Zacks Small-Cap Research
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Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: Self-Sustaining Rise to Lead in Renal Rare Disease

The valuation employs a net present value (NPV) approach and a 15% discount rate. Our model recognizes Elfabrio's approval in Fabry Disease in the United States and the EU and assigns 100% probability of success to it and Elelyso following US and European approval. The model includes contributions from global commercialization.

Current Price (11/14/2024)	$1.41
Valuation	**$14.00**

OUTLOOK

Protalix is a clinical and commercial pharmaceutical company using its proprietary ProCellEx plant-based expression system to produce therapeutic proteins for global markets. The company has two commercialized products, Elelyso that is marketed by Fiocruz in Brazil & Pfizer in the rest of the world for Gaucher Disease and Elfabrio which was approved in May 2023. Chiesi Rare Disease will commercialize Elfabrio globally.

Protalix has additional candidates in earlier stages of development including PRX-115 for the treatment of refractory gout and PRX-119, a long action DNase I for the treatment of NETs-related diseases.

Elfabrio was approved in Europe and the United States in early May 2023 and continues to be approved elsewhere. The product can fill an unmet need with several improvements over the market leader and is expected to command a premium vs. existing products. Elelyso should show moderate growth over the next quarters as partners continue their commercialization efforts. Profits from revenue generating products are expected to be invested in new candidates in coming years.

SUMMARY DATA

52-Week High	**$1.90**
52-Week Low	**$0.82**
One-Year Return (%)	**2.9**
Beta	**0.7**
Average Daily Volume (sh)	**188,651**
Shares Outstanding (mil)	**73.6**
Market Capitalization ($mil)	**103.8**
Short Interest Ratio (days)	**22.7**
Institutional Ownership (%)	**5.2**
Insider Ownership (%)	**14.5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**13.8**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**70.5**
P/E using 2025 Estimate	**2.2**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	$9.6 A	$35.1 A	$10.3 A	$10.5 A	$65.5 A
2024	$3.7 A	$13.5 E	$18.0 A	$18.2 E	$53.4 E
2025					$101.4 E
2026					$167.2 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.05 A	$0.21 A	-$0.02 A	-$0.07 A	$0.10 A
2024	-$0.06 A	-$0.03 A	$0.04 A	$0.08 E	$0.02 E
2025					$0.63 E
2026					$1.13 E

WHAT'S NEW

Third Quarter 2024 Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced third quarter 2024 financial and operational results in a November 14th, 2024 press release and in the filing of Form 10-Q. The reports were followed by a conference call which discussed recent achievements, clinical updates and financial performance. Since the second quarter update, Protalix has repaid its convertible debt and completed the eighth cohort of its Phase I PRX-115 trial in gout. With preliminary results presented at the American College of Rheumatology conference, and a Phase II planned for 2H:25, we have increased visibility on this product over the next year or so. Revenues were impressive with a 74% increase driven by a strong increase in Chiesi revenues.

Revenues for 3Q:24 were $18.0 million, which were dominated by revenues from Chiesi. This produced net income of $3.2 million or $0.03 per share.

Financial results for the quarter ending September 30th, 2024, compared to prior year comparable period:

- Revenues were $18.0 million, up 74% from $10.3 million due to strong revenues from Chiesi related to Elfabrio. milestone in the prior year period and initial inventory product build for Elfabrio. Elelyso sales to Pfizer were $3.4 million and sales to Brazil were $2.0 million compared to $2.3 and $2.3 respectively. Total Elelyso sales were up 18% compared with prior year levels. Sales of Elelyso vary widely due to timing of inventory transfers. Revenues from licensing were $120,000 representing catch up amounts for costs related to research and development related to Elfabrio;
- Cost of revenue was up 71% to $8.4 million reflecting the surge in Elelyso sales;
- Research and development expenses fell 18% to $3.0 million from $3.7 million. Completion of the Fabry clinical program and related regulatory efforts in 2023 led to the decline. Lower subcontractor expenses were partially offset by higher salary and related expenses. Materials-related and other expenses were relatively flat;
- Selling, general and administrative expenses were down 29% to $2.6 million compared to $3.7 million on a reduction in salary and related expenses as well as lower professional fees;
- Net financial income was $148,000 compared to a net financial expense of ($168,000). The difference resulted primarily from lower interest income on bank deposits, higher exchange rate costs partially offset by lower notes interest expenses due to the repayment of the convertible notes;
- Income tax of $607,000 compares to $133,000;
- Net income was $3.2 million vs a net loss of ($1.9) million, or ($0.03) per share versus $0.21 per share;

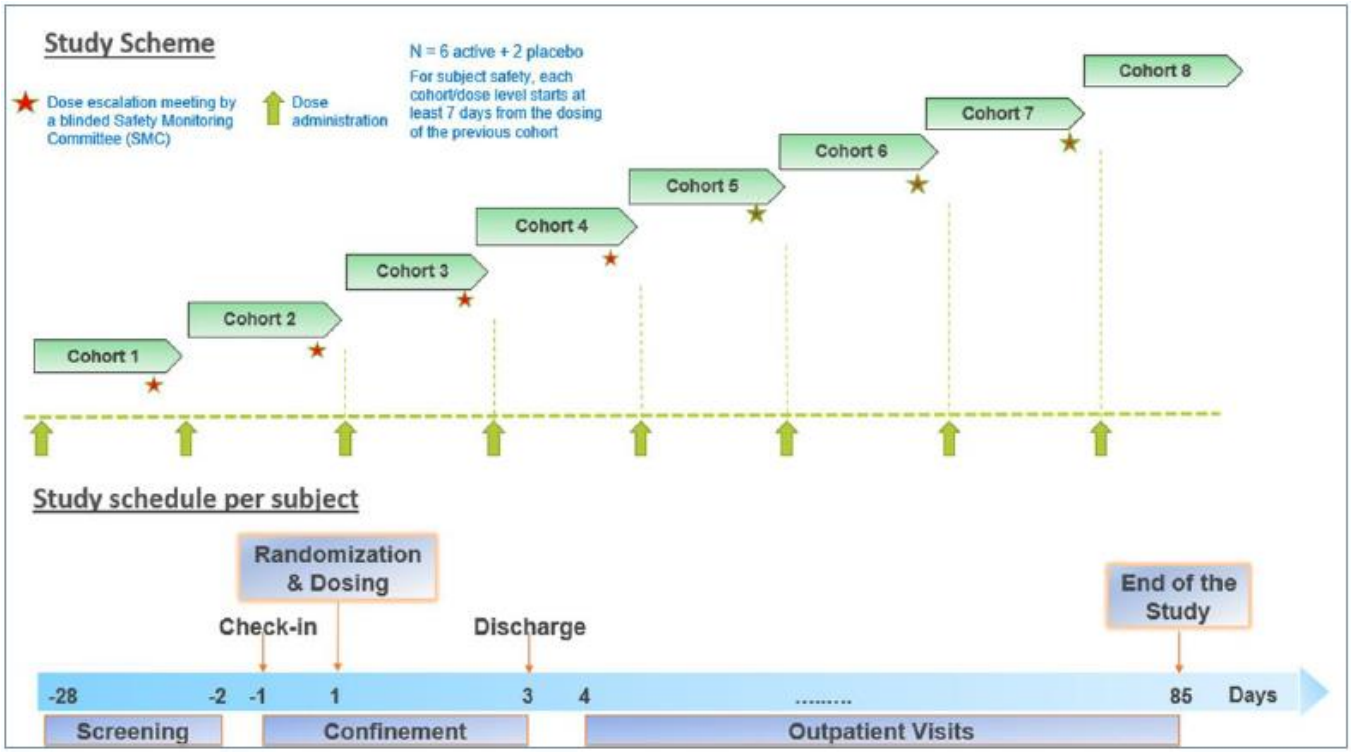
The cash and equivalents balance on September 30, 2024 totaled $27.4 million versus $44.6 million at the end of 2023. Compared to the second quarter, cash fell by $17.6 million due to the repayment of the convertible note of ($20.4) million offset by free cash flow generation of $4.0 million. After the end of the reporting period, Protalix received $3.9 million from sales to Chiesi. Protalix repaid its convertible note in the quarter and is debt free.

PRX-115

In March 2023, Protalix announced that it had dosed its first patient in the Phase I clinical trial for PRX-115 in the treatment of severe gout. Since then, Protalix has completed enrolling eight cohorts and has reported results at the American College of Rheumatology (ACR) meeting. The trial was designed as a single ascending dose, double-blinded, placebo-controlled study to examine safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of PRX-115. 64 subjects with elevated urate levels (>6.0 mg/dL) received a single intravenous (IV) infusion divided among eight cohorts. Patients were randomized in a 3:1 ratio between PRX-115 and placebo and were monitored for 85 days (12 weeks) after receiving the infusion. Plasma concentrations of PRX-115 were measured, as were serum anti-drug antibodies and plasma urate levels. Multiple measurements were taken throughout the duration of the study.

The study was conducted at New Zealand Clinical Research under the New Zealand Medicines and Medical Devices Safety Authority. Further details on the clinical trial can be found on clinicaltrials.gov and the related entry under NCT05745727.

Exhibit I – PRX-115 Trial Design



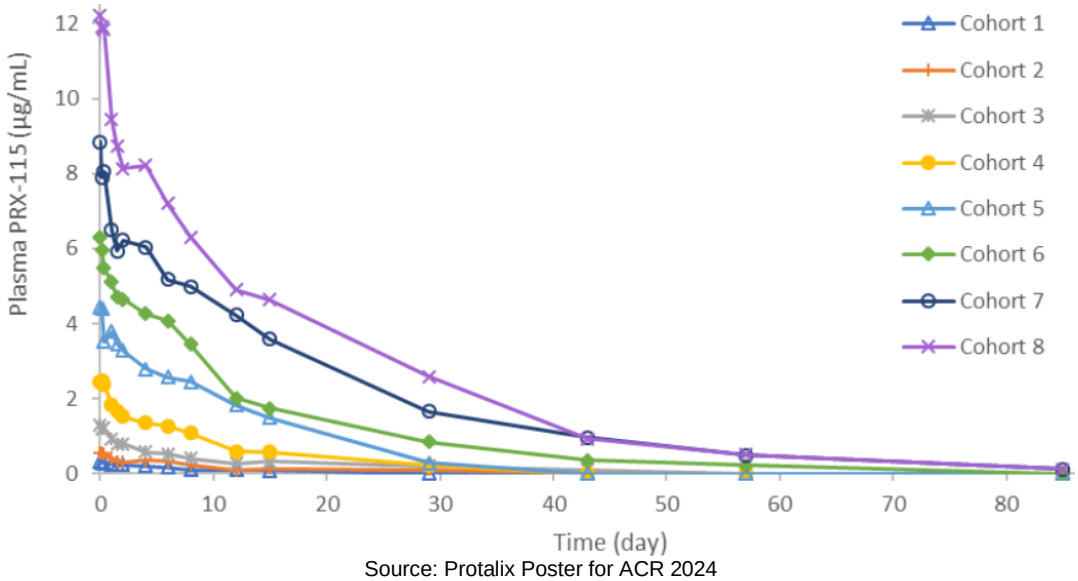
Source: Protalix Poster for ACR 2024

The Phase I trial is designed as a double-blind, placebo-controlled, single ascending dose study intended to evaluate the safety and pharmacokinetics, pharmacodynamics and immunogenicity of PRX-115. Subjects considered for enrollment presented elevated uric acid levels (>6.0 mg/dL) and no previous exposure to PEGylated uricase. The single ascending dose study has enrolled its targeted eight cohorts with patients randomized 3:1 to receive a single intravenous dose of PRX-115 or placebo. Primary endpoints will evaluate the safety and tolerability of a single infusion of PRX-115 as assessed by frequency of drug related adverse events, graded by severity. Clinical laboratory results and vital signs will also be evaluated. Secondary endpoints will examine the reduction in uric acid and dosing efficacy.

Results from the Phase I PRX-115 trial were presented at the ACR annual meeting held in Washington D.C. from November 14th to 19th 2024. The poster is entitled Prolonged Plasma Urate Lowering after a Single Intravenous Administration of PRX 115, a Novel PEGylated Uricase, in Participants with Elevated Urate Levels and was presented by Protalix' Dr. Orit Cohen Barak. PRX-115 was found to be well-tolerated. 25% of the subjects treated (12/48) reported study drug related adverse events (AEs). One subject in cohort 2 experienced an anaphylactic reaction right after infusion. The reaction resolved completely and the subject was evaluated over the course of the study for further safety assessments. No other subjects experienced this reaction and there were no other serious adverse events.

Plasma concentrations of PRX-115 produced results in a dose-dependent manner, with the highest level of concentration following infusion. PRX-115 was detectable in the plasma for up to 12 weeks after infusion for cohorts 6, 7 and 8, which were the highest dosages administered. The following exhibit shows the dose dependent concentrations and their decline over the observation period.

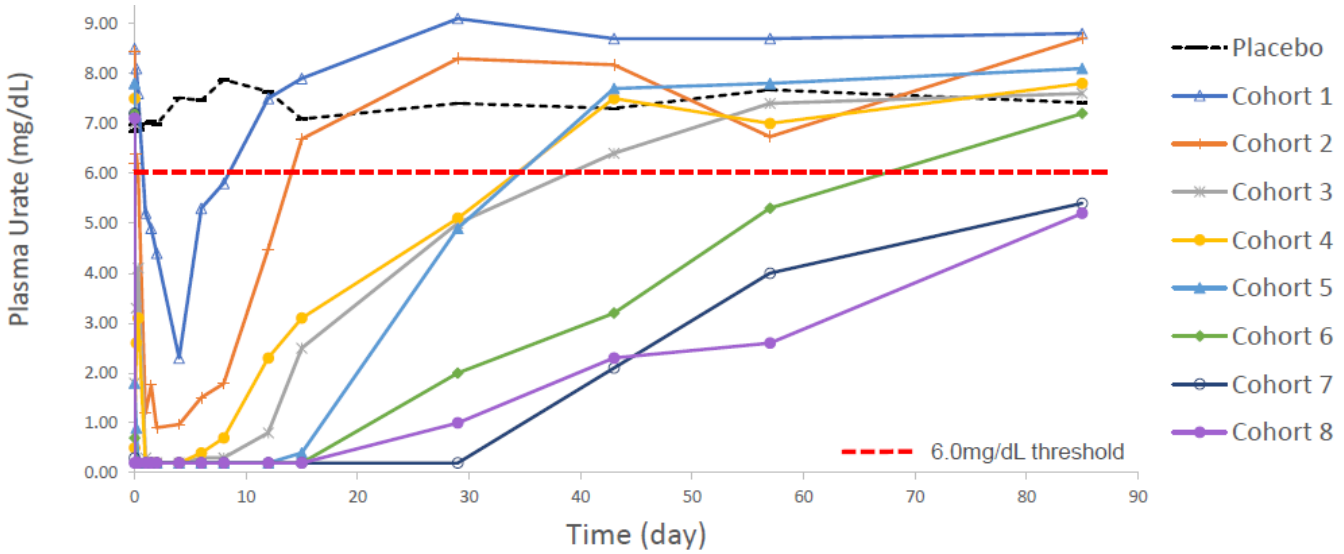
Exhibit II – PRX-115 Plasma Concentrations Over Time



Source: Protalix Poster for ACR 2024

PRX-115 was successful in reducing plasma urate levels, with responses dependent on the dose of the drug. After a single dose, mean plasma urate levels remained below 6.0 mg/dL. Reduction in urate levels also appeared to be related to dose level as shown in the following exhibit.

Exhibit III – Plasma Urate Concentrations Over Time



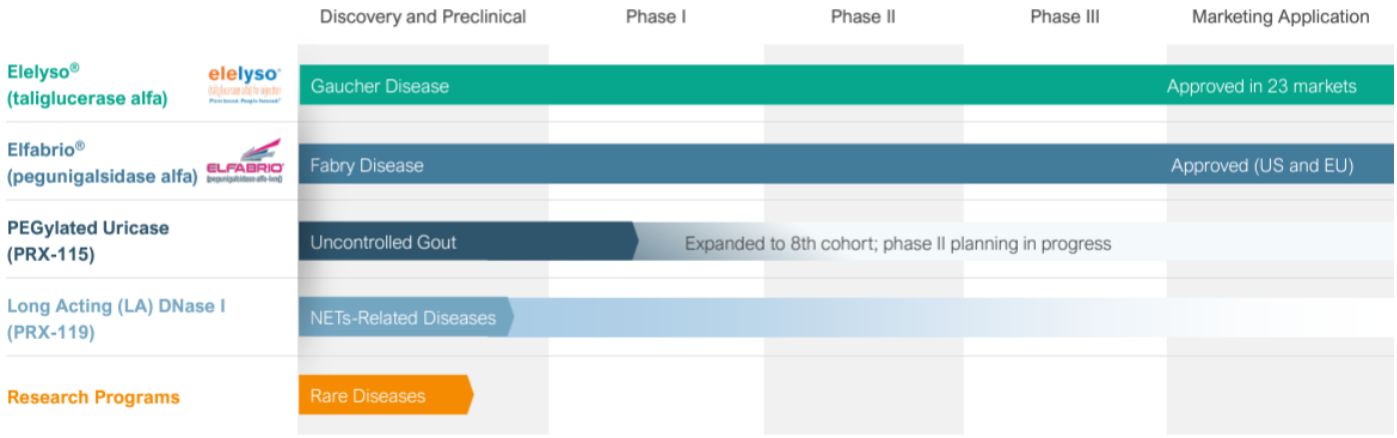
Source: Protalix Poster for ACR 2024

Results from the Phase I demonstrate that PRX-115 provides a dose dependent reduction in plasma urate levels and is able to do so in a safe and tolerable manner. The product may further offer a potentially wide dosing interval which may improve patient convenience and reduce cost. We note that approved product Krystexxa indicated for chronic gout is administered every two weeks as an intravenous infusion. Planning for the PRX-115 Phase II trial is underway with trial design details expected over the next several quarters and a launch in 2H:25.

PRX-119

PRX-119 is the plant cell-expressed PEGylated recombinant human DNase I product candidate being designed to elongate half-life in the circulation of the molecule for NETs-related diseases. Protalix has conducted preclinical studies to evaluate the feasibility of the candidate and expects to continue compiling preclinical information and conducting data analysis to review with stakeholders. Studies conducted to date have determined that the administration of PRX-119 decreased circulating DNA levels and significantly enhanced the survival of mice in both a CLP-induced sepsis model and an ARDS model. Additional preclinical development is ongoing. We expect to hear further details on the direction of the program in coming quarters.

Exhibit IV – Protalix Pipeline



Source: Protalix August 2024 Slide Presentation

Milestones

- Preliminary data announced from PRX-115 Phase I trial – May 2024
- Presentation at BIO International – June 2024
- Investor day presentations – June 2024
- Repayment of convertible debt – September 2024
- Pediatric FLY study for FDA launch - 2024
- PRX-115 data publication – 2Q:24
- Plan trial design for PRX-115 Phase II study – 3Q:24
- Completion of 8th cohort of PRT-115 study – 4Q:24
- PRX-115 data readout at ACR – November 2024
- Ongoing enrollment in Japanese RISE study (Elfabrio) - 2024
- Pediatric FLY study for Fabry disease (Elfabrio) - 2025
- Initiate Phase II study for PRX-115 in gout – 2H:25

Summary

Protalix reported third quarter revenues ahead of our estimates generating solid growth from both Elelyso and Elfabrio. The company has paid down its convertible notes and is now debt free and generating positive free cash. On the research and development side, data for the eight cohorts of the PRX-115 trial were presented. Safety was good, the drug was well tolerated, PK and reduction in uric acid were dose dependent. The results support the launch of a Phase II study which is expected next year.

Our early optimism for Elfabrio's performance has been confirmed and we look forward to increased market penetration by partner Chiesi Rare Disease as new markets such as Japan are added and the label is expanded to include a broader age range. Protalix' low valuation, positive free cash flow and growing revenues supporting a development portfolio are attractive features that support our positive view and price target. Reward to risk is very favorable for equity investors. We maintain our valuation to $14 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[1]

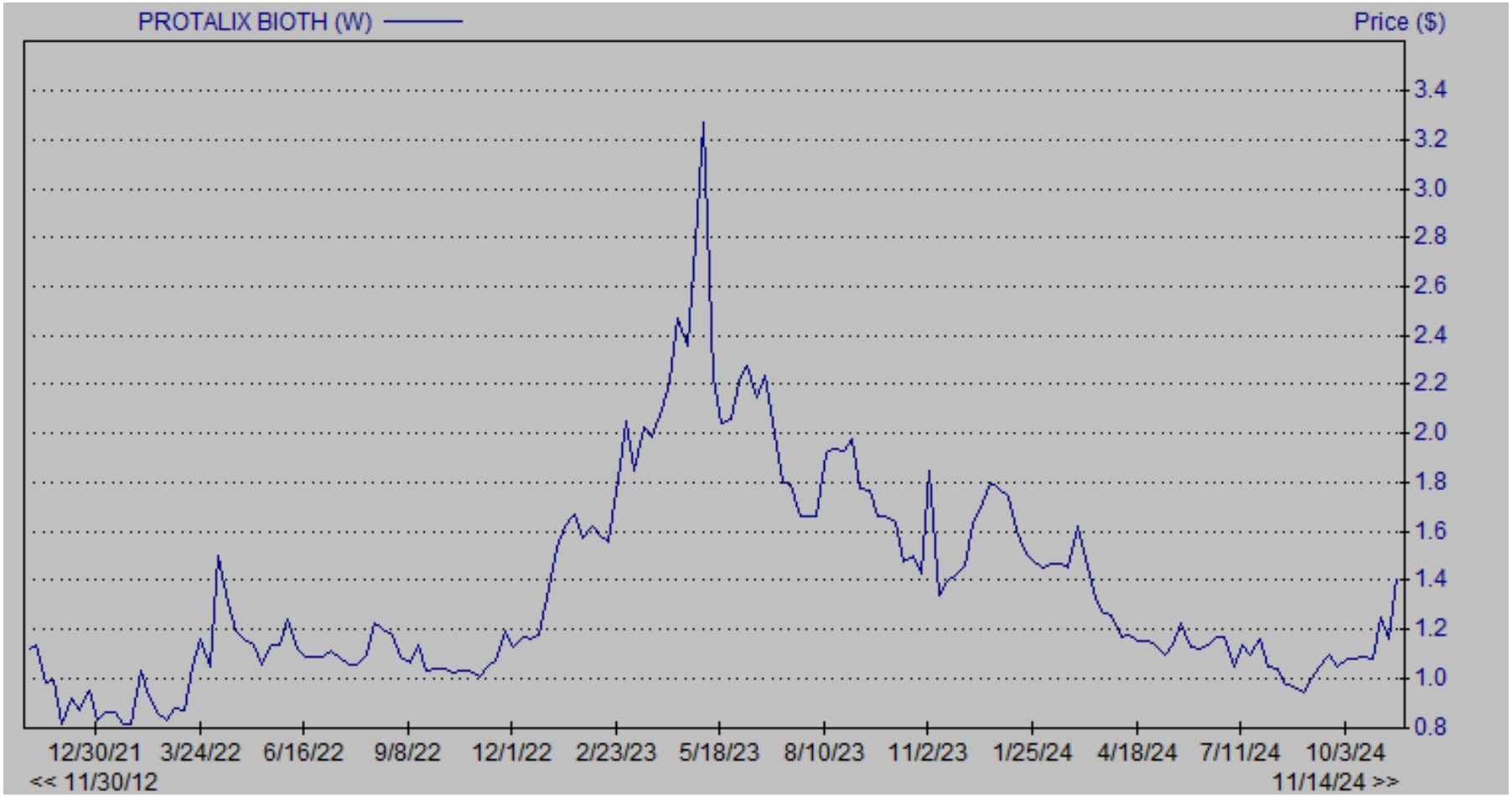
Protalix Biotherapeutics	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US '000)	**$65,494**	**$3,748**	**$13,474**	**$17,959**	**$18,206**	**$53,387**	**$101,438**	**$167,232**
YOY Growth	37%	-61%	-62%	74%	74%	-18%	90%	65%
Cost of Revenues	$22,982	$2,602	$9,456	$8,375	$5,280	$25,713	$18,604	$25,437
Product Gross Margin	43%	29%	29%		71%	52%	82%	85%
Research & Development	$17,093	$2,887	$2,961	$2,998	$4,000	$12,846	$14,280	$20,250
Selling, General & Admin	$14,959	$3,115	$3,484	$2,595	$3,450	$12,644	$12,964	$16,000
Income from operations	$10,460	($4,856)	($2,427)	$3,991	$5,476	$2,184	$55,590	$105,545
Operating Margin	16%	-130%	-18%	22%	30%	4%		*63%*
Financial Expenses	$3,180	$390	$367	$299	$0	$1,056	$1,000	$1,000
Financial Income	($1,286)	($513)	($522)	($151)	($50)	($1,000)	($800)	($600)
Pre-Tax Income	$8,566	($4,733)	($2,272)	$3,843	$5,526	$2,128	$55,390	$105,145
Provision for Income Tax	$254	($138)	($69)	$607	$0	$400	$0	$5,257
Tax Rate	3.0%	2.9%	0.0%	0.0%	0.0%	18.8%	0.0%	5.0%
Net Income	**$8,312**	**($4,595)**	**($2,203)**	**$3,236**	**$5,526**	**$1,728**	**$55,390**	**$99,887**
Net Margin	13%	-123%	-16%	18%	30%	3%	55%	0.597297957
Reported EPS	**$0.10**	**($0.06)**	**($0.03)**	**$0.04**	**$0.08**	**$0.02**	**$0.63**	**$1.13**
Diluted Shares Outstanding	82,424	73,037	73,308	81,217	73,650	75,303	87,250	88,100

Source: Company Filing // Zacks Investment Research, Inc. Estimates

[1] Financial statement information presents data as originally reported.

HISTORICAL STOCK PRICE

Protalix BioTherapeutics, Inc. – Share Price Chart[2]



[2] Source: Zacks Research System

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