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Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: 2025 Full Year 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 (3/17/2026)	$2.79
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	**$1.32**
One-Year Return (%)	**13.9**
Beta	**-0.2**
Average Daily Volume (sh)	**1,212,730**
Shares Outstanding (mil)	**80.6**
Market Capitalization ($mil)	**224.9**
Short Interest Ratio (days)	**2.4**
Institutional Ownership (%)	**24.5**
Insider Ownership (%)	**10.2**
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 2025 Estimate	**N/A**
P/E using 2026 Estimate	**16.4**
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)
2024	$3.7 A	$13.5 E	$18.0 A	$18.2 A	$53.4 A
2025	$10.1 A	$15.7 A	$17.9 A	$9.1 A	$52.7 A
2026					$79.7 E
2027					$62.0 E

Earnings per Share

	Q1 (Mar)	**Q2** (Jun)	**Q3** (Sep)	**Q4** (Dec)	**Year** (Dec)
2024	-$0.06 A	-$0.03 A	$0.04 A	$0.08 A	$0.04 A
2025	-$0.05 A	$0.00 A	$0.03 A	-$0.07 A	-$0.08 A
2026					$0.17 E
2027					$0.00 E

WHAT'S NEW

2025 Financial and Operational Review

Protalix BioTherapeutics, Inc. (NYSE: PLX) announced 2025 financial and operational results in a March 18th, 2026 press release and Form 10-K filing. The reports were followed by a conference call which discussed recent achievements, regulatory updates, trial timelines and financial performance. 2025 revenues fell by 1% as higher Elelyso sales were offset by lower Elfabrio sales, which were impacted by large initial stock-ups in 2024. Protalix and Chiesi requested a re-examination of the Committee for Medicinal Products for Human Use's (CHMP) negative opinion, which was granted. The agency later issued a positive opinion on four-week dosing. Elfabrio went on to receive European Commission approval in March, which entitles Protalix to a $25 million milestone from Chiesi.

The PRX-115 Phase II trial has launched and is enrolling patients, which is now designated RELEASE. PRX-119 is undergoing pre-investigational new drug (IND) studies this year and the collaboration continues with Secarna.

Financial results for the year ending December 31st, 2025, compared to the same prior year period:

- Revenues were $52.7 million, down 1% from $53.4 million, attributable to an increase in Elelyso sales to Pfizer offset by a decline in Elfabrio sales to Chiesi. Sales to Pfizer were $18.2 million, up by $5.6 million and sales to Brazil were a relatively flat $11.1 million. Chiesi sales were $22.5 million, falling by $6.8 million due to the prior year's inventory build by Chiesi. Protalix also recognized $942,000 in license and R&D services revenue, more than double the prior year amount;
- Cost of revenue was $27.0 million vs. $24.3 million, increasing at a greater rate than revenues;
- Research and development expenses increased to $19.6 million from $13.0 million. Higher salary, subcontractor expenses, materials and other expenses were up, driving a 51% increase. Increased spending supported preparation activities for the Phase II PRX-115 study which began in 1Q:26;
- Selling, general and administrative expenses fell slightly to $11.7 million versus $12.2 million due to a decrease in share-based compensation;
- Net financial income was $108,000 compared to a net financial expense of $237,000. The change in this line item was due to the absence of notes and their associated interest which were present in 2024;
- Income tax expense of $996,000 vs. $1.2 million;
- Net loss was $6.6 million versus net income of $2.9 million, or -$0.08 per share versus $0.04 per share;

The cash and equivalents balance on December 31st, 2025 totaled $30.3 million versus $34.8 million at the end of 2024. During 2025, Protalix generated $9.3 million from the sale of common stock and exercise of warrants and options. Cash burn was $13.6 million for the year. In March 2026, the EC approved four-week dosing of Elfabrio, qualifying Protalix for a $25 million milestone from Chiesi. We expect the amount will be recognized in the first quarter of 2026 while cash flows will occur in the second quarter.

European Commission Approval of Elfabrio Four Week Dosing

After the back and forth of submissions, responses and resubmissions which we have discussed in previous reports, the European Commission (EC) approved the 2.0 mg/kg every four weeks dosing regimen for Elfabrio in Fabry disease. The addressable patient population is adult patients who are stable on enzyme replacement therapy (ERT). Details of the decision were provided in a March 9th, 2026, press release. Along with the approval, Protalix will receive a $25 million milestone payment from Chiesi.

While the four-week dosing regimen has been approved, it will take time to shift patients to it. 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 4 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.

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.[1]

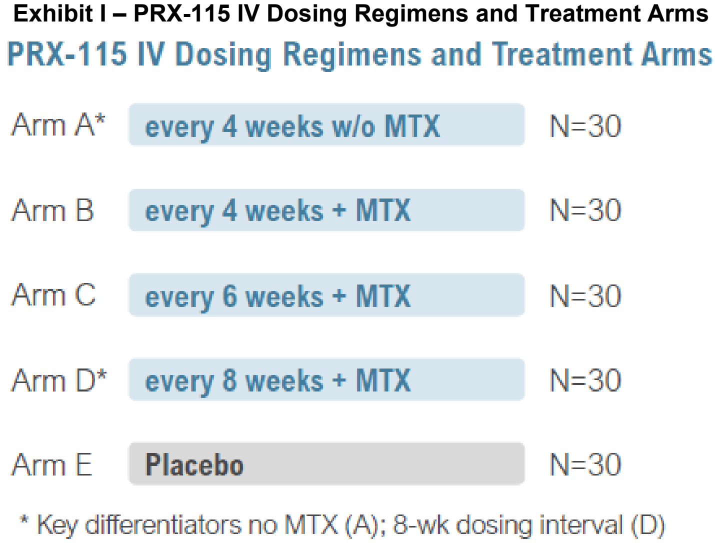
On October 17th, 2025, Chiesi and Protalix announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had issued a negative opinion on the request to approve the dosing regimen of 2.0 mg/kg body weight infused every 4 weeks for Elfabrio.

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 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.

PRX-115 Phase II Trial Enrolling

Protalix announced that the Phase II study for PRX-115 has begun enrolling. The trial, 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* is designated RELEASE and is listed on clinicaltrials.gov under 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 up and running in Miami, Florida.

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



Source: Protalix February 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.

[1] 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.

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 or help in managing flares but is rather 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.[2]

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.

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.

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.

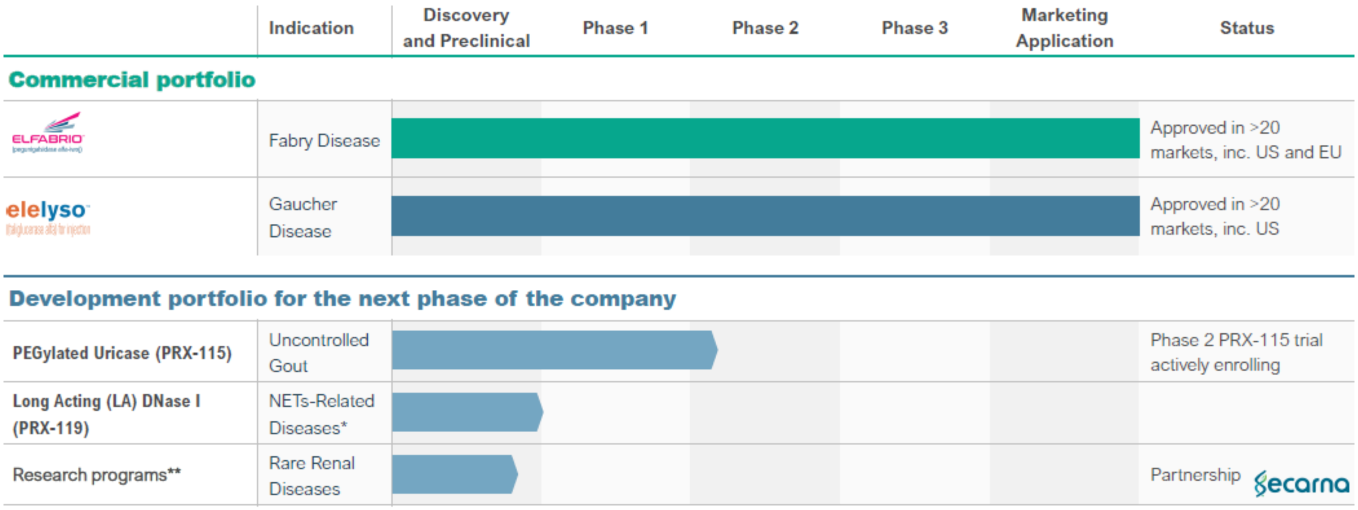
Secarna offers its OligoCreator platform which uses AI to discover and develop oligonucleotides for use in a variety of organs and tissues to address untreatable conditions. The platform offers a safety and efficacy testing system that characterizes the risk profile of a candidate and identifies a broad 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.

[2] Boston, 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.

Pipeline

Exhibit II – Protalix Product Pipeline



Source: Protalix February 2026 Presentation

Milestones

- Appointment of Gilad Mamlok as CFO – August 2025
- Participation at HC Wainwright Global Investment Conference – September 2025
- CHMP issued negative opinion of Elfabrio four-week dosing – October 2025
- Automatic 5-year extension of Pfizer-Elelyso contract to 2030 – October 2025
- Protalix & Chiesi appeal CHMP decision – November 2025
- PRX-115 IND becomes effective – November 2025
- Collaboration with Secarna Pharmaceuticals in renal rare disease – December 2025
- 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 – April 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 - 2027

Summary

Protalix reports full year 2025 results and sets 2026 revenue guidance. Revenues were behind our estimates on lower Elfabrio sales related to the timing of Chiesi's restocking cadence. Guidance calls for total revenues of $78 to $83 million. The most important recent news was the approval of four-week dosing in the EU which is an attractive convenience for patients who can cut the number of infusions in half. Monthly pricing is expected to remain the same, which will streamline pricing discussions in each of the EU member states. We anticipate that the new regimen will be introduced to patients in the second half of 2026 with the pace accelerating in 2027. Along with the approval, Protalix is entitled to a $25 million milestone payment which will arrive in 2Q:26 and is included in guidance.

The Phase II study for PRX-115 has begun and is expected to continue enrollment as the year progresses. Protalix expects that it will forge a commercial partnership for this asset following the conclusion of the trial in 2027. 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]

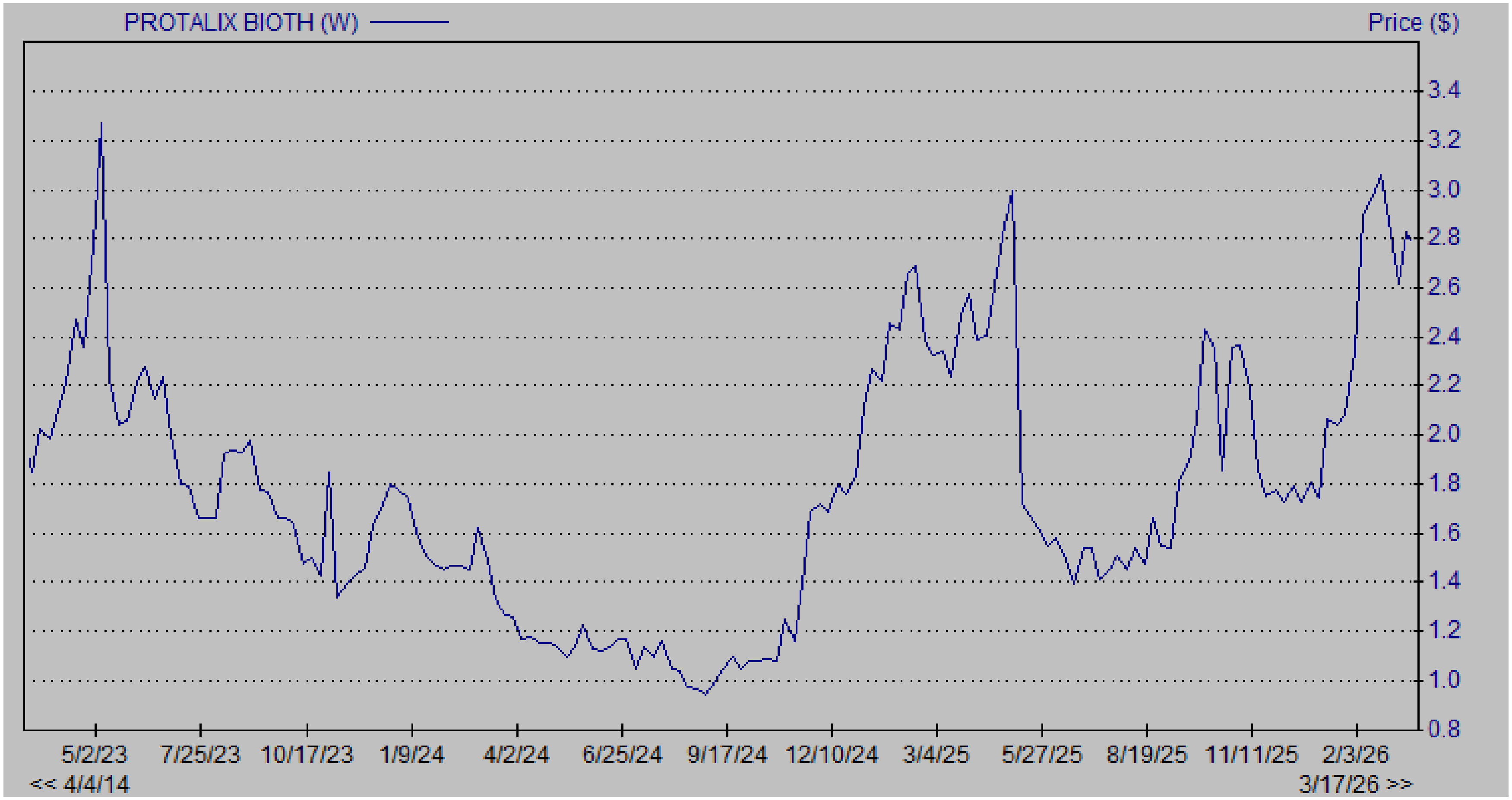
Protalix Biotherapeutics	2024 A	Q1 A	Q2 A	Q3 A	Q4 A	2025 A	2026 E	2027 E
Total Revenues ($US '000)	**$53,399**	**$10,113**	**$15,658**	**$17,851**	**$9,122**	**$52,744**	**$79,690**	**$61,987**
YOY Growth	-18%	170%	16%	-1%	-50%	-1.2%	51%	-22%
Cost of Revenues	$24,319	$8,180	$5,870	$8,324	$4,619	$26,993	$23,517	$21,695
Research & Development	$12,970	$3,475	$5,992	$4,467	$5,635	$19,569	$29,450	$27,250
Selling, General & Admin	$12,193	$2,603	$2,624	$2,929	$3,526	$11,682	$13,200	$13,650
Income from operations	$3,917	($4,145)	$1,172	$2,131	($4,658)	($5,500)	$13,523	($609)
Operating Margin	7%	-41%	7%	12%	-51%	*-10%*	*17%*	*-1%*
Financial Expenses	$1,062	$6	$783	$180	$222	$1,191	$25	$25
Financial Income	($1,299)	($419)	($272)	($288)	($104)	($1,083)	($600)	($600)
Pre-Tax Income	$4,154	($3,732)	$661	$2,239	($4,776)	($5,608)	$14,098	($34)
Provision for Income Tax	$1,222	($113)	$497	($116)	$728	$996	$705	($2)
Tax Rate	29.4%	3.0%	75.2%	-5.2%	-15.2%	-17.8%	5.0%	5.0%
Net Income	**$2,932**	**($3,619)**	**$164**	**$2,355**	**($5,504)**	**($6,604)**	**$13,393**	**($32)**
Net Margin	5%	-36%	1%	13%	-60%	-13%	17%	0%
Reported EPS	**$0.04**	**($0.05)**	**$0.00**	**$0.03**	**($0.07)**	**($0.08)**	**$0.17**	**($0.00)**
Diluted Shares Outstanding	81,057	76,612	81,272	80,815	80,420	78,546	80,600	81,000

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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