade®.

	Dose	# Doses[a]	Total Amt. Drug
Humira®	40 mg	12	480 mg
Enbrel®	50 mg	24	1200 mg
Remicade®	210 mg[b]	5	1050 mg
PRTX-100[c]	0.42 mg	9	3.8 mg

[a]number of doses in 6 months of treatment

[b]assuming 70 kg patient

[c]includes 4 monthly 'maintenance' doses

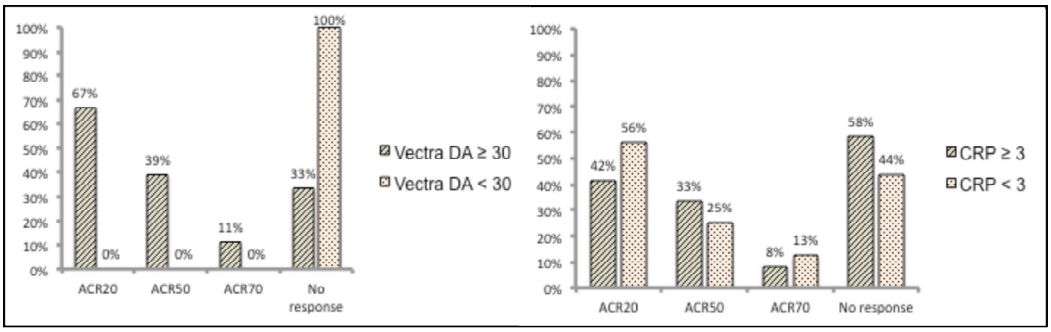
In addition, the cost of goods to produce PRTX-100 is going to be at least 100 times less than for Humira®, Enbrel®, or Remicade®, which means that a) PRTX-100 could be brought to market in less developed areas of the world where most individuals can not afford the $10,000 or more per year it costs to be treated with Humira®, Enbrel®, or Remicade® and b) PRTX-100 could be utilized in conjunction with Humira®, Enbrel®, or Remicade® as an inexpensive add-on therapy.

…Potential for personalized medicine approach to RA therapy…

Lastly, data was presented on a post-hoc analysis of patient samples from Cohorts 1-4 utilizing the Vectra DA score. Vectra DA is a quantitative laboratory test that is validated to assess RA disease activity and was developed by Crescendo Bioscience, which was acquired by Myriad Genetics (Nasdaq: MYGN) in February 2014. The test uses the concentration of 12 biomarkers in the blood and a proprietary algorithm to derive a score from 0-100. These 12 biomarkers were found to have the best ability to evaluate RA disease activity in multiple studies of over 1,100 patients. The Vectra DA score classifies RA into low (1-29), intermediate (30-44), or high (45-100) disease activity.

Protalex performed post-hoc analysis of data from Cohorts 1-4 to show that by grouping patients according to Vectra DA score they could improve trial efficacy outcomes. The Vectra DA score was determined using a blood specimen collected when the patients first entered the trial. Specifically, the data showed that three patients entered the trial with low Vectra DA scores (12, 19, 21; all three patients had DAS28-CRP scores > 5) and that none of

these three patients responded to treatment with PRTX-100. In contrast, 66.7% of patients with Vectra DA scores > 30 (intermediate or high disease activity) had at least an ACR20 response, as shown in the following graph. Grouping patients by c-reactive protein (CRP) value did not result in the same outcome.



Source: David Bautz, Zacks Investment Research

While this data does look rather encouraging, the fact remains that the Vectra DA test was only able to remove three patients from Cohorts 1-4 who did not have a score ≥ 30. In addition, this was a post-hoc analysis that may be identifying a pattern that only exist's in this cohort of patients and may not be replicated in a larger clinical trial.

Were this trend to hold up in a larger, prospective analysis we can foresee the Vectra DA test being utilized as a screening tool to predict whether or not a patient is likely to respond to treatment with PRTX-100. There is currently no personalized approach to RA treatment; in essence a patient is started on one treatment and if they do not respond they are transitioned onto another treatment option until their disease is under control. We can envision how having a validated test that could predict who is most likely to benefit from PRTX-100 treatment moving it to front-line status. This would be all the more likely if future clinical trials continue to show PRTX-100 to be safe, well tolerated, and efficacious, particularly when compared to Humira®, Enbrel®, or Remicade®.

Financing Update

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%. The same day, Protalex borrowed $0.3 million under the new agreement. 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.

Conclusion and Recommendation

Protalex continues to generate very intriguing data in regards to the use of PRTX-100 for the treatment of RA. We would be remiss, however, if we did not remind investors that PRTX-100 is still early in development as it has only been tested in Phase 1 clinical trials thus far in a limited number of patients. With that said, the fact that the results are on par with the major biologic treatments, with a much better safety profile, is highly encouraging. The company will be moving PRTX-100 into Phase 2 clinical trials for RA in 2015, which will involve a larger numbers of patients. We anticipate that the results obtained so far will be reproducible in a larger cohort of patients.

In addition to RA, the company has plans to initiate a Phase 1 clinical trial with PRTX-100 in 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. Protalex plans to start a Phase 1 trial of PRTX-100 in ITP in 2015.

If PRTX-100 continues to produce results that are on par with Humira®, Enbrel®, and Remicade®, along with continuing to exhibit a clean safety profile, then Protalex would have a blockbuster medication for the treatment of RA. We believe there is now sufficient proof-of-concept data to justify getting into the stock, thus we are upgrading our recommendation on Protalex from 'Neutral' to 'Buy'.

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*

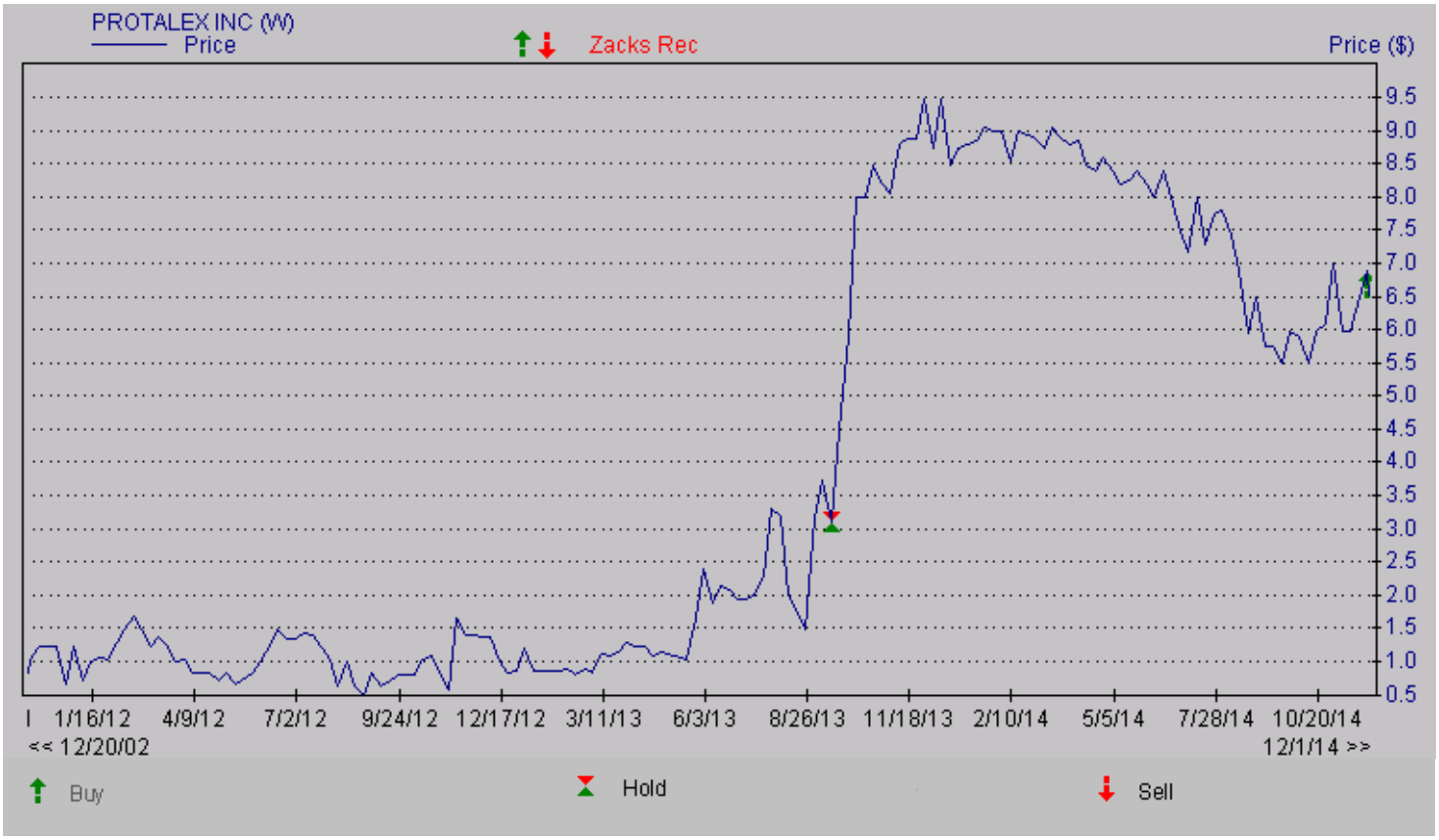
Protalex, Inc.
Balance Sheet – As of August 31, 2014

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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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.