Zacks Small-Cap Research

June 17, 2014
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Protalex, Inc.

(PRTX-OTCQB)

PRTX: Analysis Of PRTX-100 Poster at EULAR…

UPDATE

On June 13, 2014, Protalex (OTC: PRTX) presented data from Cohorts 1-4 of the Phase 1b randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate or leflunomide in adults with active rheumatoid arthritis (RA). The data was presented during a poster session at EULARs Annual European Congress of Rheumatology in Paris, France. We have reviewed the poster presentation and provide our analysis of the data below.

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	09/11/2013
Current Price (6/17/2014)	$8.40
Target Price	**$10.00**

SUMMARY DATA

52-Week High	**$9.50**
52-Week Low	**$1.30**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**5,626**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$237**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0**
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 A	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	-$0.18 A	-$0.05 E	-$0.22 E
2015					-$0.21 E
2016					$1.05 E

WHAT'S NEW

PRTX-100 Phase 1b Data

On June 13, 2014, Protalex (OTC: PRTX) presented data from Cohorts 1-4 of the Phase 1b randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate or leflunomide in adults with active rheumatoid arthritis (RA). The data was presented during a poster session at EULARs Annual European Congress of Rheumatology in Paris, France. We have reviewed the poster presentation and provide our analysis of the data below. In summary, with the small number of patients it is very difficult to determine any type of dose-response relationship. One interesting clinical observation during the study indicated that patients who experienced an RA flare after beginning PRTX-100 treatment were much more likely to experience a response to treatment (80% of 10 patients with RA flares vs. 34% of all PRTX-100 treated patients).

Protalex is developing PRTX-100, a proprietary, highly purified form of bacterial protein staphylococcal protein A (SpA) for the treatment of inflammatory and autoimmune disorders. 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 also capable of interacting with VH3 B-cells and inducing apoptosis.

In November 2012, Protalex initiated a U.S.-based Phase 1b clinical study, dubbed Study PRTX-100-104. 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 RA. Back in 2012 when the study initiated, the goal was to enroll up to 40 patients into five cohorts ranging from 1.5 micrograms/kg (µg/kg) up to 18.0 µg/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 µg, 6.0 µg, and 12.0 µg/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 µg/kg up to 12.0 µg/kg.

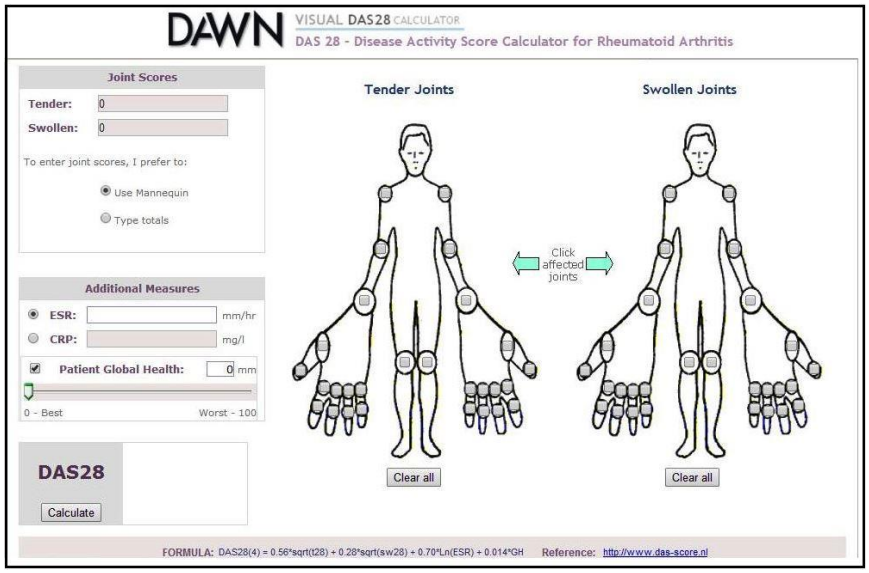
In November 2013, following completion of the Cohort 4 expansion cohorts, management initiated enrollment of the fifth and final cohort (Cohort 5) in the study. The Cohort 5 sub-study enrolled 20 patients and included additional monthly maintenance doses of PRTX-100 in the 3.0 µg/kg to 6.0 µg/kg range. Patients could receive up to nine doses of PRTX-100 over the six-month study visit period, but the cumulative dose would not exceed that of Cohort 4 (12 µg/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 Cohort 5 was fully enrolled and data from this group of patients will be available in the second half of 2014.

All patients in Study-104 had ≥ 4 swollen joints and ≥ 5 tender joints and were currently taking methotrexate. PRTX-100 was administered on days 1, 8, 15, 22, and 29. Patients were evaluated on days 57, 85, 113, and 169. The primary endpoint of the study is to evaluate safety and tolerability. Safety was evaluated through assessment of adverse events (AEs), complete blood count, blood chemistry, urinalysis, and electrocardiogram.

Pharmacokinetic (PK) profiles were determined after dosing on days 1 and 22. Antibody production to PRTX-100 in each patient was determined on days 1, 22, 57, 169. The following biomarkers were also assessed: lymphocyte phenotypes by fluorescence-activated cell sorting (FACS), a method for quantitatively determining the amount and type of lymphocyte cells in a patients' blood sample. Additional analyses included quantification of complement factors C3a, C4a, and C5a in pre- and post-dose samples on days 1 and 22. Complement factor C3a is involved in the anaphylaxis response, and significant increases in complement factors, especially C3a, could be indicative of an allergic response to PRTX-100.

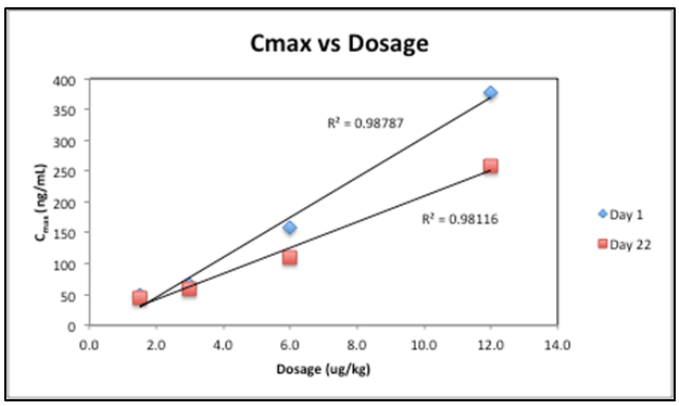
Disease activity was assessed using DAS28-CRP, American College of Rheumatology (ACR) response, and Clinical Disease Activity Index (CDAI). The ACR score is a number indicating how much a person's rheumatoid arthritis has improved, based on guidelines set forth by the American College of Rheumatology (ACR). The ACR score represents a percentage, with an ACR50 score indicating a patient's RA has improved by 50%. 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).

The DAS28 assessment is a composite score derived from the number of swollen joints, the number of tender joints, an assessment of general health, and a serum marker such as sedimentation rate (DAS28) or C-reactive protein (DAS28-CRP). The raw data from these assessments is combined to give a single score of disease activity using a mathematical formula. Remission is indicated by a score less than 2.6, low disease activity from 2.7-3.1, moderate disease activity from 3.2-5.1, and a score greater than 5.1 indicates high disease activity. The following figure was taken from an online DAS calculator to better show how the DAS score is calculated.



…***Pharmacokinetic parameters of PRTX-100 administration***…

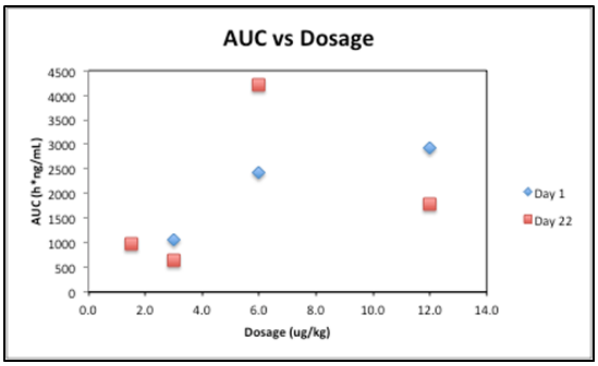
A number of pharmacokinetic (PK) parameters were examined during the trial, including the maximum concentration of drug after administration, total exposure to drug, and how quickly PRTX-100 was cleared from the patient's blood. The following graph shows that administration of PRTX-100 resulted in an approximately linear relationship between dose and C_{max}, or the maximum amount of PRTX-100 detected in a patient's blood.



Source: Protalex, Inc.

The 1.5 and 3.0 µg/kg doses had similar C_{max} values due to the difference in infusion rates (2 min infusion for 1.5 µg/kg vs. 30 min for 3.0 µg/kg). The data shows that while there is a linear relationship between dose and C_{max} on both days 1 and 22, the slopes of the lines differ with a lower C_{max} seen for doses on day 22, a result of faster clearance of PRTX-100.

Another parameter that was examined was Area Under the Curve (AUC), which represents the total drug exposure over time and is calculated by plotting the concentration of drug in the blood against time. A graph of the total AUC vs. dosage is shown below.



Source: Protalex, Inc.

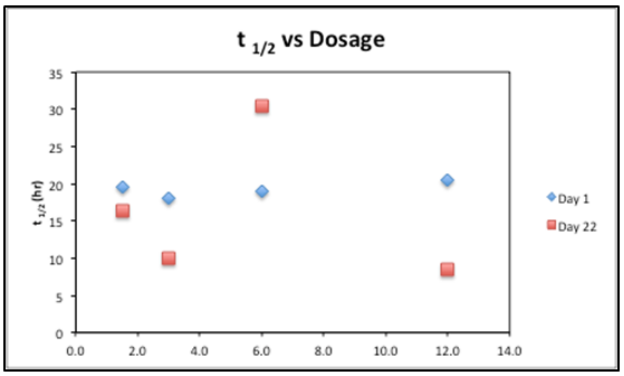
As can be seen the AUC on day 22 for the 6.0 µg/kg dose is well above the day 1 value, which is different than all the other doses that showed a decrease in AUC on day 22 compared to day 1. This is most likely the result of the considerable variability seen with the PK data and could not be ascribed to one particular outlying data point.

Interestingly, the decrease in AUC on day 22 did not correlate with the development of anti-drug antibodies (ADAs). Since PRTX-100 is a bacterial protein, it is not surprising that patients would develop an immunological response to treatment, which occurred in 76% of PRTX-100 treated patients. However, this response did not correlate with a decrease in AUC or preclude a CDAI response. In fact, those patients with a lower ADA titer had a significantly greater decrease in their day 22:day1 AUC ratio. The day 22:day 1 AUC ratio for four patients with ADA titer >800 was 0.86 (14% decrease) and for 10 patients with ADA titers <200 it was 0.24 (76% decrease) (t test, $p < 0.01$).

Incidence of anti-SpA antibodies and lack of relationship to decreased day 22 plasma AUC or to Disease Activity Responses				
Anti-SpA dilution titer day 22	**0**	**<400**	**≥400**	**All active-dosed**
Placebo-dosed	8	0	0	
SpA-dosed	7	10	12	29
Ratio day 22:day 1 AUC_{0-N}[a]	0.36 (301)	0.35 (50)	0.75 (55)	0.45 (130)
Ratio day 22:day 1 C_{max}[a]	0.83 (30)	0.70 (29)	1.01 (22)	0.84 (30)
No. active dosed with CDAI ≤14 x 3	1	5	4	10

Source: Protalex, Inc.

By day 22, PRTX-100 was being cleared from the patients' blood faster than on day 1, as indicated by a decrease in $t_{1/2}$, or the time it takes for the concentration of drug to decrease by 50%. As AUC and $t_{1/2}$ are related, there was a much higher $t_{1/2}$ for the 6.0 µg/kg dose on day 22 just as was seen for AUC.



Source: Protalex, Inc.

…***RA Disease Activity***…

With the small number of patients in each cohort it is difficult to ascertain any type of dose-response relationship. We need to remind investors, this was only a Phase 1b study. However, when looking at the data there did appear to be some early signs of efficacy. When examining all patients who were dosed with PRTX-100, approximately 32% of them achieved ACR50 at day 57, compared to only 12.5% of placebo treated patients. This was relatively consistent across the different dosage groups with approximately 33%, 38%, 22%, and 40% of patients in the 1.5, 3.0, 6.0, and 12.0 µg/kg groups achieving ACR50 at day 57.

	SpA dose					
Disease activity endpoint,[a] % of patients	1.5 µg/kg (n=6)	3.0 µg/kg (n=9)	6.0 µg/kg (n=9)	12.0 µg/kg (n=5)	All (n=29)	Placebo (n=8)
ACR50 CRP day 57	33.3	37.5	22.2	40	**32.1**	**12.5**

Source: Protalex, Inc.

ACR responses appeared less sensitive to PRTX-100 treatment than CDAI categorical analysis due to the fact that most patients had relatively high baseline CRP values and PRTX-100 does not appear to rapidly reduce CRP values, unlike anti-TNF-α treatments. CRP value is part of the ACR score but is not part of the CDAI.

For CDAI, approximately 34% of PRTX-100 treated patients reported a CDAI value of ≤ 14 at 3 consecutive visits compared to only 12.5% of placebo treated patients. However, this relationship did not appear to correlate with dosage as 50%, 11%, 22%, and 60% of patients had a CDAI ≤ 14 at 3 consecutive visits in the 1.5, 3.0, 6.0, and 12.0 µg/kg cohorts, respectively. While it is common to see a CDAI value ≤ 10 representing low disease activity, Protalex has utilized a CDAI score of ≤ 14 to capture low disease activity and patients in remission for all PRTX-100 studies.

	SpA dose					
Disease activity endpoint,[a] % of patients	1.5 µg/kg (n=6)	3.0 µg/kg (n=9)	6.0 µg/kg (n=9)	12.0 µg/kg (n=5)	All (n=29)	Placebo (n=8)
CDAI ≤14 at 3 consecutive visits	50	11.1	22.2	60	**34.4**	**12.5**

Source: Protalex, Inc.

DAS28-CRP levels showed that of all the patients treated with PRTX-100, approximately 32% had DAS28-CRP <3.2 on day 57 compared to 12.5% of placebo treated patients. A DAS28-CRP value of <3.2 represents low disease activity. However, unlike with ACR50, there appeared to be a rough correlation between dosage and DAS28-CRP < 3.2 with approximately 17%, 38%, 33%, and 60% of patients falling in that category in the 1.5, 3.0, 6.0, and 12.0 µg/kg cohorts, respectively. This trend continued up to day 85, with 80% of patients in the 12.0 µg/kg cohort reporting DAS28-CRP < 3.2.

Focusing on the 6.0 and 12.0 µg/kg cohorts, the percentage of patients with DAS28-CRP < 3.2 was 33.3%% and 80% on day 85 and 42.9% and 66.7% on day 113. In addition, on day 113, 29% of active-treated patients from the 6.0 and 12.0 µg/kg cohorts achieved DAS28-CRP scores less than 2.6 (remission). This compares quite favorably with data seen in a study of Enbrel® (etanercept) plus methotrexate for the treatment of RA (Kim *et al*., 2012). In that study, 39.1% of etanercept treated patients experience DAS28-CRP < 3.2 on day 102 with 15.7% of patients achieving DAS28-CRP < 2.6. Enbrel® global sales eclipsed $8.4 billion in 2013.

	PRTX-100 (6.0 and 12.0 ug/kg)	Etanercept (Kim *et al*., 2012)
DAS < 3.2	50.0%	39.1%
DAS < 2.6	29.0%	15.7%

The final dose of PRTX-100 occurred at day 29 with responses still noted at days 85 and 113, indicative of long-term efficacy and a mechanism of action that most likely involves some type of immune-modulation. While we do not yet know the precise mechanism of action, we point investors to this study that examined the mechanism by which SpA acts as a treatment for RA, which was published in 2011 in Arthritis and Rheumatology (MacLellan *et al*., 2011). The study utilized a mouse model of rheumatoid arthritis with results showing that injection of SpA into mice at the onset of disease inhibited the development of arthritis.

The investigators found that SpA forms highly regulated complexes with IgG that are capable of interacting with monocytes, macrophages, and preosteoclasts. Binding of the SpA-IgG complexes with macrophages causes them to enter a regulatory state that makes them unresponsive to inflammatory cytokines while at the same time promoting the production of anti-inflammatory cytokines. The authors state that SpA presumably arose as a defense mechanism to interfere with the host inflammatory responses required for immunogenicity of microbial antigens, and that this characteristic can also be utilized to serve as a potent inhibitor of autoimmune inflammatory disease.

Lastly, we were intrigued by the fact that patients who experienced moderately severe transient RA flares after beginning treatment with PRTX-100 had a higher RA response rate than the entire cohort of PRTX-100 treated patients (80% of 10 patients vs. 34% of all PRTX-100 treated patients). In all, 10 PRTX-100 treated patients experienced a ≥ moderate RA flare after starting PRTX-100 treatment, three in the 1.5 µg/kg cohort, one in the 3.0 µg/kg cohort, four in the 6.0 µg/kg cohort, and two in the 12.0 µg/kg cohort. Of those patients, 3/3 in the 1.5 µg/kg cohort, 1/1 in the 3.0 µg/kg cohort, 2/4 in the 6.0 µg/kg cohort, and 2/2 in the 12.0 µg/kg cohort reported CDAI ≤ 14 at 3 consecutive visits.

	SpA dose					
Disease activity endpoint,[a] % of patients	**1.5 µg/kg (n=6)**	**3.0 µg/kg (n=9)**	**6.0 µg/kg (n=9)**	**12.0 µg/kg (n=5)**	**All (n=29)**	**Placebo (n=8)**
Patients with RA flare ≥ moderate as related AE and CDAI ≤14 at 3 visits	3/3	1/1	2/4	2/2	80 (8 of 10)	NA

Source: Protalex, Inc.

Neither the company nor we have a good explanation for this data at this juncture, and we remind investors that at this point it only remains an interesting clinical observation that was included in the poster presentation and was not statistically significant. However, this observation could also have to do with the potential mechanism of action discussed in the MacLellan *et al*. paper. We could surmise a scenario whereby administration of PRTX-100 is in fact altering the macrophage phenotype of a patient, and during the transition stage from "pro-inflammatory" to "anti-inflammatory" state there are breakthrough flares. Of course this is only a guess at this point; however, this result is clearly something that the company will need to investigate further to elucidate exactly why it is occurring. It will be interesting to see if this phenomenon occurs in Cohort 5 and in additional clinical trials in the future. If it holds, this could represent an interesting market niche opportunity for the drug.

The following figure provides ACR50 data for Remicade®, Humira®, Enbrel®, and Xeljanz® from Phase 3 studies of each of those drugs. The columns for Dose 1 and Dose 2 refer to different dosing regimens that were utilized in the studies. For example, the Remicade® studies treated patients with either 3 mg/kg (Dose 1) or 10 mg/kg (Dose 2). The data from the previous studies look very comparable to what was reported from the PRTX-100 Phase 1b study.

		ACR50		
		Placebo	Active Dose 1	Active Dose 2
Phase 1b Study	PRTX-100 25 week	13%	32%	
Phase 3 Study 1	Remicade 30 week	5%	28%	29%
Phase 3 Study 1	Remicade 54 week	9%	28%	39%
Phase 3 Study 1	Humira 6 mo.	8%	22%	35%
Phase 3 Study 2	Humira 6 mo.	10%	39%	
Phase 3 Study 2	Humira 12 mo.	10%	42%	
Phase 3 Study 1	Enbrel 3 mo.	8%	41%	
Phase 3 Study 1	Enbrel 6 mo.	5%	40%	
Phase 3 Study 2	Enbrel 3 mo.	0%	42%	
Phase 3 Study 2	Enbrel 6 mo.	3%	39%	
Phase 3 Study monotherapy	Xeljanz 3 mo.	12%	31%	36%
Phase 3 Study monotherapy	Xeljenz 6 mo.		42%	46%
Phase 3 Study +MTX	Xeljanz 3 mo.	8%	29%	37%
Phase 3 Study +MTX	Xeljenz 6 mo.	9%	32%	44%
Phase 3 + MTX TNF NR	Xeljanz 3 mo.	8%	26%	28%
Phase 3 + MTX TNF NR	Xeljenz 6 mo.		37%	30%

Conclusion

While the data presented on PRTX-100 in the treatment of RA at EULARs Annual European Congress of Rheumatology was not powered to show significance, we were still encouraged by what we saw. The company was able to show a roughly linear relationship between C_{max} and dosage with administration of the drug being well tolerated by patients. In addition, we are intrigued by the clinical observation showing those patients experiencing an RA flare after beginning PRTX-100 treatment were more likely to respond than those who did not have a flare.

Data from Cohort 5 will be available later in 2014. Upon full analysis of the data the company will hold a meeting with the FDA to discuss their plans for a Phase 2 study, something we do not forecast to begin until approximately mid-2015.

We believe monthly maintenance doses of PRTX-100, as designed in the 5th cohort, may provide ACR50 and DAS28-CRP scores on par with blockbuster anti-TNF-alpha drugs like Humira®, Enbrel®, and Remicade®. Only these anti-TNF-alpha drugs carry significant risks of infection. 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-alpha class on safety. An abstract on this infection challenge study can be found on the company's website.

In addition to treating RA, we remind investors that Protalex is currently seeking Orphan Drug Designation for the use of PRTX-100 in the treatment of idiopathic thrombocytopenic purpura (ITP), a rare autoimmune bleeding disorder. Clinical trials for ITP will likely be initiated while the company is finalizing the data analysis from Study-104 and preparing protocols for Phase 2 trials in RA.

Protalex currently trades with a market capitalization of approximately $230 million. Sales of anti-TNF drugs eclipse $25 billion worldwide. At this stage it remains difficult to predict potential peak sales of PRTX-100. Based on the profile 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 later in 2014 as the full data from Cohort 5 becomes available. We recommend investors keep Protalex on close watch for these upcoming events over the next several quarters.

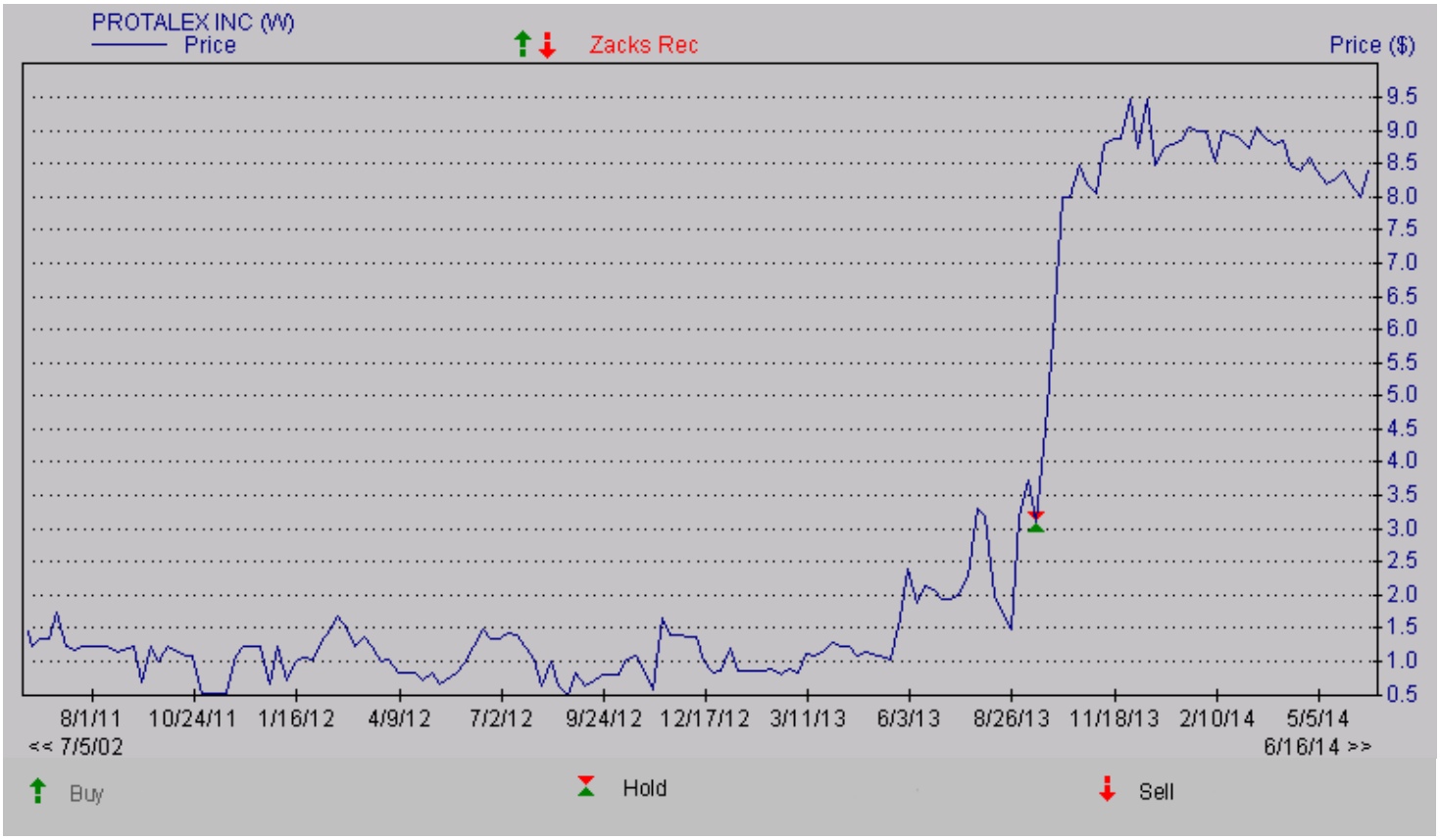
PROJECTED FINANCIALS

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*

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.