Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive
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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com
scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: 2024 Results

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 (3/17/2025)	$2.45
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	**$2.76**
52-Week Low	**$0.82**
One-Year Return (%)	**84.2**
Beta	**0.7**
Average Daily Volume (sh)	**662,266**
Shares Outstanding (mil)	**78.0**
Market Capitalization ($mil)	**191.1**
Short Interest Ratio (days)	**8.4**
Institutional Ownership (%)	**6.0**
Insider Ownership (%)	**13.7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-0.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**122**
P/E using 2024 Estimate	**122**
P/E using 2025 Estimate	**5.6**
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 A	$53.4 A
2025					$80.5 E
2026					$137.3 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 A	$0.04 A
2025					$0.43 E
2026					$0.84 E

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WHAT'S NEW

2024 Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced 2024 financial and operational results in a March 17th, 2024 press release and in its Form 10-K filing. The reports were followed by a conference call which discussed recent achievements, clinical updates and financial performance. In 2024, Protalix repaid its convertible debt and completed the Phase I PRX-115 trial in gout. A poster presentation in November summarized the findings at the American College of Rheumatology conference. A Phase II study for PRX-115 is now planned for 2H:25. 2024 product revenues rose 31%, driven by inventory builds of Elfabrio by Chiesi.

2024 revenues essentially matched our estimates at $53.4 million were dominated by revenues from Chiesi. This produced annual net income of $2.9 million or $0.04 per share.

Financial results for the year ending December 31st, 2024, compared to the prior comparable year:

- Revenues were $53.4 million, down 18% from $65.5 million due to the recognition of a $20 million milestone related to the Elfabrio approval. Product revenues rose 31% due to a material increase in sales of Elfabrio to Chiesi. Elelyso sales through Pfizer and Fiocruz rose 3% with both partners increasing their year over year revenues. Revenues from licensing were $418,000 representing catch up amounts for costs related to research and development related to Elfabrio;
- Cost of revenue was $24.3 million vs. $23.0 million reflecting greater Elelyso volumes;
- Research and development expenses fell 24% to $3.0 million from $3.7 million. Completion of the Fabry clinical program and related regulatory efforts in 2023 led to the decline;
- Selling, general and administrative expenses were down 18% to $12.2 million compared to $15.0 million on a reduction in salary and related expenses as well as lower professional fees;
- Net financial income was ($237,000) compared to a net financial expense of $1.9 million. The difference resulted primarily from note conversions that reduced income expense in 2023 and convertible note repayments in 2024 and higher income on bank deposits;
- Income tax of $1.2 million compares to $254,000;
- 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 December 31st, 2024 totaled $34.8 million versus $44.6 million at the end of 2023. Compared to the third quarter end, cash rose by about $7 million due to cash from equity issuance and positive free cash flow generation. Compared to the end of 2023, cash fell due to the repayment of the convertible note in the third quarter. After the end of the reporting period, Protalix collected $6.9 million from Elelyso sales, sold 1.22 million shares to raise $2.5 million and issued 908,000 shares from warrant exercise, receiving $2.1 million. No warrants remain outstanding.

Reasons To Own / A Compelling Idea for 2025

In February, we highlighted the investment thesis for owning Protalix Biotherapeutics. The company has two approved products generating revenues and a pipeline with multiple candidates in development. Its products are produced and manufactured using the ProCellEx platform which uses a plant cell line rather than the usual mammalian one, to produce its therapeutic proteins. The company recently eliminated all debt from its balance sheet and holds over $27 million in cash on its balance sheet. We expect positive free cash flow generation over the next 12 months, which should strengthen the balance sheet even further. See our video summary here.

The first of its approved products is Elelyso, which was approved in 2012 for Gaucher disease. Protalix signed commercialization agreements with Pfizer and Fiocruz, an arm of the Brazilian Ministry of Health. This has led to annual sales from $16 to $23 million for the product worldwide. In May 2023, Elfabrio was approved by the FDA and EMA for Fabry disease. The product has been approved for marketing in the United States, the European Union, Great Britain, Switzerland, Peru, Israel, Russia and Singapore. This is a $2 billion market dominated by three products[1] and one where legacy offerings present several shortcomings. Many patients develop antibodies against the

[1] Other products include Fabrazyme by Sanofi, Galafold by Amicus Therapeutics, and Replagal by Takeda. We rely on Evaluate, Ltd. for Fabry disease market size estimates.

enzyme in Fabrazyme and Replagal which reduces its effectiveness. Galafold is only appropriate for a subset of Fabry patients that have a certain galactosidase alpha gene (GLA) mutation. This creates a wide opening for Elfabrio to step in and take market share in the underserved Fabry population.

Exhibit I – Protalix' Approved Products



Source: Protalix December 2024 Slide Presentation

In December, Protalix' partner Chiesi submitted a Variation Application to the EMA that requested a change in the dosing regimen for Elfabrio. Based in part on the findings in the BRIGHT study and on new pharmacokinetic data, the sponsors are seeking a less frequent dosing regimen at a dose of 2 mg/kg body weight administered every four weeks in adult patients with Fabry disease in the European Union. Analysis of the BRIGHT study concluded that treatment with Elfabrio every four weeks could offer a new treatment option for patients with Fabry disease.[2]

Both Replagal and Fabrazyme are administered every two weeks, which equates to 26 administrations per year. If Elfabrio were able to gain approval for administration every four weeks, this could reduce the number of administrations relative to these older medicines by half to 13 infusions per year. Elfabrio is a PEGylated,[3] recombinant human α-Gal A. As a result of PEGylation, Elfabrio is stable in plasma, under lysosome-like conditions and presents a prolonged plasma half-life in humans of approximately 80 hours, compared with other commercially available enzyme replacement therapies with half-lives of less than two hours.

Other benefits of Elfabrio over peers is:

- Use of a plant-based expression system which avoid many of the viral contamination problems faced by mammalian cells;
- Fewer patients with anti-drug and neutralizing antibodies vs. Fabrazyme in BALANCE at end of study;
- Reduction in mean annualized estimated glomerular filtration rate (eGFR) slope in the BRIDGE study;[4]
- Potential for infusions every four weeks vs. every two weeks for Fabrazyme and Replagal.

Development Portfolio

Protalix' development portfolio consists of two named products and additional early-stage discovery programs. The named programs are PRX-115 in gout and PRX-119 for neutrophil extracellular traps (NETs) related diseases. PRX-115 has completed eight planned cohorts in a Phase I study and preliminary results have been presented at the ACR Convergence conference.

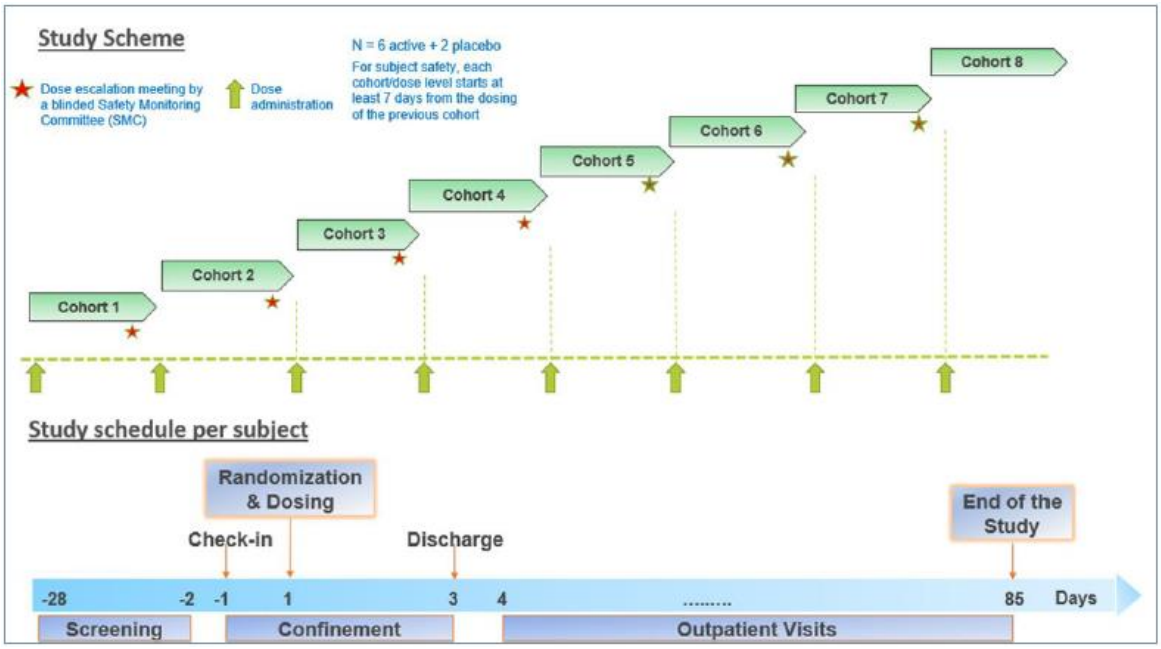
[2] Holida, M., *et al*. A phase III, open-label clinical trial evaluating pegunigalsidase alfa administered every 4 weeks in adults with Fabry disease previously treated with other enzyme replacement therapies, Journal of Inherited Metabolic Disease. October 2024.
[3] A pegylated drug is a therapeutic molecule that has been chemically modified by attaching polyethylene glycol (PEG) chains. The PEG coating essentially acts as a protective shield, making the medicine more effective and longer-lasting in the body.
[4] BRIDGE participants improved from -5.90 mL/min/1.73m^2/year on Replagal to -1.19 mL/min/1.73m2/year on Elfabrio in all patients.

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. 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 II – PRX-115 Trial Design



Source: Protalix Poster for ACR 2024

Subjects considered for enrollment presented elevated uric acid levels (>6.0 mg/dL) and no previous exposure to PEGylated uricase. 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.

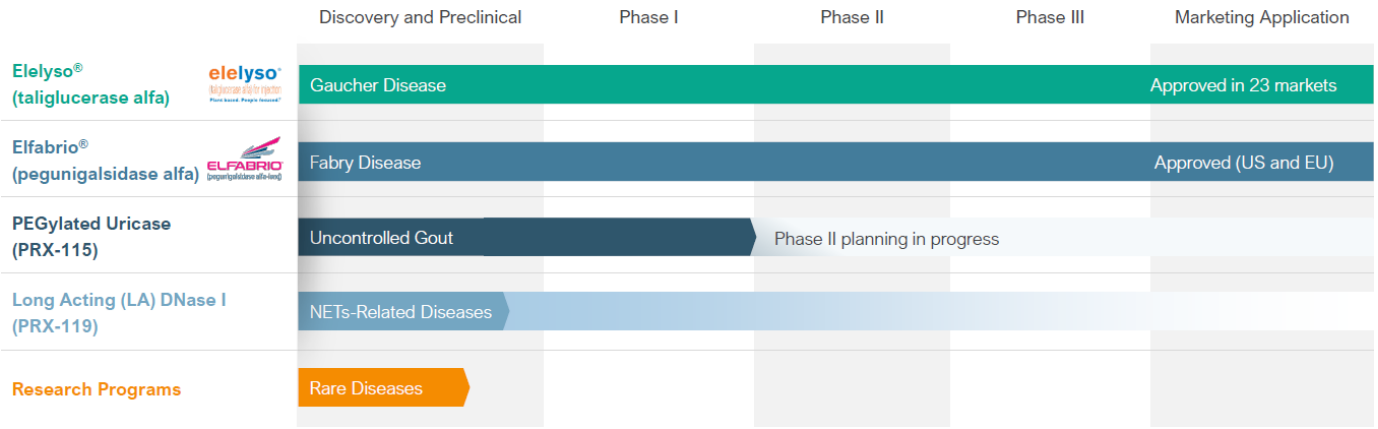
Results from the Phase I PRX-115 trial were presented at the American College of Rheumatology (ACR) Convergence annual meeting last November. The poster is entitled Prolonged Plasma Urate Lowering after a Single Intravenous Administration of PRX 115, a Novel PEGylated Uricase, in Participants with Elevated Urate Levels and was presented by Protalix' Dr. Orit Cohen Barak. The poster summarized findings from the Phase I comparing PRX-115 plasma concentrations over time and plasma urate concentrations over time, noting effect and duration were dose-dependent. Poster conclusions asserted that there was compelling evidence of prolonged PRX-115 exposure with corresponding prolonged duration of effect on plasma urate levels. Protalix' candidate was safe and well tolerated following single IV doses and it may offer an effective urate-lowering treatment with a potentially wide dosing interval which may enhance compliance and treatment flexibility. 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.

Results from the Phase I support moving on to the next stage of development. One of the most visible benefits of PRX-115 is that the product may allow for a reduction in the number of infusions required for successful treatment compared with approved products. We note that Krystexxa which is approved by the FDA and 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 III – Protalix Pipeline



Source: Protalix February 2025 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
- Participation in BIO CEO & Investor Conference – February 2025
- Ongoing enrollment in Japanese RISE study (Elfabrio) - 2025
- Pediatric FLY study for Fabry disease (Elfabrio) - 2025
- Initiate Phase II study for PRX-115 in gout – 2H:25
- Topline results from PRX-115 Phase II study - 2027

Summary

Protalix reports 2024 results showing an increase in product revenues over the prior year, driven by increased sales of Elfabrio to Chiesi Rare Disease. We see material upside from the latest closing price due to anticipated continued revenue growth, a clean balance sheet holding no debt and expected positive free cash generation. The company features two approved products that we expect to grow and a development portfolio that has shown early success in the gout indication. One of the primary risks in the small cap space is absent for Protalix, which is the need to raise capital and dilute earlier investors shifting the balance of investors towards long only. We maintain our valuation to $14 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[5]

Protalix Biotherapeutics	2023 A	Q1 A	Q2 A	Q3 A	Q4 A	2024 A	2025 E	2026 E
Total Revenues ($US '000)	**$65,494**	**$3,748**	**$13,474**	**$17,959**	**$18,218**	**$53,399**	**$80,490**	**$137,271**
YOY Growth	37%	-61%	-62%	74%	74%	-18%	51%	71%
Cost of Revenues	$22,982	$2,602	$9,456	$8,375	$3,886	$24,319	$15,616	$22,441
Research & Development	$17,093	$2,887	$2,961	$2,998	$4,124	$12,970	$14,280	$20,250
Selling, General & Admin	$14,959	$3,115	$3,484	$2,595	$2,999	$12,193	$12,501	$16,000
Income from operations	$10,460	($4,856)	($2,427)	$3,991	$7,209	$3,917	$38,092	$78,579
Operating Margin	16%	-130%	-18%	22%	40%	7%		57%
Financial Expenses	$3,180	$390	$367	$299	$6	$1,062	$1,000	$1,000
Financial Income	($1,286)	($513)	($522)	($151)	($113)	($1,299)	($800)	($600)
Pre-Tax Income	$8,566	($4,733)	($2,272)	$3,843	$7,316	$4,154	$37,892	$78,179
Provision for Income Tax	$254	($138)	($69)	$607	$822	$1,222	$0	$3,909
Tax Rate	3.0%	2.9%	0.0%	0.0%	0.0%	29.4%	0.0%	5.0%
Net Income	**$8,312**	**($4,595)**	**($2,203)**	**$3,236**	**$6,494**	**$2,932**	**$37,892**	**$74,270**
Net Margin	13%	-123%	-16%	18%	36%	5%	47%	0.541050565
Reported EPS	**$0.10**	**($0.06)**	**($0.03)**	**$0.04**	**$0.08**	**$0.04**	**$0.43**	**$0.84**
Diluted Shares Outstanding	82,424	73,037	73,308	81,217	82,250	81,057	87,250	88,100

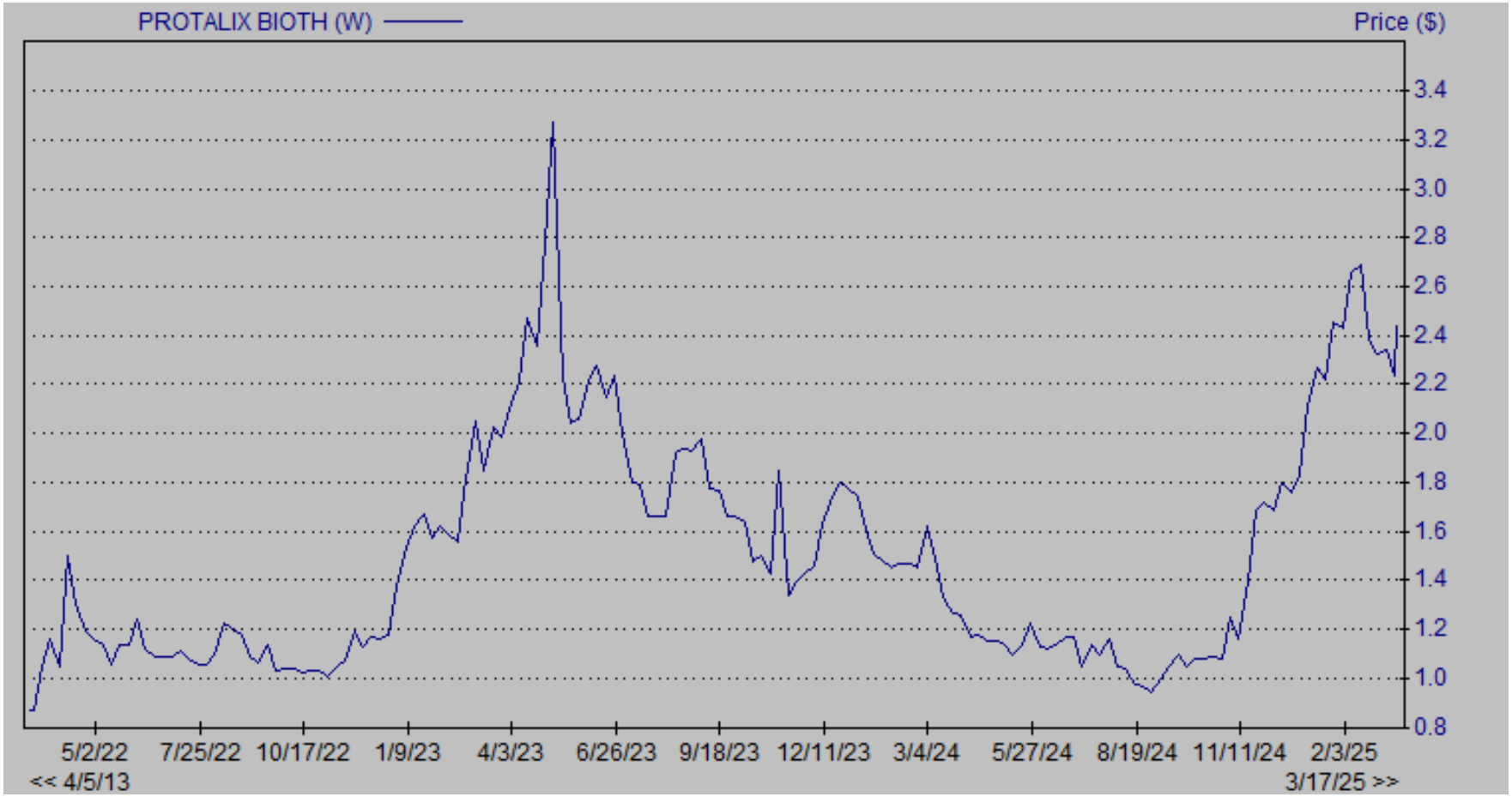
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

Protalix BioTherapeutics, Inc. – Share Price Chart[6]



[6] Source: Zacks Research System

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