Zacks Small-Cap Research

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Protalex, Inc.

(PRTX-OTCQB)

PRTX: Preliminary PRTX-100 Phase 1b data looks encouraging…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	09/11/2013
Current Price (6/03/2014)	$8.40
Target Price	**$10.00**

UPDATE

On June 3, 2014, Protalex announced preliminary unblinded results from cohorts 1-4 of the Phase 1b trial testing PRTX-100 as a treatment for rheumatoid arthritis (RA). While the study was not powered to show statistically significant efficacy, the results still look encouraging. PRTX-100 was generally safe and well tolerated, with no reports of any immediate hypersensitivity reactions or serious adverse events. Analysis of the higher dosing cohorts showed positive effects on certain measures of disease activity.

We will have more to say after we perform a detailed analysis of the full data set, which will be presented at EULAR's Annual European Congress of Rheumatology on June 13, 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 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

Preliminary Unblinded Findings from Cohorts 1-4 of Phase 1b Trial

On June 3, 2014, Protalex announced preliminary unblinded results from cohorts 1-4 of the Phase 1b trial testing PRTX-100 as a treatment for rheumatoid arthritis (RA). The primary endpoint of this study is to assess 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. The results of the study will be presented in a poster at the 2014 EULAR Annual European Congress of Rheumatology meeting in Paris, France on June 13, 2014.

The preliminary results indicated that PRTX-100 was generally safe and well tolerated. There were no reports of any immediate hypersensitivity reactions or any serious adverse events. The PK analysis indicated an approximately linear increase in plasma maximum concentrations with increasing doses of PRTX-100 of 1.5, 3.0, 6.0, and 12.0 micrograms/kg.

The efficacy data disclosed in today's press release notes both ACR50 and DAS28-CRP scores. 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 meaning that 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.

While more data will be disclosed with the poster presentation, the company has alluded to some early indications of effects on disease activity for those patients in the 6.0 and 12.0 mcg/kg dosing cohorts. For example, four weeks following the final dose of PRTX-100, 32% of active-treated and 13% of placebo-treated patients had attained an ACR50 response.

At day 113, 29% of active-treated achieved DAS28-CRP scores less than 2.6, which is indicative of clinical remission. The placebo group showed no patients in remission. When examining all patients treated with PRTX-100, 43% had DAS28-CRP scores less than 3.2 (which indicates low disease activity) on both Day 57 and Day 85. Only 14% of placebo-treated patients showed a similar reduction in RA disease activity.

The Phase 1b study is currently ongoing, with 16 out of 20 patients in cohort 5 having completed dosing through Day 85. Patients in this cohort received five weekly doses of PRTX-100 just as those patients in cohorts 1-4, with an addition four monthly maintenance doses thereafter. All the patients in cohort 5 will receive their last doses of PRTX-100 in July 2014.

…***Data compares favorably with past RA clinical trials***…

We will perform a detailed analysis of the full data when the poster is made available; however, as a preliminary examination of the data presented thus far, we have looked into past clinical trial results for other RA treatments to get a sense of the percentage of patients who had attained an ACR50 response and how that compares to the preliminary numbers reported by Protalex in this Phase 1b study. We caution that it is very difficult to compare data across clinical trials, and this is an early look at the data, however we still believe it is worthwhile and helps us to get a sense for how the data is starting to come together.

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, and we are looking forward to performing a more detailed analysis of the data after the poster is presented.

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

Although only preliminary results, we view these data as encouraging. The Phase 1b study continues with the 5th cohort. All patients are on methotrexate or leflunomide, with a randomization to placebo, 1.5 mcg/kg, 3.0 mcg/kg, 6.0 mcg/kg, or 12.0 mcg/kg. In the first four cohorts, patients received five weekly intravenous infusions in a physician's office over 28 days. In the ongoing 5th cohort, patients will receive monthly maintenance doses of PRTX-100 up to 240 mcg or 420 mcg total. This data will become available later in 2014. We are encouraged to see good safety and tolerability. We are also encourage to see evidence of a disease modulation effect, as patients continued to show good response to the drug out to day 57 and 85.

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.

We are eagerly awaiting the full data presentation of the first four cohorts from the Phase 1b PRTX-100-104 study at EULAR on June 13, 2014. Protalex will have a poster presentation and has already made available an abstract to the oral presentation. At EULAR, we will be focusing on the results for the 6.0 mcg/kg and 12.0 mcg/kg cohorts, looking to compare both ACR50 and DAS28-CRP data to the anti-TNF-alpha class. We believe comparable efficacy with improved safety / tolerability is indicative of PRTX-100 being a blockbuster drug.

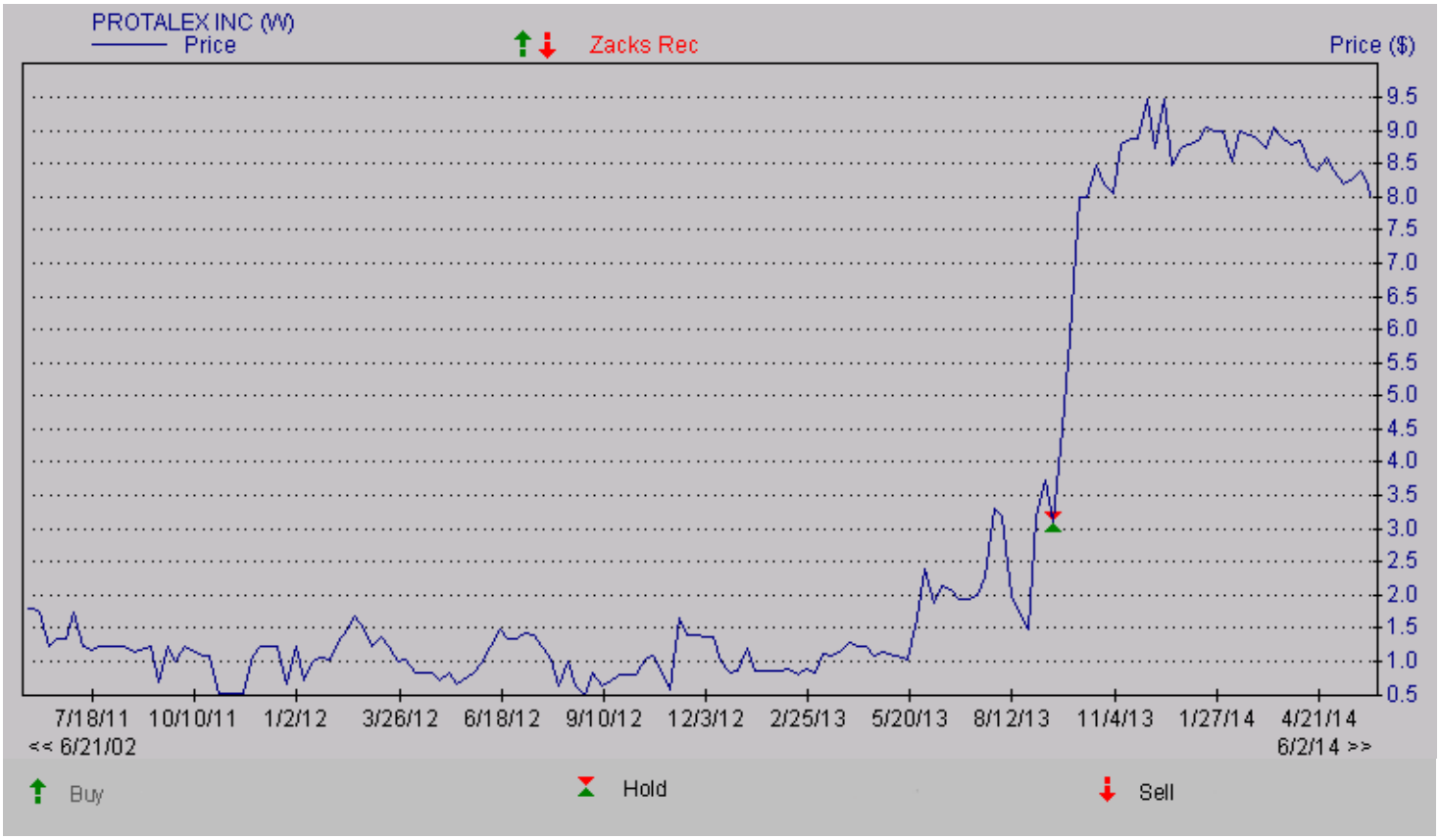
PROJECTED FINANCIALS

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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