Zacks Small-Cap Research
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Protalix BioTherapeutics, Inc.

(PLX: NYSE American)

PLX: Elfabrio Estimates Up, Again

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 Elelyso sales by Fiocruz and Pfizer. The model includes contributions from global commercialization.

Current Price (11/11/2026)	$3.13
Valuation	**$12.00**

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 is marketed by Fiocruz in Brazil & Pfizer in the rest of the world for Gaucher disease. Elfabrio is marketed by Chiesi Global Rare Diseases in all territories around the world for Fabry disease.

Protalix offers 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 in other geographies. It can address an unmet need with several improvements over the market leader. 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	**$1.65**
One-Year Return (%)	**47.2**
Beta	**0.0**
Average Daily Volume (sh)	**822,359**
Shares Outstanding (mil)	**84.3**
Market Capitalization ($mil)	**263.9**
Short Interest Ratio (days)	**4.3**
Institutional Ownership (%)	**25.1**
Insider Ownership (%)	**3.9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**19**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**12.5**
P/E using 2026 Estimate	**11.2**
P/E using 2027 Estimate	**60.0**
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	$19.9 A	$21.9 A	$16.2 E	$91.8 E
2027					$69.2 E
2028					$77.0 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	$0.05 A	$0.05 A	-$0.04 E	$0.28 E
2027					$0.05 E
2028					$0.07 E

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WHAT'S NEW

Third Quarter 2026 Financial and Operational Review

Protalix BioTherapeutics, Inc. (NYSE American: PLX) produced another upside revenue surprise this quarter with a 23% topline increase. On a year over year basis, sales to Pfizer of Elelyso and to Chiesi of Elfabrio drove the gains. Gross margins were also better, offsetting an increase in research and development costs to produce net earnings of $4.0 million or 5 cents per share. Management expects to meet or exceed its previously provided revenue guidance of $78 to $83 million. Partner Chiesi obtained marketing authorization in Brazil from the Agência Nacional de Vigilância Sanitária (ANVISA) on October 5th for both two-week and four-week Elfabrio dosing regimens.

Protalix' other recent achievements include presentations at various investor conferences and PRX-115 data presented at the American College of Rheumatology (ACR) conference. The PRX-115 poster at ACR reported an extended duration of uric acid control, which may argue for class-leading dosing intervals if approved. The PRX-115 Phase II study for uncontrolled gout continues to enroll. Management reiterates its expectations for a 2H:27 topline readout for the Phase II RELEASE trial.

Protalix' financial and operational results were reported in a November 10th, 2026 press release and Form 10-Q filing. The reports were followed by a conference call which provided further updates. Total revenues were up 23% due to better-than-expected revenues for Elelyso and Elfabrio. The company saw 50% or greater year over year increases in sales to Pfizer and Chiesi. Net income was $4.0 million or $0.05 per share. Further discussion of financial results for the quarter ending September 30th, 2026, is provided below and compare to the same prior year period:

- Revenues were $21.9 million, up 23% from $17.9 million, attributable to 50% growth in Elfabrio sales and a 54% increase in Pfizer Elelyso revenues. Sales to Fiocruz in Brazil rose sequentially, but fell 29% to $4.4 million on a year over year basis. License and R&D services revenues were a modest $91,000, falling relative to the prior year on account of fewer services provided to Chiesi;
- Cost of revenue was $7.9 million vs $8.3 million. Product gross margin rose to 63.9% from 52.9% due to product mix;
- Research and development expenses rose 55% to $6.9 million from $4.5 million. The increase was due to the impact from higher salary and subcontractor expenses related to the RELEASE study partially offset by lower materials and other expenses. Protalix additionally recognized $989,000 from an R&D grant which provided another offset to increases elsewhere;
- Selling, general and administrative expenses rose 5% to $3.1 million versus $2.9 million due to higher professional fees, salary and related expenses;
- Net financial income was $575,000 compared to $108,000. The change in this line item was due to exchange rate fluctuations and higher interest income;
- Income tax expense of $661,000 vs a tax benefit of $116,000;
- Net income was $4.0 million or $0.05 per share versus $2.4 million or $0.03 per share.

The cash and equivalents balance on September 30th, 2026 totaled $48.5 million versus $30.3 million at the end of 2025. During the first nine months of 2026, Protalix' free cash flow was $13.4 million with $3.2 million of the total achieved in the third quarter. Primary differences between net income for the first nine months ($26.1 million) and cash from operations ($15.5 million) were related to increase in trade receivable ($5.4 million), an increase in inventories ($8.6 million) and an increase in R&D grant receivable ($3.0 million). Cash from financing for the first nine months was $4.7 million with $4.2 million of this amount from common stock issuance in the third quarter from the at-the-market (ATM) agreement with H.C. Wainwright. Following third quarter end, Protalix raised an additional net $4.9 million from ATM sales. We believe that Protalix holds sufficient cash to support operations for the foreseeable future.

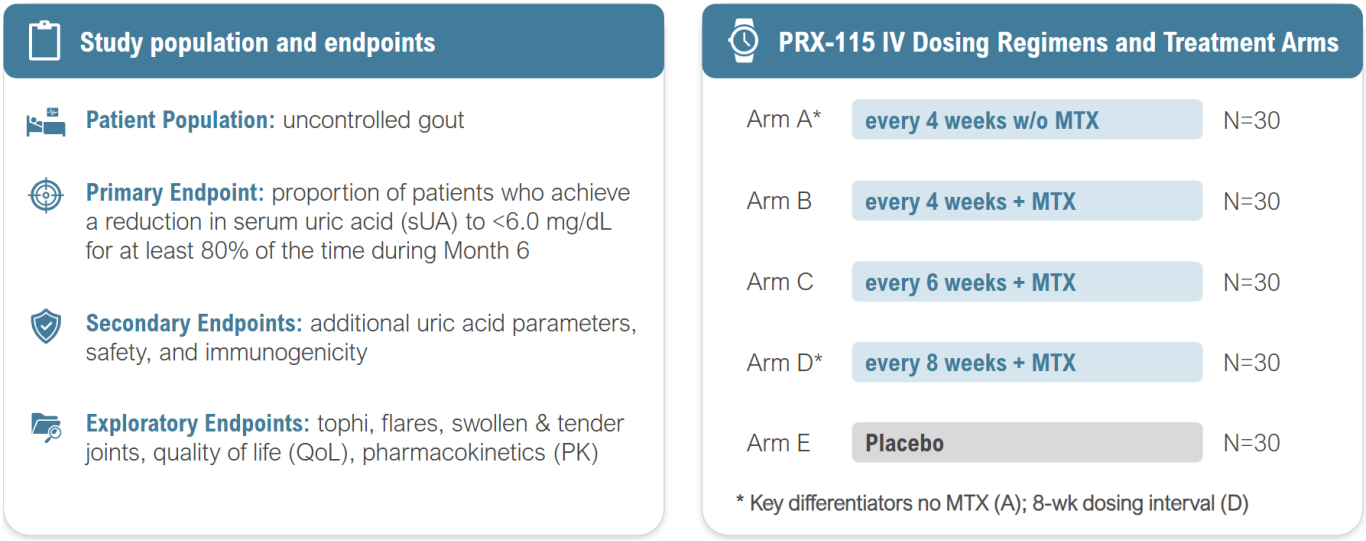
Protalix repeated its guidance of $78.0 to $83.0 million for 2026, which includes the contribution from the Chiesi milestone. It believes that it can meet or exceed this range for 2026. For it to hit the $83 million top end, the company would need to generate $7.4 million in revenues in 4Q:26, which is well behind the levels achieved in earlier quarters. We think the company can generate $7.2 million of Elelyso sales and $9.0 million of Elfabrio sales to produce $16.2 million in fourth quarter revenues and $91.8 million of 2026 revenues.

PRX-115

PRX-115 Phase II Trial Continues to Enroll

As of November 2026, Protalix continues to enroll 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 placebo groups in adult patients with gout. 35 sites are listed as active and enrolling on clinicaltrials.gov. Locations include those in the US, the country of Georgia and Israel. Management reiterates its expectations for a report of top-line results in 2H:27.

Exhibit I – PRX-115 Phase II Trial Design

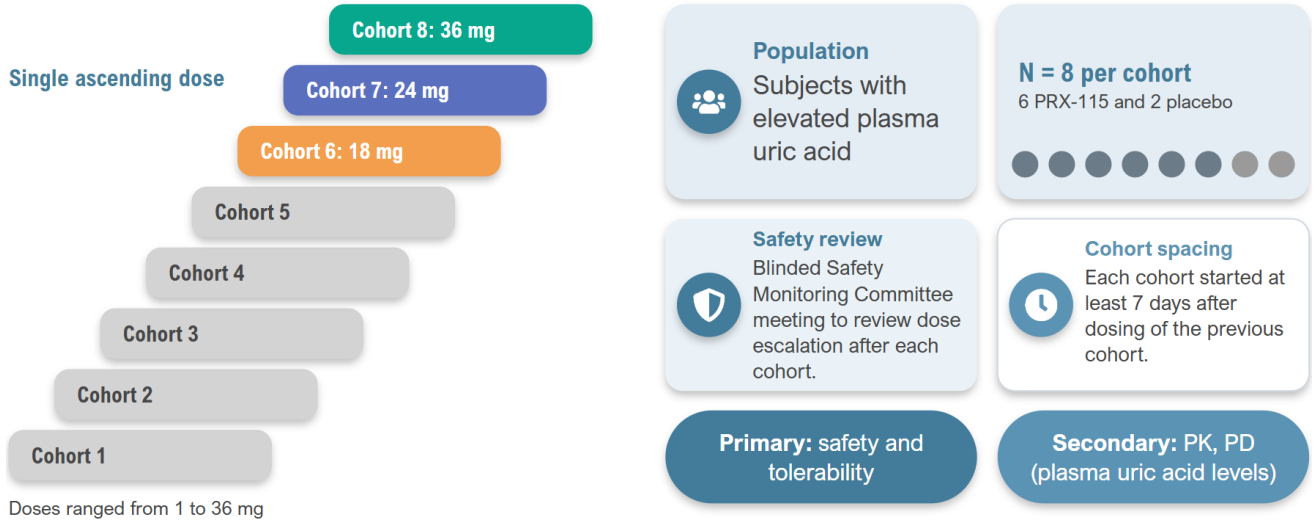


Source: Protalix November 2026 Corporate Presentation

PRX-115 Phase I Data Readout

On November 9th, Protalix issued a press release providing data from its Phase I trial. The data was presented the next day in a poster at the American College of Rheumatology (ACR) Convergence event taking place in Orlando, Florida from November 6th to 11th, 2026. At ACR 2024, the company reported that higher single doses of PRX–115 lowered mean plasma uric acid for longer durations in participants with elevated plasma uric acid levels. Protalix' Orit Cohen-Barak, Ph.D. presented the poster entitled PRX-115, a Novel PEGylated Uricase: Focus on Plasma levels, Urate Responses and PK-PD Relations Following Single High-Dose Administrations on November 10th.

Exhibit II – Protalix Phase I PRX-115 Trial Design



Source: Protalix November 2026 Corporate Presentation

New patient data presented at ACR 2026 reinforce this finding and show the effect associated with PRX-115 in plasma levels persisting for up to 85 days. The analysis focuses on the higher dose cohorts of 18, 24 and 36 mg. In the pharmacokinetics (PK) realm, PRX-115 exposure increased in step with a higher dose. Peak plasma concentrations coincided with the end of infusion. In the pharmacodynamic (PD) realm, PRX-115 brought about rapid, profound reductions in plasma urate levels for the higher dose cohorts after one infusion. Investigators observed a dose-dependent response. At the 36 mg dose, mean plasma uric acid stayed below the 6.0 mg/dL target for up to 12 weeks after a single administration. PRX-115 was generally well-tolerated with mild to moderate and transient related adverse events. One patient in the 64-patient study experienced an anaphylactic reaction that resolved.

Exhibit III – Dose-Dependent Reduction in Urate Levels at Day 57

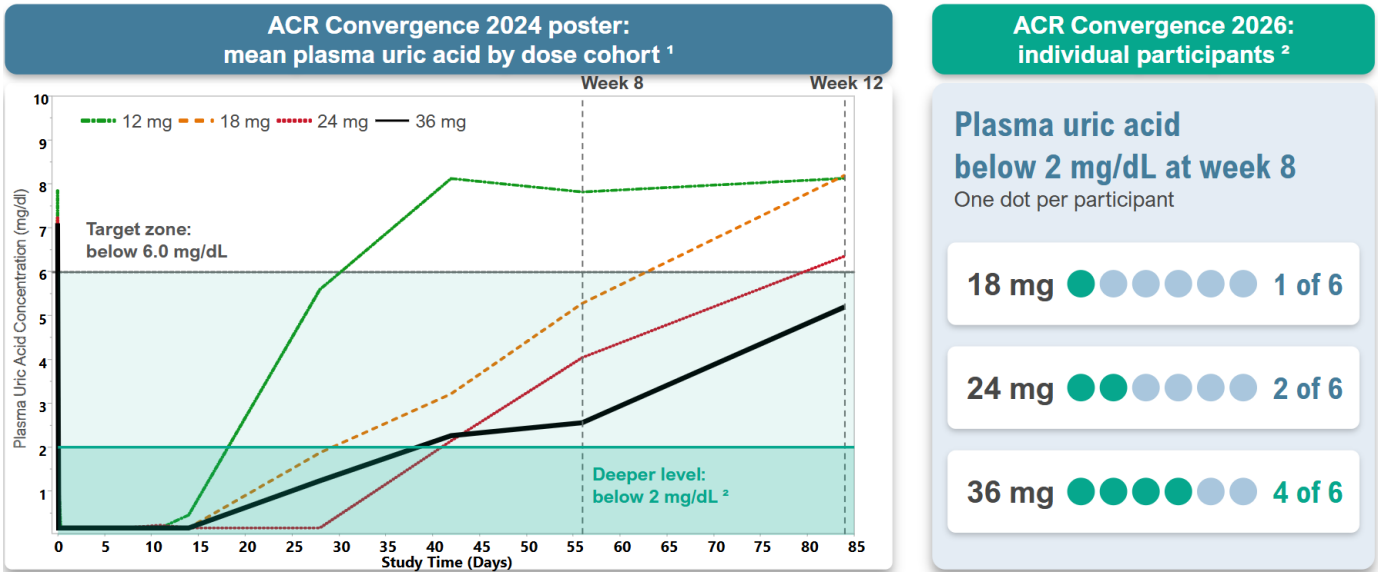
Cohort # (dose)*	Mean (SD) Baseline UA (mg/dL)	Number (%) of participants with UA reduction >75% from baseline	Number (%) of participants with UA<2 mg/dL
6 (18 mg)	7.2 (1.3)	1 (16.7 %)	1 (16.7 %)
7 (24 mg)	7.2 (0.5)	2 (33.3 %)	2 (33.3 %)
8 (36 mg)	7.1 (1.3)	4 (66.7 %)	4 (66.7 %)

Source: Protalix November 2026 ACR Poster

Investigators observed that the PK and PD profiles demonstrated a relationship between sustained PRX-115 plasma exposure and prolonged plasma urate lowering effect. Participants with prolonged measurable PRX-115 concentrations maintained plasma urate levels below the therapeutic target for extended time periods. Conversely, declining PRX-115 concentrations were associated with gradual recovery of plasma urate levels.

The poster concluded that PRX-115 demonstrated prolonged, dose-dependent, systemic persistence after a single intravenous administration. PK and PD analyses showed an exposure-response relationship with sustained concentrations of PRX-115 associated with durable reduction in plasma urate.

Exhibit IV – PRX-115 Uric Acid Control



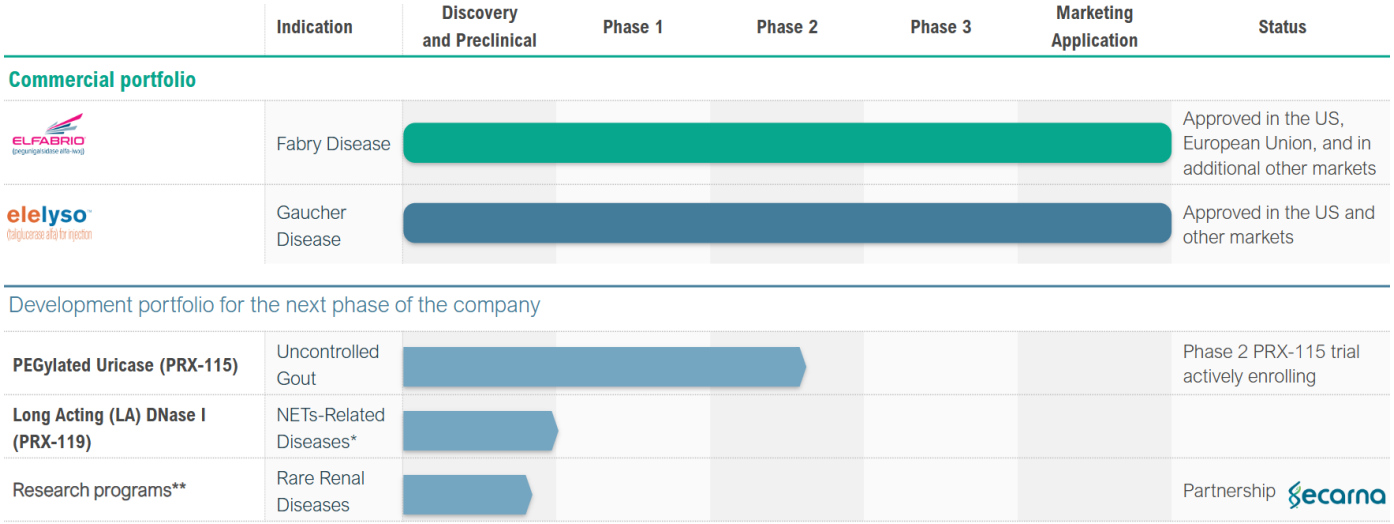
Source: Protalix November 2026 Corporate Presentation

PRX-115 Background
The PRX-115 Phase I study was completed in 2024 generating data that were presented at conferences including November's 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 2025. It was cleared in November 2025 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 US market of 11.3 million gout patients with about 180,000 suffering from the uncontrolled form.

Pipeline

Exhibit V – Protalix Product Pipeline



Source: Protalix November 2026 Corporate 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 milestone for EU approval of Elfabrio four-week dosing – 1Q:26
- Elfabrio patent (#9,194,011) term extension to November 17th, 2035 – May 2026
- Elfabrio receives orphan drug designation and marketing authorization in South Korea – May 2026
- USPTO issued patent #12,674,146 for PRX-115 – July 2026
- H.C. Wainwright Global Investment Conference – September 2026
- Morgan Stanley Global Healthcare Conference – September 2026
- Brazil's marketing authorization for Elfabrio – October 5th, 2026
- American College of Rheumatology (ACR) Convergence 2026 attendance – November 2026
- Stifel Healthcare Conference – November 2026
- Ongoing enrollment in Phase II RELEASE trial for PRX-115 - 2026
- 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 – 2H:27

Valuation

We update our valuation to reflect higher product revenues in 2027 and 2028 and a flip from net loss to positive earnings for 2027. The higher product revenue baseline in 2026, upon which future estimates are built, contributes to higher cash flows in subsequent years which increases the value of our discounted cash flow model. This is partially offset by an increased share count that rose by about 5% over the last three months due to ATM issuances. The net result of these changes in our model supports an increase in our valuation from $10 per share to $12 per share.

Summary

Protalix reported third quarter results and posted better than expected revenues due to contributions from Pfizer and Chiesi. While there is still volatility in Chiesi's ordering patterns, after two quarters of better-than-expected sales, we use a higher baseline to estimate 2027 and later revenues. The higher product revenues carry through to the bottom line, flipping our previous net loss estimate to positive EPS in 2027. Protalix' new guidance language anticipates that the company will "meet or exceed" the previous revenue guidance of $78.0 to $83.0 million. The result of these changes that reflects management's greater confidence supports an increase in our DCF-based valuation. Further support for future growth comes from the approval of Elfabrio in Brazil, whose regulatory agency has cleared both the two-week and four-week dosing regimens in the beginning of the fourth quarter.

Protalix is advancing its PRX-115 asset through further Phase I analysis and the Phase II RELEASE trial. The former shows results that support the durable activity of PRX-115 in suppressing plasma urate levels and the latter is expected to produce topline data in 2H:27. Management continues to attend to other preclinical development programs and will report on their progress and its future plans for them in coming periods. Our valuation increases to $12 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[1]

Protalix Biotherapeutics	2025 A	Q1 A	Q2 A	Q3 A	Q4 E	2026 E	2027 E	2028 E
Total Revenues ($US '000)	**$52,744**	**$33,750**	**$19,896**	**$21,925**	**$16,200**	**$91,771**	**$69,224**	**$76,971**
YOY Growth	-1.2%	234%	27%	23%	78%	74%	-25%	11%
Cost of Revenues	$26,993	$4,127	$7,762	$7,876	$6,966	$26,731	$24,228	$26,940
Research & Development	$19,569	$5,426	$4,351	$6,923	$8,974	$25,674	$27,250	$29,500
Selling, General & Admin	$11,682	$3,051	$3,111	$3,079	$3,664	$12,905	$13,650	$14,105
Income from operations	($5,500)	$21,146	$4,672	$4,047	($3,404)	$26,461	$4,095	$6,426
Operating Margin	*-10%*	63%	23%	18%	-21%	*29%*	*6%*	*8%*
Financial Expenses	$1,191	$193	$494	$24	$0	$711	$25	$25
Financial Income	($1,083)	($188)	($682)	($599)	($190)	($1,659)	($600)	($600)
Pre-Tax Income	($5,608)	$21,141	$4,860	$4,622	($3,214)	$27,409	$4,670	$7,001
Provision for Income Tax	$996	$2,824	$1,083	$661	($161)	$4,407	$234	$770
Tax Rate	-17.8%	13.4%	22.3%	14.3%	5.0%	16.1%	5.0%	11.0%
Net Income	**($6,604)**	**$18,317**	**$3,777**	**$3,961**	**($3,053)**	**$23,002**	**$4,437**	**$6,231**
Net Margin	-13%	54%	19%	18%	-19%	25%	6%	8%
Reported EPS	**($0.08)**	**$0.22**	**$0.05**	**$0.05**	**($0.04)**	**$0.28**	**$0.05**	**$0.07**
Diluted Shares Outstanding	78,546	83,049	82,560	83,587	84,500	83,049	85,000	87,000

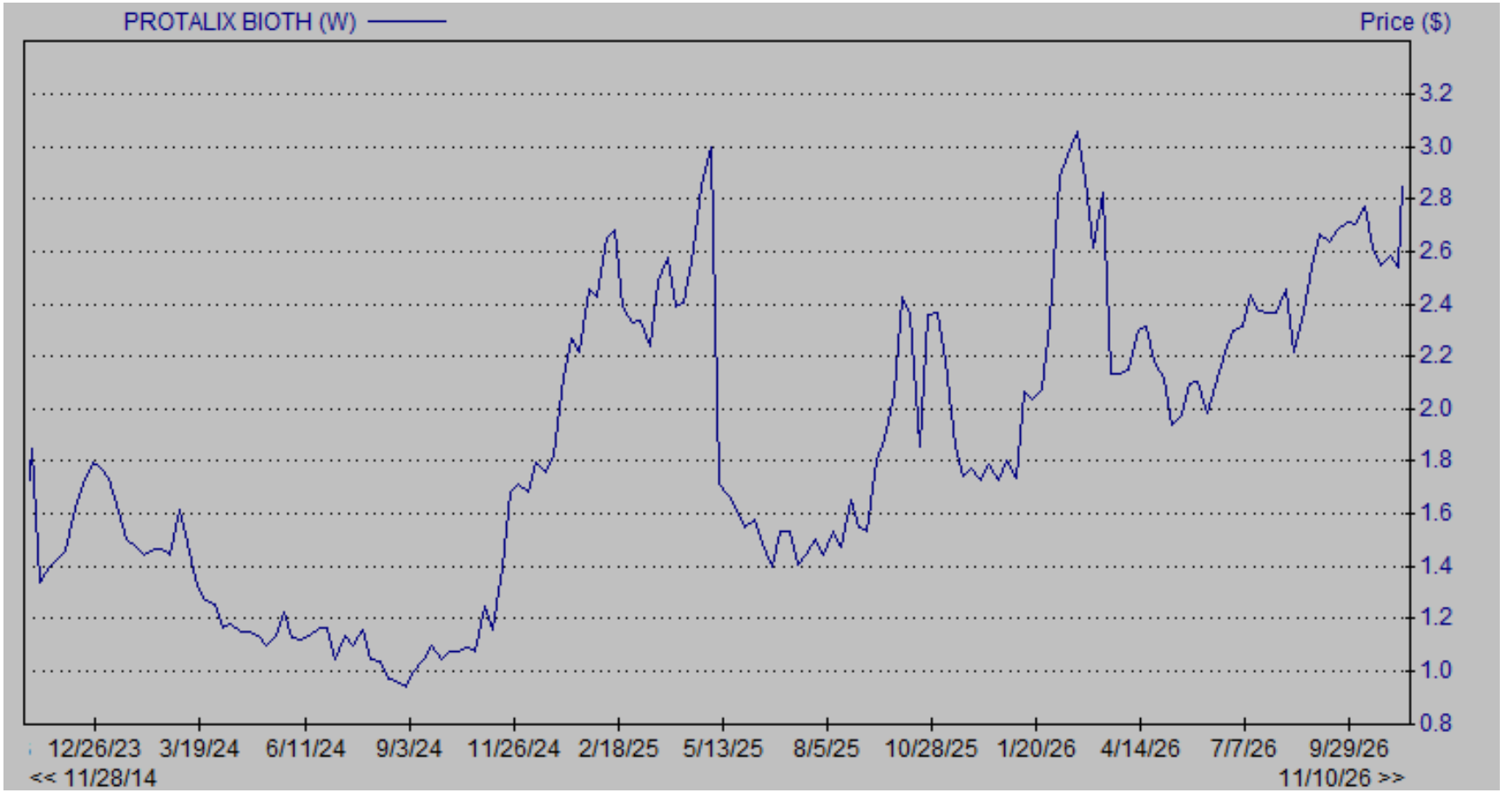
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

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



[2] Source: Zacks Research System

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