

Zacks Small-Cap Research

Sponsored – Impartial – Comprehensive

August 13, 2026

John D. Vandermosten

312-265-9588 / jvandermosten@zacks.com

scr.zacks.com

101 N. Wacker Drive, Chicago, IL 60606

Protalix BioTherapeutics, Inc.

(PLX: NYSE American)

PLX: Elfabrio Estimates Up

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 following US and European approval. The model includes contributions from global commercialization.

Current Price (8/12/2026)

\$2.62

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 & Elfabrio which was approved in May 2023. Chiesi Global Rare Diseases 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 address an unmet need with several improvements over the market leader and is expected to command a premium to 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	\$1.46
One-Year Return (%)	56.8
Beta	0.0
Average Daily Volume (sh)	682,079

Shares Outstanding (mil)	80.6
Market Capitalization (\$mil)	211.2
Short Interest Ratio (days)	7.2
Institutional Ownership (%)	22.0
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	11.4
P/E using 2026 Estimate	13.8
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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2025	\$10.1 A	\$15.7 A	\$17.9 A	\$9.1 A	\$52.7 A
2026	\$33.8 A	\$19.9 A	\$11.7 E	\$16.2 E	\$81.6 E
2027					\$60.2 E
2028					\$68.8 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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 E	-\$0.04 E	\$0.19 E
2027					-\$0.01 E
2028					\$0.02 E

WHAT'S NEW

Second Quarter 2026 Financial and Operational Review

Protalix BioTherapeutics, Inc. (NYSE: PLX) surprised to the upside with a strong quarter of sales for Elfabrio, generating revenues of over \$14 million for the product in 2Q:26. The result vaulted total revenues to almost \$20 million which helped tip earnings into positive territory. Elelyso revenues were also ahead of our estimates, rising 3%.

Other positive news since the first quarter update includes a five-year grant of patent term extension lengthening Elfabrio's intellectual property protection to November 2035. Additionally, Elfabrio received orphan drug designation and marketing authorization in South Korea. PRX-115 posted positive news with the issuance of a new patent along with management's continued anticipation for a 2H:27 topline readout for the gout treatment. The [RELEASE](#) trial continues to enroll subjects at almost 30 sites located in the US, Georgia and Israel. Topline results are expected in 2H:27.

In the preclinical arena, Protalix continues its relationship with Secarna along with other undisclosed early partners focusing on renal rare disease. The focus extends to further development of the preclinical asset PRX-119, the long-acting DNase I program.

Despite the strong revenue report, Protalix maintains its topline guidance of \$78 to \$83 million for 2026. Elfabrio comes in at \$33 to \$35 million and Elelyso is expected to range from \$20 to \$23 million.

Protalix' financial and operational results were reported in an August 12th, 2026 [press release](#) and [Form 10-Q](#) filing. The reports were followed by a [conference call](#) which provided further updates. Total revenues were up 27% due to better-than-expected revenues for both Elelyso and Elfabrio. Net income was \$3.8 million or \$0.05 per share. Further discussion of financial results for the quarter ending June 30th, 2026, are provided below and compare to the same prior year period:

- Revenues were \$19.9 million, up 27% from \$15.7 million, attributable to a 43% growth in Elfabrio and a 3% increase in Elelyso revenues generated from selling to partners. While Elelyso sales to Pfizer declined, sales to Brazil were \$1.5 million vs \$0, helping drive the overall increase for the Gaucher disease treatment. License and R&D services revenues were a modest \$68,000, falling relative to the prior year;
- Cost of revenue was \$7.8 million vs \$5.9 million. Product gross margin fell to 61% from 62% due to product mix;
- Research and development expenses fell 27% to \$4.4 million from \$6.0 million. The decrease was due to the impact from an offsetting R&D grant of \$2.1 million and reduced subcontractor-related expenses offset by higher salary, materials and other expenses. Absent the grant, R&D expenses rose 8%;
- Selling, general and administrative expenses rose 19% to \$3.1 million versus \$2.6 million due to higher salary and selling expenses;
- Net financial income was \$188,000 compared to a net financial expense of \$511,000. The change in this line item was due to exchange rate fluctuations;
- Income tax expense of \$1.1 million vs \$497,000;
- Net income was \$3.8 million or \$0.05 per share versus \$164,000 or \$0.00 per share.

The cash and equivalents balance on June 30th, 2026 totaled \$40.7 million versus \$30.3 million at the end of 2025. During the first six months of 2026, Protalix' cash from operations was \$11.6 million with offsets related to an increase in accounts receivable and increase in inventories. 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 placebo groups in adult patients with gout. 27 sites are listed as active and enrolling on clinicaltrials.gov.

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

Exhibit I – PRX-115 Phase II Trial Design	
Patient Population: uncontrolled gout	PRX-115 IV Dosing Regimens and Treatment Arms
Primary Endpoint: proportion of patients who achieve a reduction in serum uric acid (sUA) to <6.0 mg/dL for at least 80% of the time during Month 6	Arm A* every 4 weeks w/o MTX N=30
Secondary Endpoints: additional uric acid parameters, safety, and immunogenicity	Arm B every 4 weeks + MTX N=30
Exploratory Endpoints: tophi, flares, swollen & tender joints, quality of life (QoL), pharmacokinetics (PK)	Arm C every 6 weeks + MTX N=30
	Arm D* every 8 weeks + MTX N=30
	Arm E Placebo N=30
	* Key differentiators no MTX (A); 8-wk dosing interval (D)
Source: Protalix August 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.

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

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.

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.

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



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 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 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

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.

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

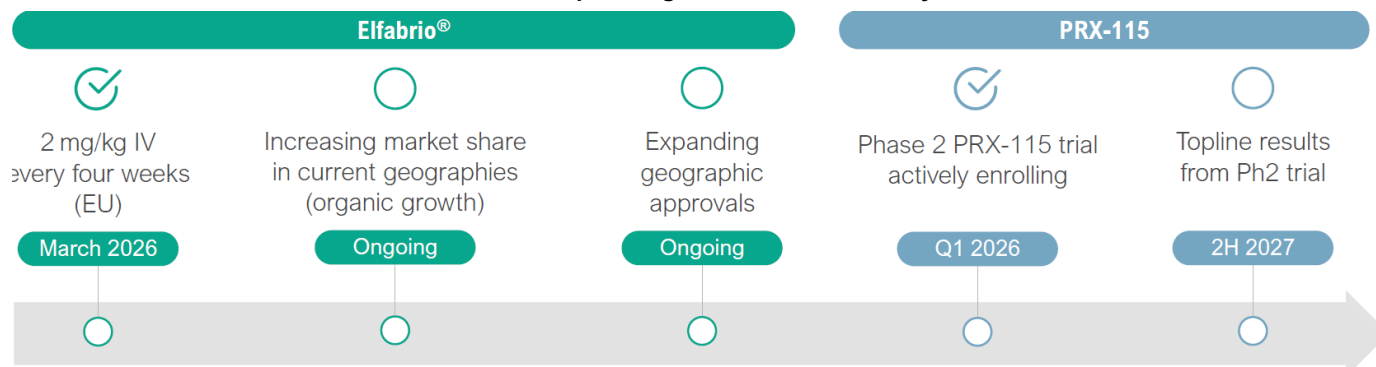
Exhibit III – Protalix Product Pipeline							
	Indication	Discovery and Preclinical	Phase 1	Phase 2	Phase 3	Marketing Application	Status
Commercial portfolio							
	Fabry Disease						Approved in the US, European Union, and in additional other markets
	Gaucher Disease						Approved in the US and other markets
Development portfolio for the next phase of the company							
PEGylated Uricase (PRX-115)	Uncontrolled Gout						Phase 2 PRX-115 trial actively enrolling
Long Acting (LA) DNase I (PRX-119)	NETs-Related Diseases*						
Research programs**	Rare Renal Diseases						Partnership 

Source: Protalix [August 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 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
- 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

Exhibit IV – Upcoming Milestones and Catalysts



Source: Protalix [August 2026 Presentation](#)

Summary

Protalix reports second quarter results and posts better than expected revenues due to a sharp rise in Elfabrio revenues. The revenue beat led to positive net earnings and a favorable view on future sales trends. We increase our revenue estimates for 2026 and beyond to reflect estimate increases for Elfabrio. Better-than-expected second-quarter Elfabrio revenue, EU approval of the new every-four-week dosing regimen, and continued geographic expansion, including marketing authorization in South Korea, support our higher sales estimates.

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. Preclinical work on projects related to rare renal disease continues in the background with additional programs beyond PRX-119 and the Secarna collaboration advancing. Our valuation remains at \$10 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement³

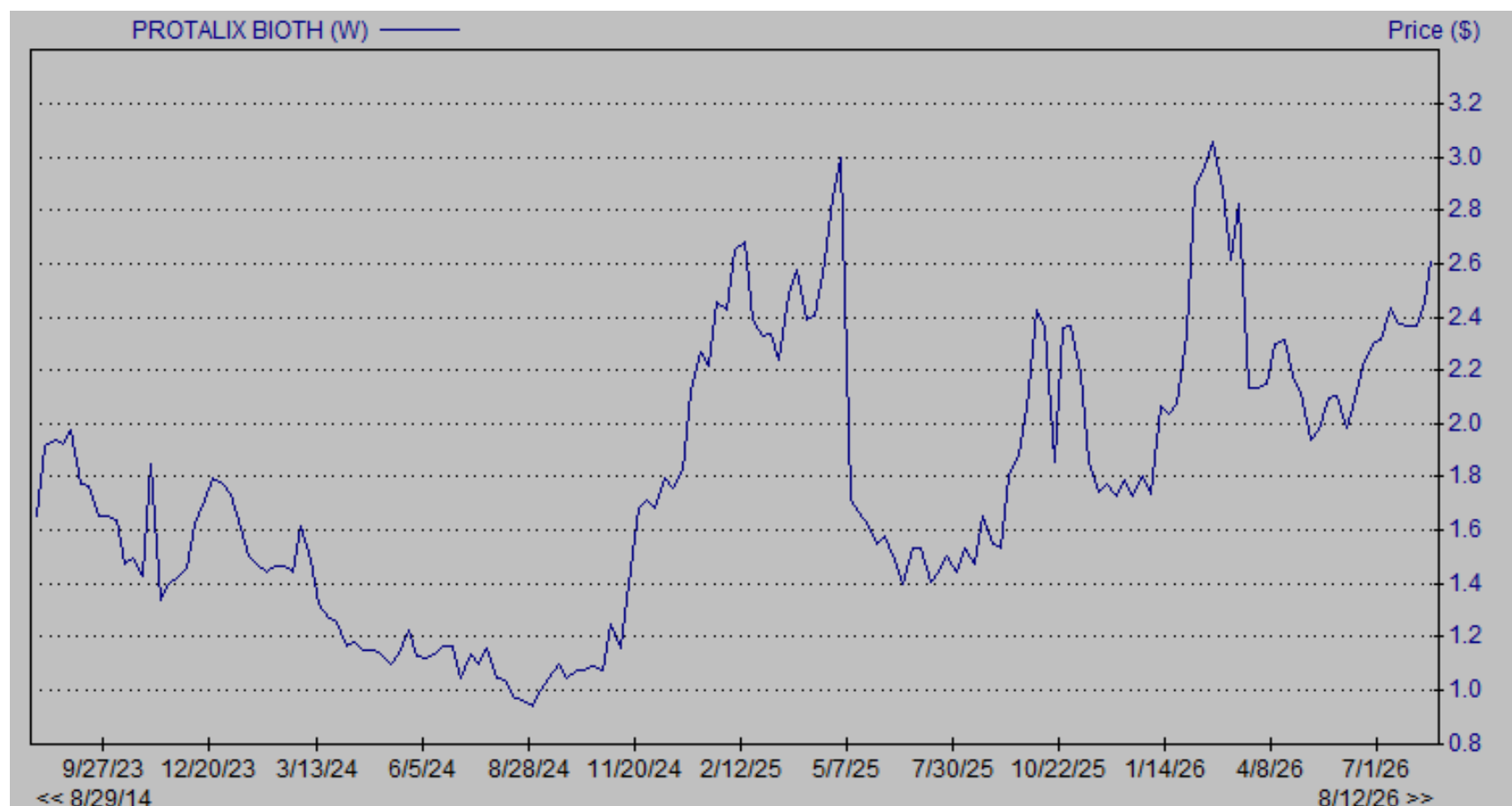
Protalix Biotherapeutics	2025 A	Q1 A	Q2 A	Q3 E	Q4 E	2026 E	2027 E	2028 E
Total Revenues (\$US '000)	\$52,744	\$33,750	\$19,896	\$11,740	\$16,200	\$81,586	\$60,278	\$68,824
YOY Growth	-1.2%	234%	27%	-34%	78%	55%	-26%	14%
Cost of Revenues	\$26,993	\$4,127	\$7,762	\$5,048	\$6,966	\$23,903	\$21,097	\$24,088
Research & Development	\$19,569	\$5,426	\$4,351	\$7,450	\$8,974	\$26,201	\$27,250	\$29,500
Selling, General & Admin	\$11,682	\$3,051	\$3,111	\$3,310	\$3,664	\$13,136	\$13,650	\$14,105
Income from operations	(\$5,500)	\$21,146	\$4,672	(\$4,068)	(\$3,404)	\$18,346	(\$1,719)	\$1,131
Operating Margin	-10%	63%	23%	-35%	-21%	22%	-3%	2%
Financial Expenses	\$1,191	\$193	\$494	\$0	\$0	\$687	\$25	\$25
Financial Income	(\$1,083)	(\$188)	(\$682)	(\$210)	(\$190)	(\$1,270)	(\$600)	(\$600)
Pre-Tax Income	(\$5,608)	\$21,141	\$4,860	(\$3,858)	(\$3,214)	\$18,929	(\$1,144)	\$1,706
Provision for Income Tax	\$996	\$2,824	\$1,083	(\$193)	(\$161)	\$3,553	(\$57)	\$188
Tax Rate	-17.8%	13.4%	22.3%	5.0%	5.0%	5.0%	5.0%	11.0%
Net Income	(\$6,604)	\$18,317	\$3,777	(\$3,665)	(\$3,053)	\$15,375	(\$1,087)	\$1,518
Net Margin	-13%	54%	19%	-31%	-19%	19%	-2%	2%
Reported EPS	(\$0.08)	\$0.22	\$0.05	(\$0.05)	(\$0.04)	\$0.19	(\$0.01)	\$0.02
Diluted Shares Outstanding	78,546	83,049	82,560	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 Chart⁴



⁴ Source: Zacks Research System

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. This research report was prepared under the aforementioned engagement.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business. SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.