Zacks Small-Cap Research
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Protalix BioTherapeutics, Inc.

(PLX: NYSE American)

PLX: Chiesi Milestone Received

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 (5/13/2026)	$1.93
Valuation	**$10.00**

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-acting DNase I for the treatment of NETs-related diseases. It is also working with Secarna to discover novel antisense oligonucleotides in rare renal indications.

Elfabrio was approved in Europe and the United States in early May 2023 and is pursuing approval elsewhere. It 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.

SUMMARY DATA

52-Week High	**$3.19**
52-Week Low	**$1.32**
One-Year Return (%)	**15.6**
Beta	**0.0**
Average Daily Volume (sh)	**990,288**
Shares Outstanding (mil)	**80.6**
Market Capitalization ($mil)	**155.6**
Short Interest Ratio (days)	**7.8**
Institutional Ownership (%)	**23.7**
Insider Ownership (%)	**3.9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-3.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2026 Estimate	**N/A**
P/E using 2027 Estimate	**N/A**
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)
2025	$10.1 A	$15.7 A	$17.9 A	$9.1 A	$52.7 A
2026	$33.8 A	$12.6 E	$14.7 E	$17.5 E	$78.6 E
2027					$59.0 E
2028					$67.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	-$0.05 A	$0.00 A	$0.03 A	-$0.07 A	-$0.08 A
2026	$0.22 A	-$0.03 E	-$0.03 E	-$0.03 E	$0.14 E
2027					-$0.02 E
2028					$0.01 E

WHAT'S NEW

First Quarter 2026 Financial and Operational Review

While Protalix BioTherapeutics, Inc. (NYSE: PLX) has been quiet since the last financial update in mid-March, the company has been active with its development portfolio while continuing to support its commercialization partners for Elfabrio and Elelyso. The Phase II RELEASE trial, which is evaluating PRX-115 in gout, continues to enroll patients and expects topline results in 2H:27. PRX-119 persists in its preclinical work as Protalix narrows the indication in NETs-related diseases and work continues with Secarna to identify indications in renal rare disease using RNA-based therapeutics. Total revenues for 1Q:26 were ahead of our estimates due to the earlier recognition of the milestone related to European approval of every-four-week dosing for Elfabrio. Elelyso revenues were ahead but Elfabrio sales were behind our estimates.

2026 guidance of $78 to $83 million was reaffirmed. This includes the now recognized Chiesi milestone. By product, Protalix expects Elfabrio revenues of $30 to $35 million and Elelyso revenues of $20 to $23 million.

Protalix' financial and operational results were reported in a May 13th, 2026 press release and Form 10-Q filing. The reports were followed by a conference call which provided further updates. Total revenues were up 234% due to the recognition of the Chiesi milestone and net income was $18.3 million or $0.22 per share. Further discussion of financial results for the year ending March 31st, 2026, are provided below, compared to the same prior year period:

- Revenues were $33.8 million, up 234% from $10.1 million, attributable to the recognition of the Chiesi milestone related to European Commission approval of Elfabrio for every-four-week dosing. Elelyso sales to Pfizer fell 79% to $1.5 million and to Brazil fell 19% to $2.5 million. The decline was attributable to shipment timing for both partners. Elfabrio sales of $3.5 million compared to zero sales in the prior year. License and R&D services revenues increased to $26.3 million from $118,000 related to the abovementioned milestone;
- Cost of revenue was $4.1 million vs. $8.2 million. Product gross margin increased to 44.4% from 18.2% due to product mix;
- Research and development expenses increased 56% to $5.4 million from $3.5 million. The increase was due to higher expenses across the board, including salary, subcontractor expenses, materials and other expenses. The rise is due to greater activity related to the initiation of the RELEASE study;
- Selling, general and administrative expenses rose 17% to $3.1 million versus $2.6 million due to higher salaries;
- Net financial expense was $5,000 compared to a net financial expense of $413,000. The change in this line item was due to exchange rate fluctuations;
- Income tax expense of $2.8 million vs. a tax benefit of $113,000;
- Net income was $18.3 million or $0.22 per share versus net loss of $3.6 million or $0.05 per share.

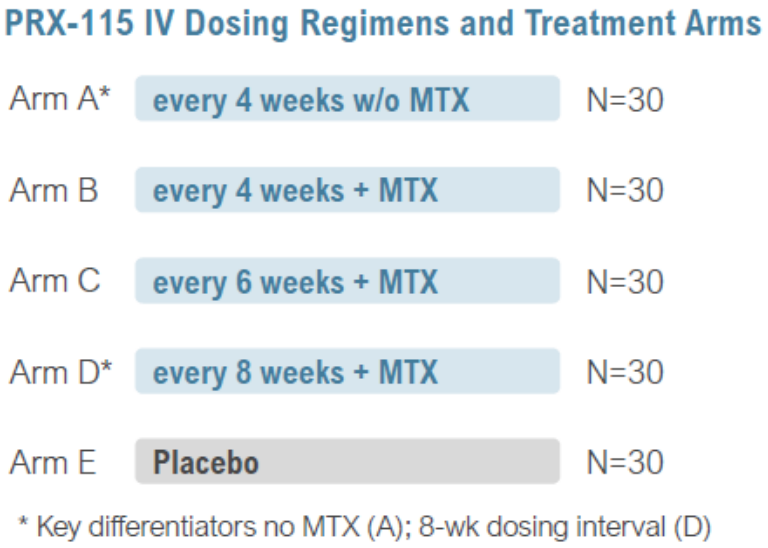
The cash and equivalents balance on March 31st, 2026 totaled $51.1 million versus $30.3 million at the end of 2025. During the first quarter, Protalix' cash from operations was $21.2 million derived primarily from net income and from a decrease in accounts receivable. Cash from financing was minimal. We believe that Protalix holds sufficient cash to support operations for the foreseeable future.

PRX-115 Phase II Trial Enrolling

Protalix is enrolling subjects in its Phase II study for PRX-115. Under the acronym RELEASE, the trial is entitled *A Study to Investigate the Clinical Effect and the Safety of PRX-115 Infused Intravenously at Different Dosing Regimens, With and Without Methotrexate, Versus Placebo in Adult Gout Patients.* It is listed on clinicaltrials.gov under the designator NCT07280156. The multicenter, randomized, double-blind, placebo-controlled study will assess the efficacy, safety and dosing regimen selection of multiple IV infusions of PRX-115 over 24 weeks, with or without methotrexate (MTX), versus the respective placebos in adult patients with gout. One site is active in Miami, Florida.

Protalix anticipates that RELEASE topline results will be available in 2H:27.

Exhibit I – PRX-115 IV Dosing Regimens and Treatment Arms



Source: Protalix May 2026 Presentation

The primary endpoint is the proportion of patients who achieve a reduction in serum uric acid to less than 6.0 mg/dL for at least 80% of the time during month six. Secondary endpoints will measure additional uric acid parameters, safety and immunogenicity. The study will additionally record tophi, flares, swollen and tender joints, quality of life and pharmacokinetics.

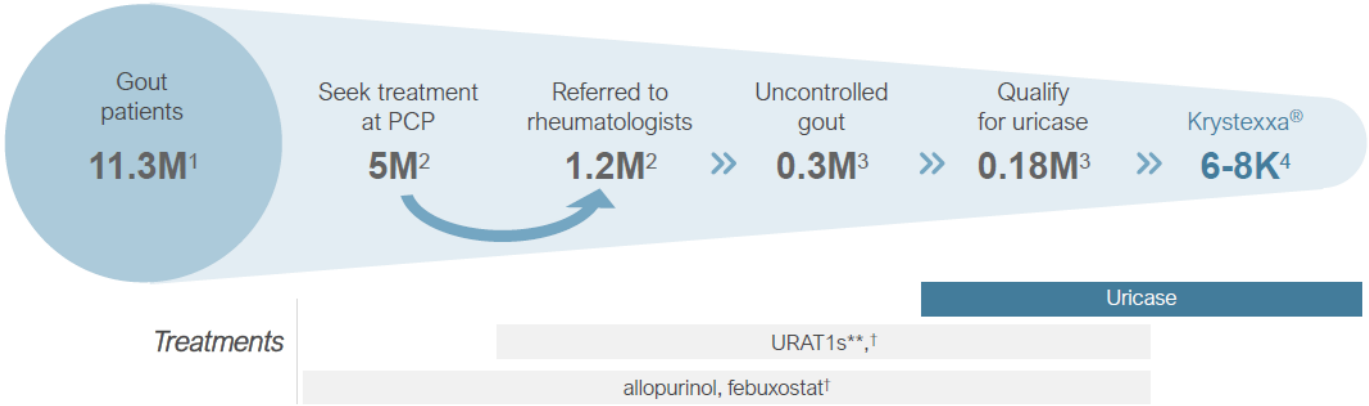
Participants will receive PRX-115 by intravenous (IV) infusions according to different treatment schedules, with and without MTX. MTX itself does not reduce uric acid levels or manage flares directly but instead is used in combination with treatments that may activate antibodies and an immune response. In a study evaluating pegloticase, MTX was used to reduce antidrug antibody development and infusion reactions as well as improve efficacy. The use of MTX with pegloticase improved the response rate for gout patients compared to the use of pegloticase alone.[1]

PRX-115 Background

The PRX-115 Phase I study was completed in 2024 generating data that was presented at conferences including ACR Convergence. Results from the trial supported advancement to the next stage of development. Planning for the PRX-115 Phase II trial was conducted during 2025 and an investigational new drug (IND) application was filed with the FDA in October. It was cleared in November and the Phase II started shortly after, enrolling subjects in 1Q:26.

PRX-115 is a plant-cell expressed recombinant PEGylated uricase (urate oxidase) intended to treat uncontrolled gout. Protalix has identified a market of 11.3 million gout patients with about 300,000 suffering from the uncontrolled form.

Exhibit II – US Gout Market



Source: Protalix May 2026 Presentation

[1] Botson, J.K., *et al*. A Randomized, Placebo-Controlled Study of Methotrexate to Increase Response Rates in Patients with Uncontrolled Gout Receiving Pegloticase: Primary Efficacy and Safety Findings. Arthritis Rheumatology. December 2022.

European Commission Approval of Elfabrio Four Week Dosing

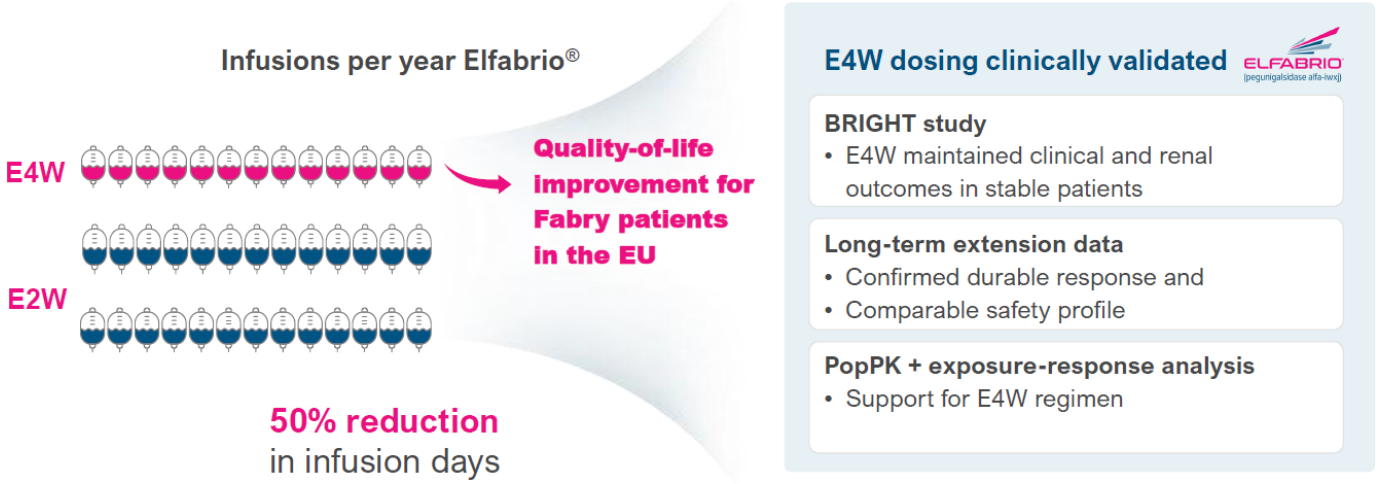
On March 9th, Protalix announced that the European Commission (EC) approved the 2.0 mg/kg every-four-weeks dosing regimen for Elfabrio in Fabry disease. The addressable population is adult patients who are stable on enzyme replacement therapy (ERT). Protalix has received a $25 million milestone payment from Chiesi following the approval.

While the four-week dosing regimen has been approved, it will take time for patients to make the shift. There are country-specific logistics and regulatory requirements that must be satisfied before patients and providers can make the change.

The Phase III BRIGHT study generated the supportive data to justify extended dosing. Elfabrio offers a prolonged half-life which enables the change. Adults with Fabry disease already stable on biweekly ERT (agalsidase alfa or beta) for more than three years switched to intravenous pegunigalsidase alfa (Elfabrio) 2.0 mg/kg every-four weeks for 52 weeks. Kidney function in the stable ERT-experienced group was maintained over a year. There was also an extension to the BRIGHT study which allowed patients to continue on this regimen. Longer term data from the extension group demonstrated that the change did not increase immunogenicity or create new administration risks.

The three approved ERTs (Fabrazyme, Replagal and Elfabrio) all require an intravenous (IV) infusion every two weeks, which is a burden that can be reduced by doubling the time between infusions. The change can also reduce provider costs, due to fewer infusions. Other benefits include less venous access trauma, easier scheduling and a higher quality of life for the Fabry patient.

Exhibit III – EC Approves Every-Four-Weeks Dosing for Elfabrio



Source: Protalix May 2026 Presentation

Background on CHMP Opinion
In December 2024, 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 sought 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]

On October 17th, 2025, Chiesi and Protalix announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had issued a negative opinion on the request to approve the dosing regimen of 2.0 mg/kg body weight infused every four weeks for Elfabrio.

Two and a half weeks after the negative opinion, Chiesi and Protalix issued a press release stating that they would seek re-examination of the EMA's negative opinion for Elfabrio regarding the four-week alternative dosing regimen. The process requires that the sponsor submit a written notice to the EMA within 15 days of the CHMP opinion and 60 days later submit the grounds for examination. A different rapporteur and co-rapporteur were appointed to conduct the re-examination. Chiesi and Protalix employed consultants and dedicated internal personnel with EMA and

[2] Holida, M., *et al*. A phase III, open-label clinical trial evaluating pegunigalsidase alfa administered every four weeks in adults with Fabry disease previously treated with other enzyme replacement therapies, Journal of Inherited Metabolic Disease. October 2024.

CHMP experience who developed the argument for four-week dosing. Following re-submission, the CHMP gave a positive opinion and the EC approved the new dosing regimen.

Collaboration with Secarna Pharmaceuticals

Protalix BioTherapeutics, Inc. (NYSE: PLX) announced a collaboration with the Germany-based Secarna Pharmaceuticals to develop novel antisense oligonucleotide (ASO) therapies using Secarna's OligoCreator platform. The arrangement will seek pharmaceutical candidates for rare renal indications. Details of the arrangement were provided in a December 17th press release. In the first quarter update, Protalix states that it continues to collaborate with Secarna to identify RNA–based therapeutic candidates that may complement its proprietary ProCellEx platform.

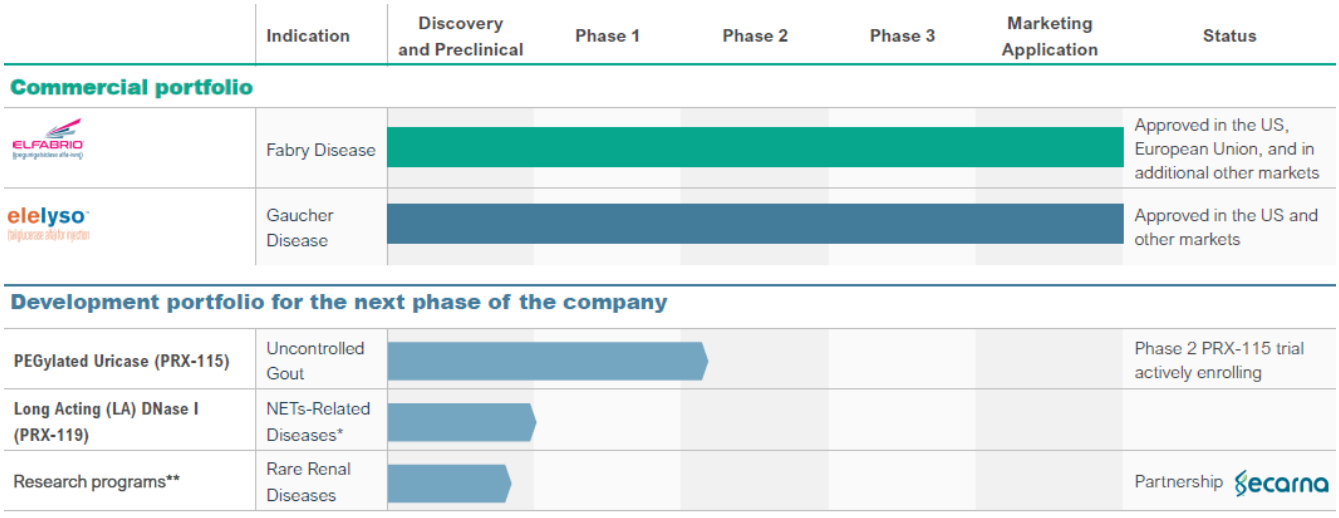
Secarna Pharmaceuticals is an artificial intelligence (AI)-powered therapeutics development company with two platforms and a pipeline of assets focused on discovery and investigational new drug (IND)-enabling studies. It has several partners including Lipigon Pharmaceuticals, Denali Therapeutics, Curie Bio, SciNeuro Pharmaceuticals and Evotec/Bristol Myers Squibb that are developing their own products using Secarna's platforms. The most advanced of the partner projects is Lipigon's Phase II Lipisense asset.

Secarna offers its OligoCreator platform which uses AI to discover and develop oligonucleotides for use in a variety of organs and tissues to address untreatable conditions. The platform offers a safety and efficacy testing system that characterizes the risk profile of a candidate and identifies a broad therapeutic window for a drug candidate. It provides a variety of chemical oligonucleotide modifications that enable calibration of drug properties such as reduction of immune-stimulatory potential or off-target toxicities. OligoCreator further combines AI bioinformatics with wet lab data to refine predictive algorithms. Over 50 projects have been conducted to optimize the *in-silico* selection strategy.

Protalix plans to use the collaboration and platform to identify several new candidates as the relationship matures. No money has yet changed hands; however, Protalix will pay for the collaborative research. If a candidate shows promise, Protalix plans to obtain intellectual property protection for the asset before disclosing the molecule and indication. In terms of the financial design of the arrangement, there will be milestones during the development stage which are minimal until pivotal studies are complete. If commercialized, Protalix will pay royalties on sales to Secarna. We think this broadens Protalix' pipeline at the very early discovery stage and can be executed at negligible cost.

Pipeline

Exhibit IV – Protalix Product Pipeline

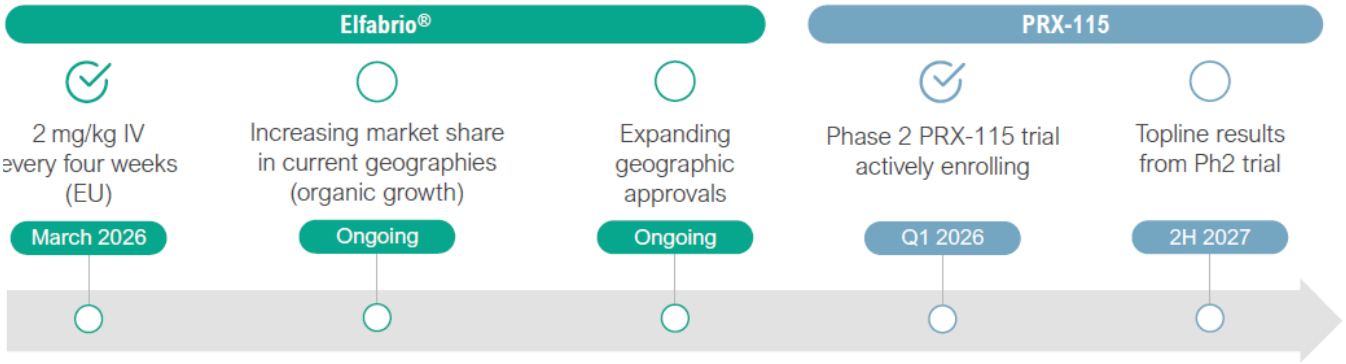


Source: Protalix May 2026 Presentation

Milestones

- Positive opinion from CHMP for Elfabrio four-week dosing – January 2026
- PRX-115 Phase II trial start – 1Q:26
- EC approval of Elfabrio four-week dosing – March 2026
- Receipt of $25 million Elfabrio milestone – 1Q:26
- Ongoing enrollment in Japanese RISE study (Elfabrio) - 2026
- Pediatric FLY study active for Fabry disease (Elfabrio) - 2026
- Topline results from PRX-115 Phase II study - 2027

Exhibit V – Upcoming Milestones and Catalysts



Source: Protalix May 2026 Presentation

Summary

Protalix reports first quarter results and posts better than expected revenues on early recognition of the Chiesi milestone. Product revenues were below our estimates on lower Elfabrio sales related to the pace of Chiesi's restocking; however, Elelyso sales were ahead of our numbers. Management reaffirmed revenue guidance of $78 to $83 million. The Phase II study for PRX-115 continues to enroll patients and is forecast to report topline results in 2H:27. Work on PRX-119 continues and management has promised further details on the indication and market in the next few months. The collaboration with Secarna is focused on discovering RNA-based therapeutic candidates that may complement its ProCellEx platform. Our valuation remains at $10 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[3]

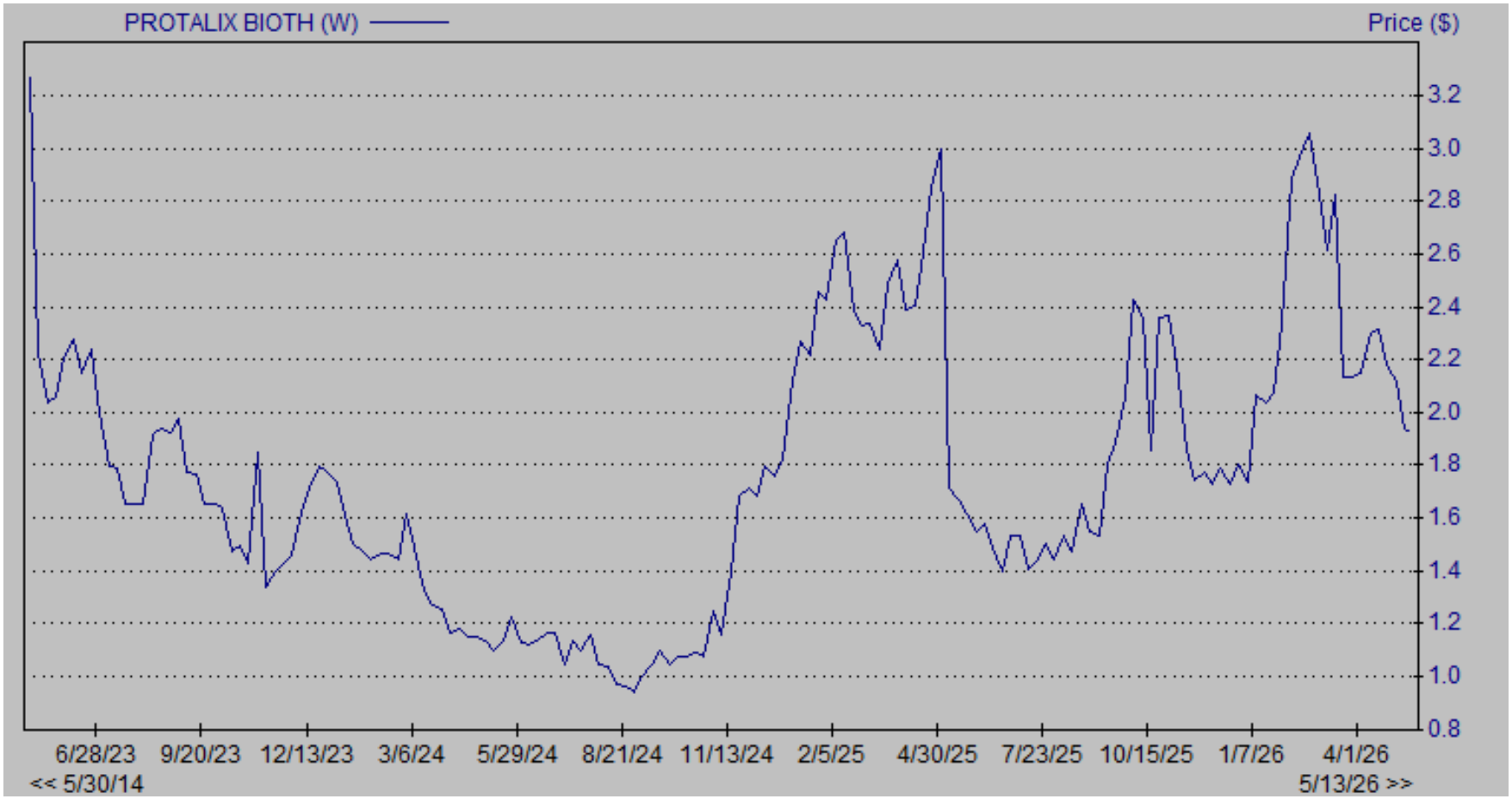
Protalix Biotherapeutics	2025 A	Q1 A	Q2 E	Q3 E	Q4 E	2026 E	2027 E	2028 E
Total Revenues ($US '000)	**$52,744**	**$33,750**	**$12,600**	**$14,740**	**$17,500**	**$78,590**	**$59,017**	**$67,464**
YOY Growth	-1.2%	234%	-20%	-17%	92%	49%	-25%	14%
Cost of Revenues	$26,993	$4,127	$5,418	$6,338	$7,525	$23,408	$20,656	$23,612
Research & Development	$19,569	$5,426	$6,800	$7,450	$8,974	$28,650	$27,250	$29,500
Selling, General & Admin	$11,682	$3,051	$3,175	$3,310	$3,664	$13,200	$13,650	$14,105
Income from operations	($5,500)	$21,146	($2,793)	($2,358)	($2,663)	$13,332	($2,539)	$247
Operating Margin	*-10%*	63%	-22%	-16%	-15%	*17%*	*-4%*	*0%*
Financial Expenses	$1,191	$193	$0	$0	$0	$193	$25	$25
Financial Income	($1,083)	($188)	($255)	($210)	($190)	($843)	($600)	($600)
Pre-Tax Income	($5,608)	$21,141	($2,538)	($2,148)	($2,473)	$13,982	($1,964)	$822
Provision for Income Tax	$996	$2,824	($127)	($107)	($124)	$2,466	($98)	$90
Tax Rate	-17.8%	13.4%	5.0%	5.0%	5.0%	5.0%	5.0%	11.0%
Net Income	**($6,604)**	**$18,317**	**($2,411)**	**($2,041)**	**($2,349)**	**$11,516**	**($1,866)**	**$731**
Net Margin	-13%	54%	-19%	-14%	-13%	15%	-3%	1%
Reported EPS	**($0.08)**	**$0.22**	**($0.03)**	**($0.03)**	**($0.03)**	**$0.14**	**($0.02)**	**$0.01**
Diluted Shares Outstanding	78,546	83,049	80,580	80,580	80,580	83,049	81,000	84,500

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

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

HISTORICAL STOCK PRICE

Protalix BioTherapeutics, Inc. – Share Price Chart[4]



[4] Source: Zacks Research System

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