Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive

November 17, 2025
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: Protalix Seeks Re-Examination of CHMP 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 (11/14/2025)	$1.86
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 action DNase I for the treatment of NETs-related diseases.

Elfabrio was approved in Europe and the United States in early May 2023 and continues to seek approval elsewhere. The product 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	**$1.32**
One-Year Return (%)	**31.9**
Beta	**-0.3**
Average Daily Volume (sh)	**825,018**
Shares Outstanding (mil)	**80.4**
Market Capitalization ($mil)	**149.5**
Short Interest Ratio (days)	**3.9**
Institutional Ownership (%)	**17.6**
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	**31.0**
P/E using 2025 Estimate	**93.0**
P/E using 2026 Estimate	**12.4**
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	$15.3 E	$58.9 E
2026					$61.8 E
2027					$69.5 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	$0.02 E
2026					$0.15 E
2027					$0.19 E

WHAT'S NEW

Third Quarter 2025 Financial and Operational Review

Protalix BioTherapeutics, Inc. (NYSE: PLX) announced 3Q:25 financial and operational results in a November 13th, 2025 press release and in its Form 10-Q filing. The reports were followed by a conference call which discussed recent achievements, regulatory updates, trial timelines and financial performance. During the third quarter, Protalix' overall revenues were essentially flat as growth in Elelyso sales were offset by a decline in Elfabrio sales. Elfabrio's decline in 3Q:25 was attributable to Chiesi's initial inventory build and stock up in 3Q:24. Protalix and Chiesi's application for a longer dosing regimen for Elfabrio was denied, leading them to seek re-examination of the opinion from the European Medicines Agency (EMA).

Management refined its timeline to launch the PRX-115 Phase II trial in the next few weeks, enroll the first patient before year end and generate topline results in 2027. Gilad Mamlok takes over as CFO to review financial performance and joins the conference call for the first time. Protalix has also participated in investor conferences including HC Wainwright and the Investor Summit since our last update.

Financial results for the quarter ending September 30th, 2025, compared to the same quarter in the prior year:

- Revenues were $17.9 million, down 1% from $18.0 million, attributable to an increase in Elelyso sales offset by a decline in Elfabrio sales to Chiesi. Sales to Pfizer were $2.8 million, down by $625,000 and sales to Brazil were $6.1 million up $4.1 million due to timing of orders. Protalix also recognized $178,000 in license and R&D services revenue;
- Cost of revenue was $8.3 million vs. $8.4 million, declining at a similar rate to revenues;
- Research and development expenses increased to $4.5 million from $3.0 million. Higher salary, materials and other expenses were partially offset by lower subcontractor related expenses which supported preparation activities for the anticipated Phase II PRX-115 study;
- Selling, general and administrative expenses rose 13% to $2.9 million versus $2.6 million on higher salary and selling expenses;
- Net financial income was $108,000 compared to a net financial expense of $148,000. The change in this line item was due to the absence of notes and their associated interest which were present for most of the quarter in 3Q:24;
- Income tax benefit of $116,000 compared to an income tax expense of $607,000 due to faster deductibility of research and development expenses resulting from new tax legislation in the United States;
- Net income was $2.4 million versus $3.2 million, or $0.03 per share versus $0.04 per share;

The cash and equivalents balance on September 30th, 2025 totaled $29.4 million versus $34.8 million at the end of 2024. During the first nine months of 2025, Protalix generated $9.2 million from the sale of common stock and exercise of warrants and options. Cash burn was $15.3 million for the first nine months. Following the end of the quarter, stock options were exercised, generating $94,000 in proceeds.

Four Week Dosing of Elfabrio

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 mg/kg body weight infused every 4 weeks for Elfabrio.

[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.

Two and a half weeks after the negative opinion, Chiesi and Protalix issued a press release stating that they will seek re-examination of the EMA's negative opinion for Elfabrio and the four-week alternative dosing regimen. The sponsor must 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.

PRX-115

Results from the Phase I PRX-115 trial were presented at the American College of Rheumatology (ACR) Convergence annual meeting last November. The poster is entitled Prolonged Plasma Urate Lowering after a Single Intravenous Administration of PRX 115, a Novel PEGylated Uricase, in Participants with Elevated Urate Levels and was presented by Protalix' Dr. Orit Cohen Barak. Results from the Phase I study support 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 Protalix anticipates starting its Phase II study for PRX-115 in the next few weeks.

Chief Financial Officer (CFO) Transition

A July 21st press release announced that Gilad Mamlok would take the financial reins of Protalix and serve as CFO beginning August 2025. As shared in the announcement, Mr. Mamlok is an experienced financial executive with three decades of experience in healthcare and technology companies. He has an extensive background in capital markets transactions, mergers and acquisitions, business development, investor relations and corporate governance matters. Most recently, he served as the Chief Financial Officer of TytoCare, a privately-held company in the remote healthcare space. Prior to his role at TytoCare, Mr. Mamlok served as the Chief Financial Officer of Sol-Gel Technologies Ltd. In this role, he was responsible for an initial public offering and other capital markets transactions, as well as in-licensing and out-licensing transactions. Prior to his role at Sol-Gel, he served in other medical device companies, including Given Imaging which was acquired by Covidien in 2014. Mr. Mamlok holds a BA in Economics, magna cum laude, and a Master's degree in Business/Managerial Economics, both from the Tel Aviv University.

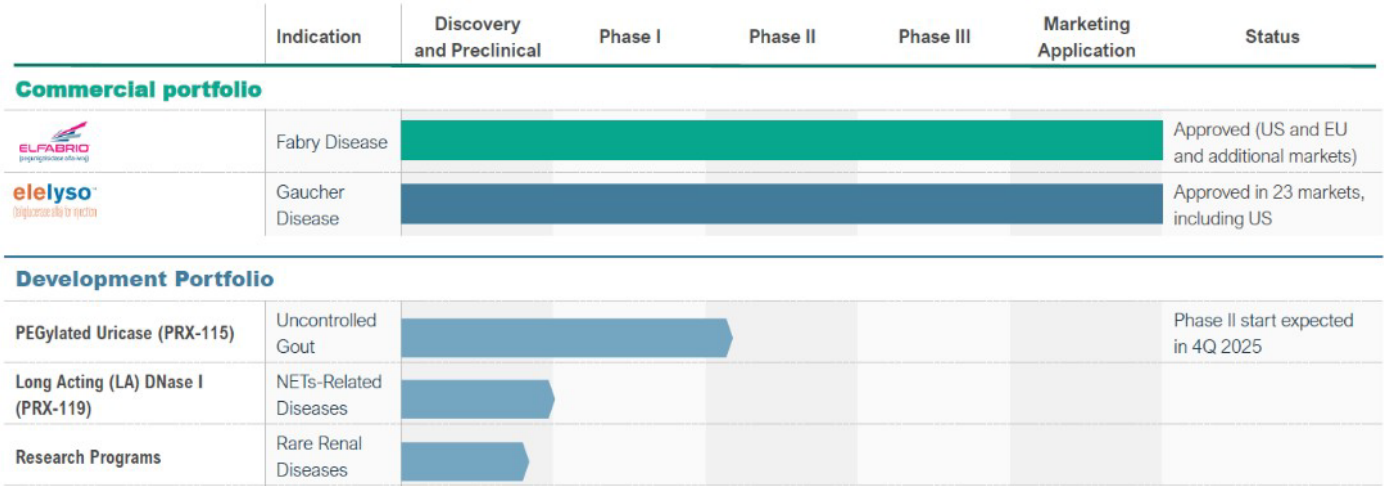
Valuation

We update our valuation for Protalix recognizing a slower ramp up in sales compared to our initial expectations and later achievement of milestones that were previously anticipated. The Fabry Disease market size is estimated to be $2.2 billion in 2025 growing to $3.3 billion by 2030.[2] To put a framework around what level of revenues Elfabrio can generate, we assume a 15% market share and the midpoint of the royalty range of 27.5%, which ignores any milestone contributions. With product revenues of $495 million, this could generate $136 million in revenues by 2030. This compares to management suggesting that the company can reach $100 million in revenues by 2030. The path to these revenues is not expected to be linear, but it should accelerate in subsequent years. Elelyso is also given value in our model, which is forecast to grow at mid-single digits, we also account for shares outstanding and other claims on equity and move our discounted cash flow model ahead by one year. The result of our efforts generates a valuation of $10 per share.

[2] Evaluate, Ltd. estimates accessed November 2025.

Pipeline

Exhibit I – Protalix Product Pipeline



Source: Protalix 3Q:25 Form 10-Q

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
- PRX-115 Phase II trial start – December 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
- Enrollment of first patient in PRX-115 Phase II gout study – 4Q:25
- Topline results from PRX-115 Phase II study - 2027

Summary

Protalix reported its third quarter 2025 results, reporting a slight contraction in total revenue. Some of this decline is attributable to a difficult comparison as Chiesi filled its initial inventory order for Elfabrio in 3Q:24. Elelyso sales have continued to grow, although there is substantial variation in sales due to Pfizer's and Fiocruz's periodic inventory builds. It has been difficult to forecast Elfabrio revenues due to the lack of guidance and communication from private company Chiesi and few details on milestone requirements. Based on the most recent quarter's results, we think our previous revenue and milestone estimates are too high and adjust them to reflect a slower ramp towards our 15-20% market share over the next five years. Despite the change to our valuation, we think Protalix' shares fall well below a conservative valuation. Furthermore, our model does not give any credit to the PRX-115 program which is moving forward in gout and has been recently cleared in an IND.

Protalix suffered a regulatory setback with Elfabrio's application for use every four weeks rather than every two. The sponsors have appealed the decision with the CHMP of the EMA and their advisors believe there is a good case to be made to overturn the decision in front of new evaluators. Irrespective of the appeal outcome, marketing of Elfabrio in Europe will continue as it has for the more than two years since initial approval. We adjust our valuation to $10 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[3]

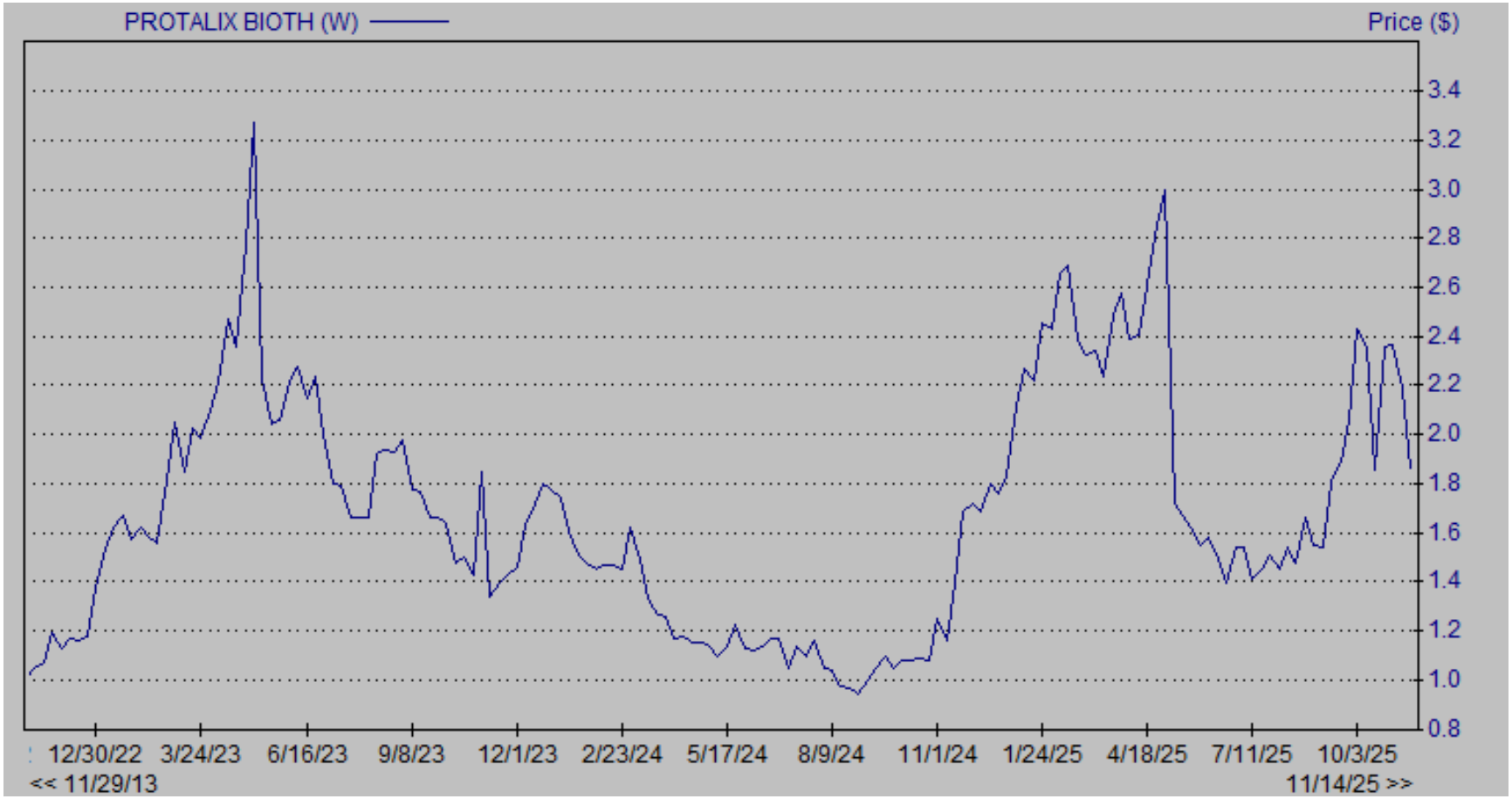
Protalix Biotherapeutics	2024 A	Q1 A	Q2 A	Q3 A	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($US '000)	**$53,399**	**$10,113**	**$15,658**	**$17,851**	**$15,260**	**$58,882**	**$61,799**	**$69,530**
YOY Growth	-18%	170%	16%	-1%	-16%	10%	5%	13%
Cost of Revenues	$24,319	$8,180	$5,870	$8,324	$6,600	$28,974	$14,894	$15,929
Research & Development	$12,970	$3,475	$5,992	$4,467	$3,800	$17,734	$21,450	$22,250
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	$1,860	$1,018	$12,255	$15,701
Operating Margin	7%	-41%	7%	12%	12%		*20%*	*23%*
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	$2,131	$1,299	$12,830	$16,276
Provision for Income Tax	$1,222	($113)	$497	($116)	$0	$0	$642	$814
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**	**$2,131**	**$1,299**	**$12,189**	**$15,462**
Net Margin	5%	-36%	1%	13%	14%	2%	20%	22%
Reported EPS	**$0.04**	**($0.05)**	**$0.00**	**$0.03**	**$0.03**	**$0.02**	**$0.15**	**$0.19**
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

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

HISTORICAL STOCK PRICE

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



[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.