Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive

February 3, 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)

PLX: CHMP Delivers Positive Opinion

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 (2/2/2026)	$2.60
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	**$3.10**
52-Week Low	**$1.32**
One-Year Return (%)	**7.0**
Beta	**-0.2**
Average Daily Volume (sh)	**702,428**
Shares Outstanding (mil)	**80.4**
Market Capitalization ($mil)	**209.0**
Short Interest Ratio (days)	**5.7**
Institutional Ownership (%)	**17.9**
Insider Ownership (%)	**10.2**
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	**41.4**
P/E using 2025 Estimate	**N/A**
P/E using 2026 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)
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	$10.4 E	$54.0 E
2026					$64.5 E
2027					$72.7 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	-$0.03 E	-$0.04 E
2026					-$0.06 E
2027					$0.08 E

WHAT'S NEW

CHMP Positive Opinion for Elfabrio Four-Week Dosing

In October 2025 Protalix BioTherapeutics, Inc. (NYSE: PLX) announced that the Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion regarding Chiesi's request for four-week dosing via a post-authorization variation. In response Chiesi and Protalix requested a re-examination and new CHMP recommendation. In January, the European agency reversed its prior conclusion following the appeal. The committee issued a positive opinion recommending approval of the 2.0 mg/kg every four weeks dosing regimen for Elfabrio in Fabry disease adult patients stable with an enzyme replacement therapy (ERT) treatment.

The data to support the extension of time between infusions was generated in the Phase III BRIGHT study. Elfabrio has a prolonged half-life which enables the dosing period to be extended. 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 next step in the process is for the European Commission (EC) to decide whether or not to approve the abbreviated dosing schedule recommended by the CHMP. If approved, Protalix will be eligible to receive a regulatory milestone payment of $25 million. We do not include the milestone in our revenue estimates.

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 cost where a provider administers the infusion. Other benefits include less venous access trauma, easier scheduling and a higher quality of life for the Fabry patient. Chiesi and Protalix management anticipate that the EC will issue a decision by March 2026.

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 will be appointed to conduct the re-examination. Chiesi and Protalix have consultants and/or internal personnel with EMA and CHMP experience who will help develop the argument for four-week dosing. In the meantime, two-week dosing remains approved and the standard for administering Elfabrio.

Letter to Stockholders

In the first days of 2026, Protalix CEO Dror Bashan penned a letter to stockholders highlighting the company's accomplishments in the prior year and looking ahead to future sales mix and revenue trends. Along with two commercial assets, Protalix has one clinical program, another on the cusp of an investigational new drug (IND) application and other assets in discovery. The company's priorities emphasize the relationship with Chiesi for commercialization of Elfabrio, support the advancement of PRX-115 into a Phase II study and beyond if appropriate and further development of the rare renal disease programs.

[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.

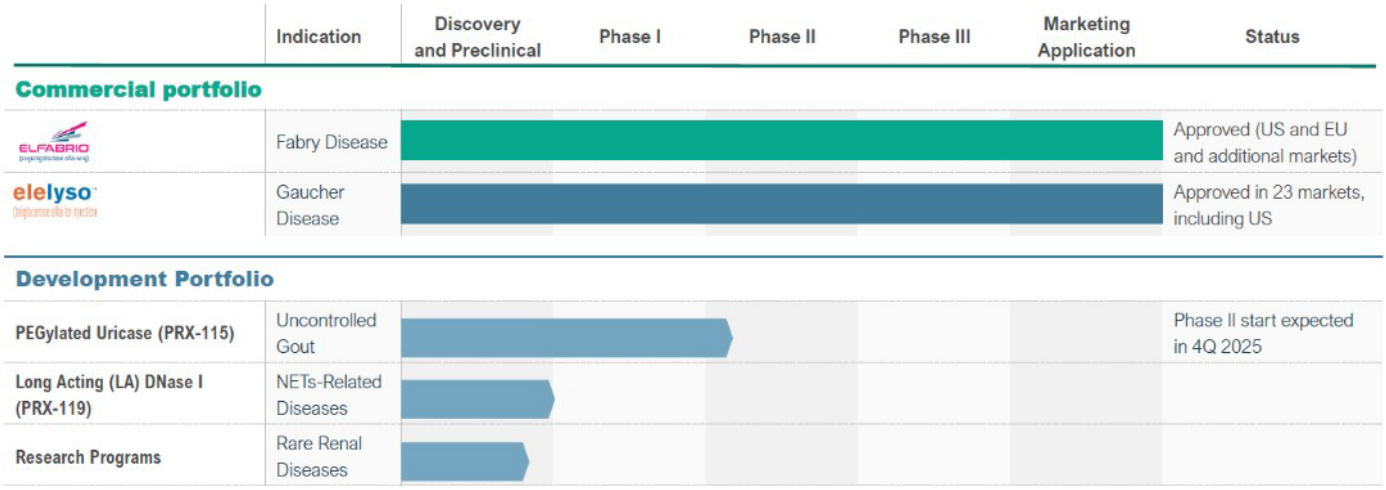
The lead development program, PRX-115, has shown a rapid and durable urate-lowering effect with a favorable tolerability profile in a Phase I study in gout. It is pursuing an indication that is increasing in prevalence and with many patients suffering from uncontrolled disease. Management believes that PRX-115 has the potential to deliver a differentiated clinical profile with rapid onset and durable urate control and potentially emerge as a third molecule for commercialization.

As mentioned in our previous report, 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.

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.

Pipeline

Exhibit I – Protalix Product Pipeline



Source: Protalix November 2025

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
- Ongoing enrollment in Japanese RISE study (Elfabrio) - 2025
- Pediatric FLY study active for Fabry disease (Elfabrio) - 2025
- Initiate Phase II study for PRX-115 in gout – 2H:25
- Collaboration with Secarna Pharmaceuticals in renal rare disease – December 2025
- Enrollment of first patient in PRX-115 Phase II gout study – 4Q:25
- Positive opinion from CHMP for Elfabrio four-week dosing – January 2026
- PRX-115 Phase II trial start – 1Q:26
- EC decision for Elfabrio four-week dosing – March 2026
- Topline results from PRX-115 Phase II study - 2027

Summary

Protalix announces good news with the positive opinion from the CHMP. The opinion was the result of Chiesi's request for re-examination of data from Protalix' BRIGHT study. BRIGHT examined the long-term effects of a 2.0 mg/kg dose administered every four weeks of Elfabrio. The CHMP will pass the application package on to the EC who has about two months to review. Based on management commentary and a review of other literature on the topic, in most cases the EC follows the CHMP opinion. We expect that the EC will approve the new regimen which will entitle Protalix to a $25 million milestone payment. We have not included this contribution in our model.

Prior to the positive CHMP announcement, CEO Dror Bashan wrote a letter to investors highlighting the company's commercial and development prospects. Growing revenues for Elfabrio and Elelyso join pipeline candidates including PRX-119 for NETs-related diseases and PRX-115 for uncontrolled gout. The Phase II PRX-115 trial is expected to start soon. While the revenue profile for both assets is volatile, we think that Elfabrio revenues have substantial upside that will be clearer after initial inventory for each of the regions is consumed and patient demand patterns can be predicted. Our valuation remains at $10 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[2]

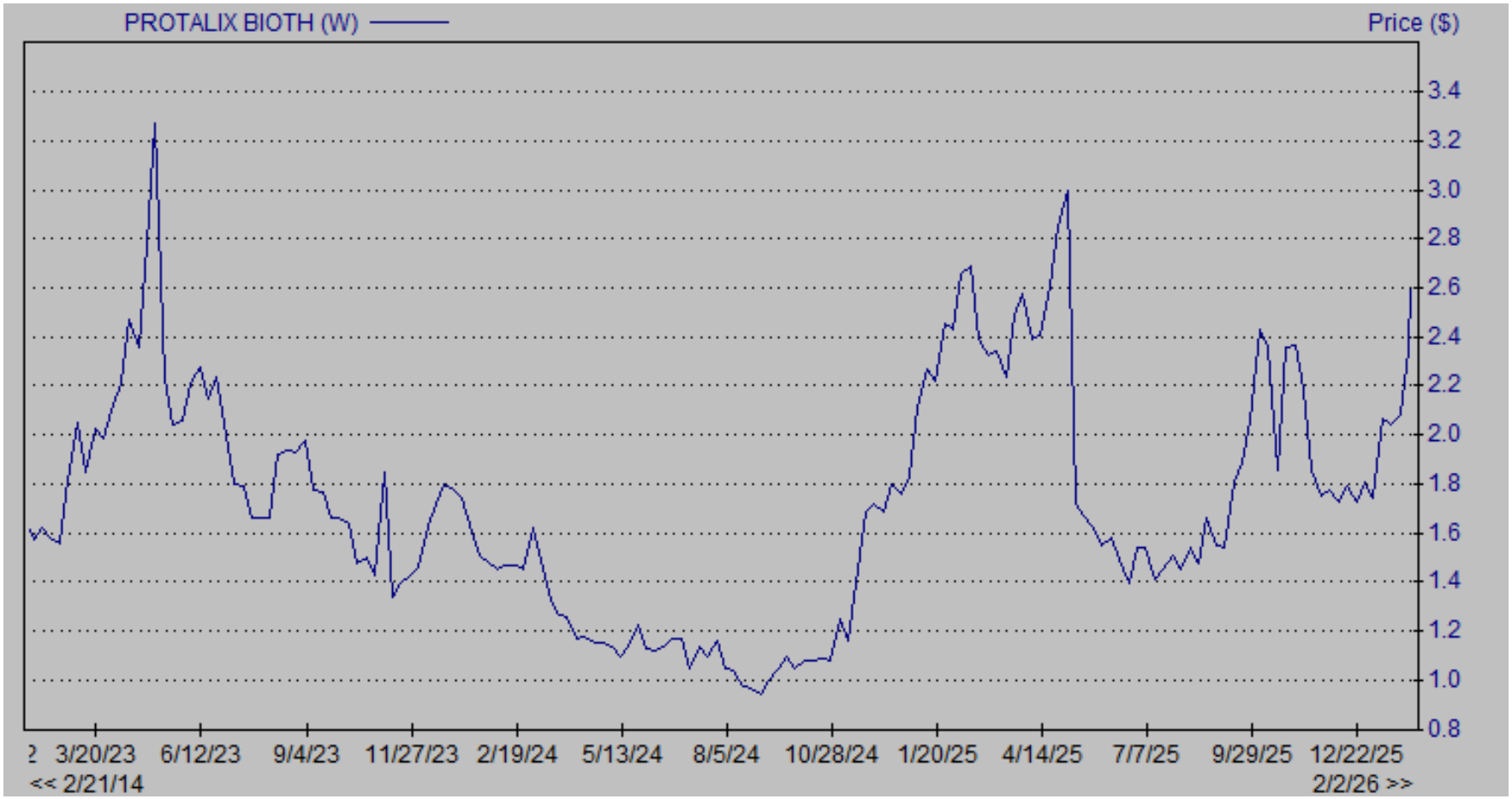
Protalix Biotherapeutics	2024 A	Q1 A	Q2 A	Q3 A	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($US '000)	**$53,399**	**$10,113**	**$15,658**	**$17,851**	**$10,371**	**$53,993**	**$64,452**	**$72,713**
YOY Growth	-18%	170%	16%	-1%	-43%	1%	19%	13%
Cost of Revenues	$24,319	$8,180	$5,870	$8,324	$6,600	$28,974	$27,714	$25,450
Product Gross Margin	54%	18%	62%	53%	36%	46%	57%	65%
Research & Development	$12,970	$3,475	$5,992	$4,467	$3,800	$17,734	$29,450	$25,250
Selling, General & Admin	$12,193	$2,603	$2,624	$2,929	$3,000	$11,156	$13,200	$15,650
Income from operations	$3,917	($4,145)	$1,172	$2,131	($3,029)	($3,871)	($5,912)	$6,363
Operating Margin	7%	-41%	7%	12%	-29%	-7%	-9%	9%
Financial Expenses	$1,062	$6	$783	$180	$6	$975	$25	$25
Financial Income	($1,299)	($419)	($272)	($288)	($277)	($1,256)	($600)	($600)
Pre-Tax Income	$4,154	($3,732)	$661	$2,239	($2,758)	($3,590)	($5,337)	$6,938
Provision for Income Tax	$1,222	($113)	$497	($116)	$0	$0	($267)	$347
Tax Rate	29.4%	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	5.0%
Net Income	**$2,932**	**($3,619)**	**$164**	**$2,355**	**($2,758)**	**($3,590)**	**($5,070)**	**$6,592**
Net Margin	5%	-36%	1%	13%	-27%	-7%	-8%	9%
Reported EPS	**$0.04**	**($0.05)**	**$0.00**	**$0.03**	**($0.03)**	**($0.04)**	**($0.06)**	**$0.08**
Diluted Shares Outstanding	81,057	76,612	81,272	80,815	82,000	80,175	82,500	83,220

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

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

HISTORICAL STOCK PRICE

Protalix BioTherapeutics, Inc. – Share Price Chart[3]



[3] 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.