Zacks Small-Cap Research

August 12, 2014
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# Protalex, Inc.

**(PRTX-OTCQB)**

***PRTX: Awaiting Cohort 5 data from Study PRTX-100-104…***

| | |
|---|---|
| **Current Recommendation** | **Neutral** |
| Prior Recommendation | N/A |
| Date of Last Change | 09/11/2013 |
| Current Price (8/12/2014) | $7.45 |
| **Target Price** | **$10.00** |

## UPDATE

On August 5, 2014, Protalex reported financial results for the fourth quarter and full year for FY 2014. For the three months ending May 31, 2014 the company reported no revenues, a net loss of approximately $3.8 million, equating to $0.13 per share, and total cash burn in the quarter of approximately $1.1 million.

For the FY, the company had a net loss of approximately $11.9 million, or $0.45 per share. The sizable net loss was due to nearly $6.4 million in non-cash stock based compensation. The company exited the FY with $1.6 million in cash and cash equivalents. Upcoming catalysts for the next six months include filing an IND for an orphan indication and the final data from Study PRTX-100-104 Cohort 5.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$9.50** |
| **52-Week Low** | **$1.30** |
| **One-Year Return (%)** | **272.50** |
| **Beta** | **5.98** |
| **Average Daily Volume (sh)** | **950** |
| **Shares Outstanding (mil)** | **29** |
| **Market Capitalization ($mil)** | **$214** |
| **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 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 E | 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 | -$0.08 E | -$0.09 E | -$0.08 E | -$0.09 E | -$0.34 E |
| 2016 | | | | | $0.92 E |

## WHAT'S NEW

**Financial Results**

On August 5, 2014, Protalex, Inc. reported financial results and filed its Form 10-K for the fourth quarter and full year Fiscal 2014 that ended May 31, 2014. As expected, Protalex did not report any revenues in the quarter. Net loss for the fourth quarter totaled $3.8 million, and was comprised of $0.78 million in R&D, $2.95 million in G&A, and $0.07 million in D&A and other expenses. Net loss for the quarter equated to $0.13 per share based on 28.8 million shares outstanding. Total cash burn for the fourth quarter was $1.1 million.

For the fiscal year, the company had no revenues with a net loss of $11.9 million, or $0.45 per share. The net loss was comprised of $3.2 million in R&D, $8.3 million in G&A, and $0.3 million in D&A and other expenses. The $8.3 million in G&A expenses included $6.4 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 seven dollars there was a large expense that the company recorded to account for the vesting of these options. Total cash burn for the FY was $4.6 million. The company exited FY 2014 with $1.6 million in cash and cash equivalents, thus with a quarterly cash burn of approximately $1.1 million they will need to raise additional funds in the next 6 months.

**PRTX-100-104 Study**

PRTX-100 is currently being evaluated in study PRTX-100-104 as a treatment for rheumatoid arthritis. On June 13, 2014, the company presented data from Cohorts 1-4 of the Phase 1b randomized, multiple-dosed, dose-escalation study during a poster session at EULARs Annual European Congress of Rheumatology in Paris, France. For a detailed analysis of the study results please refer to our Zacks report dated June 17, 2014.

Data from patients in Cohort 5 is expected by the end of September 2014. After top-line data for Cohort 5 are released the company will perform all necessary *in vitro* testing of serum samples in support of an "end of study" report to be filed with the FDA. We expect this to be filed during the first quarter of 2015.

The next step in the development of PRTX-100 in RA is entirely dependent upon what the data from Cohort 5 indicates, including but not limited to the number of patients necessary in a larger trial, the optimum dosage, and the number and timing of doses. 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. 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 2$^{nd}$ 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 in the third quarter of 2014 and initiate a Phase 1 trial no later than the fourth quarter of 2014.

## Expansion of Clinical Development Team

On May 5, 2014 Protalex announced the hiring of three senior industry leaders to strengthen their clinical development team. The company hired John B.L. McClain, M.D. as Medical Director, Richard J. Francovitch, Ph.D. as Vice President of ITP Programs, and Michelle Cataline, Ph.D. as Director of Preclinical Studies. All three individuals also joined the company's Scientific Advisory Board.

Dr. McClain has 18 years of broad international industry experience in clinical development, product safety, and as a chief medical officer. Prior to entering industry, Dr. McClain spent over 20 years in clinical and academic positions. Dr. McClain worked most recently as a pharmaceutical consultant focused primarily in infectious disease research programs. Prior to entering consulting, Dr. McClain was Chief Medical Officer at Aeras Global TB Vaccine Foundation for eight years, and for nine years prior to that he was an executive with Medimmune, first as Director, Clinical Development Transplantation and later as Medical Director, Pharmacovigilance.

Dr. Francovitch has 27 years of experience developing and commercializing pharmaceutical products with a significant focus in oncology and hematology. For the past 15 years he was an executive with GlaxoSmithKline where he most recently was Vice President and Head of the Hematology Franchise and Global Commercial Leader for Promacta®/Revolade™ in the Global Oncology Commercial Center of Excellence. In leading the global commercialization for Promacta®/Revolade™, he was responsible for launching indications in ITP and hepatitis C associated thrombocytopenia.

Dr. Catalina has worked as an immunology consultant to Protalex for the past year and was responsible for designing and implementing *in vitro* and *in vivo* preclinical studies for the company's drugs along with key preclinical and clinical immunological assays. In addition, Dr. Catalina managed technical transfer and provided oversight for assays being developed externally or outsourced. Prior to joining Protalex, Dr. Catalina was an instructor at the University of Massachusetts Medical Center in Worcester (UMass), where she directed projects related to the production of tetrameric molecules for detection of antigen-specific T-cells and the generation and maintenance of antigen-specific T-cells.

## 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.

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.

Protalex currently trades with a market capitalization of approximately $215 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 2013 A | FY 2014 A | Aug-14 E | 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 | $0.8 | $1.0 | $1.2 | $1.5 | $4.5 | $5.0 |
| SG&A | $1.8 | $8.3 | $1.4 | $1.5 | $1.5 | $1.6 | $6.0 | $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)** | **($2.2)** | **($2.5)** | **($2.7)** | **($3.1)** | **($10.5)** | **$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) | ($2.3) | ($2.6) | ($2.8) | ($3.2) | ($10.9) | $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) | ($2.3) | ($2.6) | ($2.8) | ($3.2) | ($10.9) | $37.0 |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.33)** | **($0.45)** | **($0.08)** | **($0.09)** | **($0.08)** | **($0.09)** | **($0.34)** | **$0.92** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Basic Shares Outstanding | 18.9 | 26.2 | 29.0 | 29.5 | 35.0 | 36.0 | 32.4 | 40.0 |

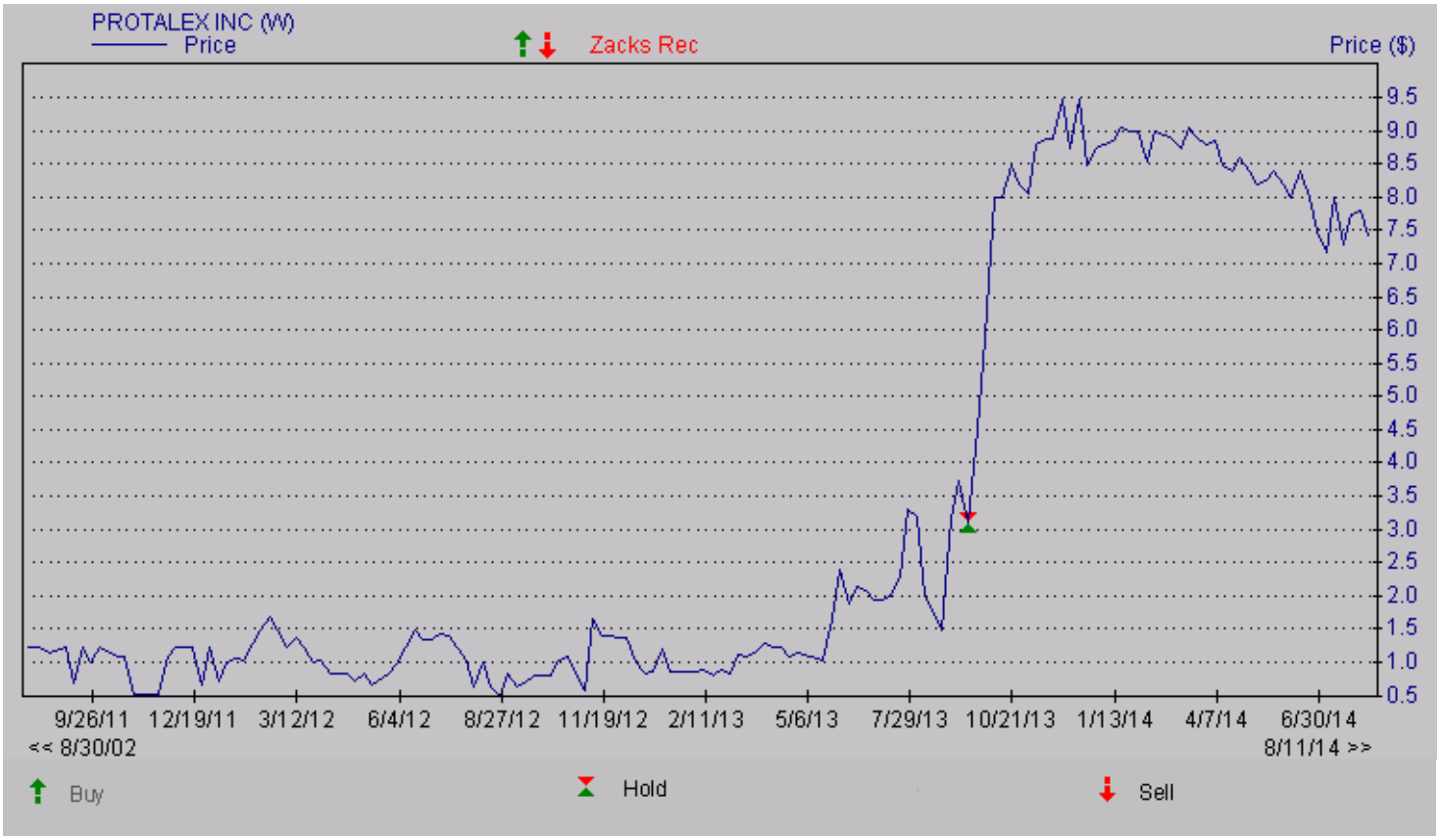
*Source: Zacks Investment Research, Inc.* *Jason Napodano, CFA*

**Protalex, Inc.**
Balance Sheet – As of May 31, 2014

**PROTALEX, INC.**
**BALANCE SHEETS**

| | May 31, 2014 | May 31, 2013 |
|---|---|---|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 1,614,758 | $ 2,457,046 |
| Prepaid expenses | 45,327 | 42,320 |
| Total current assets | 1,660,085 | 2,499,366 |
| OTHER ASSETS: | | |
| Intellectual technology property, net of accumulated amortization of $14,088 and $13,068 as of May 31, 2014 and May 31, 2013, respectively | 5,447 | 6,467 |
| Total other assets | 5,447 | 6,467 |
| Total Assets | $ 1,665,532 | $ 2,505,833 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 412,718 | $ 671,738 |
| Accrued expenses | 40,135 | 62,517 |
| Current portion – long term debt– related party | 0 | 4,210,833 |
| Total current liabilities | 452,853 | 4,945,088 |
| LONG TERM LIABILITIES: | | |
| Senior Secured Note – related party | 9,000,000 | 6,000,000 |
| Senior Secured Note Accrued Interest – related party | 397,168 | 57,616 |
| Total liabilities | 9,850,021 | 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 | 65,402,505 | 53,237,993 |
| Accumulated deficit | (73,587,282) | (61,735,053) |
| Total stockholders' equity (deficit) | (8,184,489) | (8,496,871) |
| Total liabilities and stockholders' equity (deficit) | $ 1,665,532 | $ 2,505,833 |

## HISTORICAL ZACKS RECOMMENDATIONS



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