Zacks Small-Cap Research

Sponsored – Impartial – Comprehensive

August 22, 2024
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: A Focus on Renal Rare Disease

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 (8/21/2024)	$0.97
Valuation	**$14.00**

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 be approved 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 in coming years.

SUMMARY DATA

52-Week High	**$2.05**
52-Week Low	**$0.82**
One-Year Return (%)	**-49.5**
Beta	**0.8**
Average Daily Volume (sh)	**427,885**
Shares Outstanding (mil)	**73.5**
Market Capitalization ($mil)	**71.3**
Short Interest Ratio (days)	**13.4**
Institutional Ownership (%)	**7.8**
Insider Ownership (%)	**14.5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**13.8**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**15.8**
P/E using 2025 Estimate	**1.5**
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)
2023	$9.6 A	$35.1 A	$10.3 A	$10.5 A	$65.5 A
2024	$3.7 A	$13.5 E	$15.3 E	$18.2 E	$50.7 E
2025					$101.4 E
2026					$167.2 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.05 A	$0.21 A	-$0.02 A	-$0.07 A	$0.10 A
2024	-$0.06 A	-$0.03 A	$0.04 E	$0.08 E	$0.02 E
2025					$0.62 E
2026					$1.13 E

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Second Quarter 2024 Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced second quarter 2024 financial and operational results in an August 14th, 2024 press release and in the filing of Form 10-Q. The reports were followed by a conference call which discussed recent achievements, clinical updates and financial performance. Since the beginning of the year, with respect to Elfabrio (PRX-102) partner Chiesi has continued its commercialization activities, obtained additional approvals and launched new studies for a pediatric indication and for approval in Japan. In its research and development portfolio, Protalix provided an interim update on its PRX-115 Phase I trial in gout and launched an eighth cohort with an eye on a Phase II study.

Revenues for 2Q:24 were $13.5 million, which were dominated by product sales of Elelyso. This produced a net loss of ($2.3) million or ($0.03) per share.

Financial results for the quarter ending June 30th, 2024, compared to prior year comparable period:

- Revenues were $13.5 million, down 62% from $35.1 million due to the recognition of the Chiesi milestone in the prior year period and initial inventory product build for Elfabrio. Elelyso sales to Pfizer were $6.9 million and sales to Brazil were $4.7 million compared to $3.4 and $0 respectively. Total Elelyso sales were up 3.4x prior year levels. Sales of Elelyso vary widely due to timing of inventory transfers. Chiesi product sales were $1.7 million;
- Cost of revenue was up 54% to $9.5 million reflecting the surge in Elelyso sales. Gross margin was 29%. This number contains many moving parts and gross margin excludes previously recognized costs that will be recognized in future batches of product. We expect Elfabrio gross margins to be substantially higher than Elelyso; however, sales volumes surged for the latter, diluting Elfabrio's margin contribution. Additionally, a significant portion of drug substance was recognized as research and development expense, also impacting margins;
- Research and development expenses fell 34% to $3.0 million from $4.5 million. Completion of the Fabry clinical program and related regulatory efforts in 2023 led to the decline. Lower subcontractor expenses, reduced salary and related expenses were partially offset by slightly higher materials related expenses;
- Selling, general and administrative expenses were down 13% to $3.5 million compared to $4.0 million on a reduction in salary and related expenses;
- Net financial income was $155,000 compared to a net financial expense of ($774,000) due to reduced financial expenses;
- Income tax benefit of $69,000 compares to income tax expense of ($308,000);
- Net loss was ($2.2) million vs $19.3 million, or ($0.03) per share versus $0.21 per share;

The cash and equivalents balance on June 30, 2024 totaled $45.0 million versus $44.6 million at the end of 2023. The increase was attributable to an increase in short term bank deposits. Cash burn was ($0.2) million for 1H:24. There was no cash from financing. We do not anticipate the need to raise capital in at least the next 12 months and perhaps for a substantially longer period depending on Elfabrio's growth trajectory. After the end of the reporting period, Protalix received $6.9 million from partners for Elelyso sales. Protalix holds over $20 million in convertible notes on its balance sheet which are due in September 2024. The company plans to repay them in full from its cash balance.

Key Opinion Leader (KOL) Event

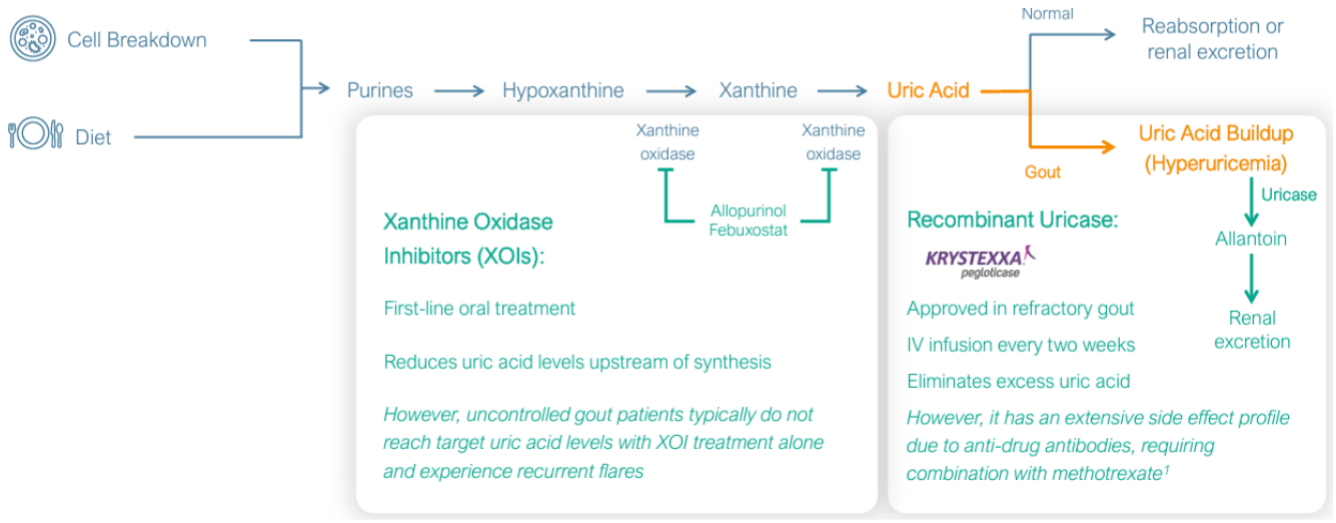
Protalix held a Key Opinion Leader (KOL) event on June 26th, 2024 featuring luminaries in the Fabry disease and gout fields as well as Protalix' CEO, Dror Bashan. The in-person, New York City event was headlined by Aleš Linhart and Naomi Schlesinger. Aleš Linhart, DSc, FESC of Charles University in Prague discussed the treatment landscape for Fabry disease and his perspectives on Elfabrio. Naomi Schlesinger, MD of the University of Utah discussed the current treatment landscape for uncontrolled gout and top-line results from the Phase I clinical trial of PRX 115.

Dr. Linhart is encouraged that there is now another alternative for Fabry disease and for his 250 patients in the Czech Republic with the disorder. Administration of Fabrazyme is every two weeks, and by the end of this period,

they are not feeling well, due to the product's half-life. Elfabrio's PEGylated formulation allows for longer activity and may address this. Neutralizing antibodies also emerge in patients given Fabrazyme. With a new alternative on the market that stimulates a less severe antibody response, patients can enjoy greater effectiveness of the drug.

Dr. Schlesinger provided some background on gout, noting that more than 5% of Americans suffer from the condition. Gout is a type of inflammatory arthritis caused by a buildup of uric acid crystals in the joints. This buildup leads to sudden, severe attacks of pain, swelling, redness, and tenderness in one or more joints. Existing drugs on the market have shortcomings including the inducement of anti-drug antibodies which may lead to failure to achieve sustained reductions in uric acid.

Exhibit I – Available Urate-Lowering Therapies



Source: Protalix August 2024 Slide Presentation

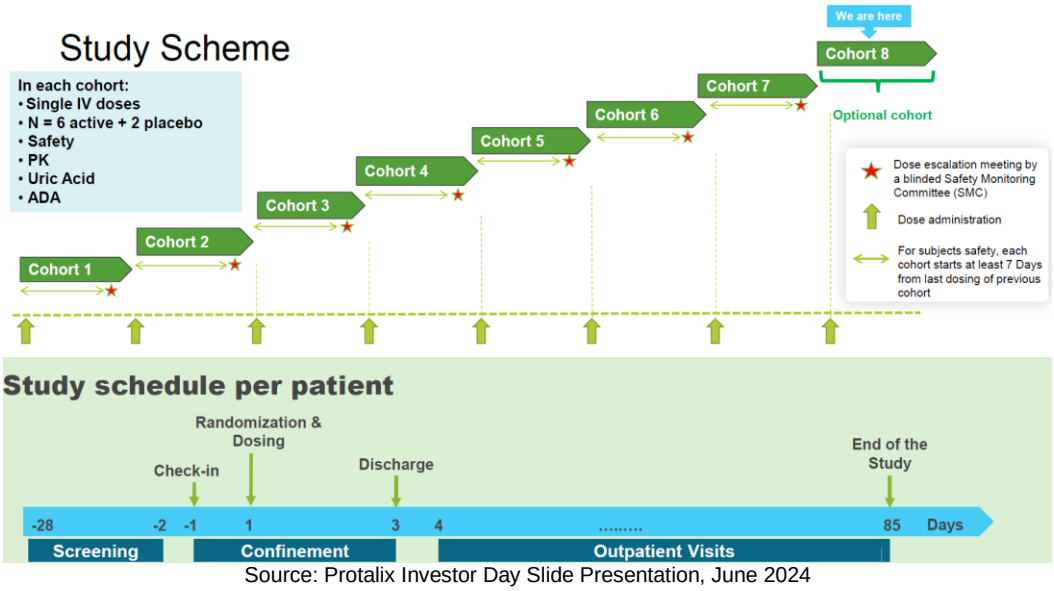
Dror Bashan wrapped up the event with a discussion of anticipated milestones including the clinical study report for PRX-115 by 4Q:24. Now that Protalix is receiving revenues from two different products, the company is focused on rare renal diseases. These revenues allow the company to be self-sufficient with respect to funding its development activities. The event wound down with an opportunity for participants to ask questions.

PRX-115

In March 2023, Protalix announced that it had dosed its first patient in the Phase I clinical trial for PRX-115 in the treatment of severe gout. Protalix has completed enrolling seven of eight cohorts and has reported results from these groups. We expect to see topline results from all eight cohorts in the third quarter of 2024. Planning for a Phase II trial is underway with trial design details expected over the next several quarters and a launch in mid-2025.

The ongoing Phase I trial is designed as a double-blind, placebo-controlled, single ascending dose study intended to evaluate the safety and pharmacokinetics, pharmacodynamics and immunogenicity of PRX-115. Subjects considered for enrollment will present elevated uric acid levels (>6.0 mg/dL) and no previous exposure to PEGylated uricase. The single ascending dose study enrolled seven cohorts with patients randomized 3:1 to receive a single intravenous dose of PRX-115 or placebo. Other secondary endpoints will examine the reduction in uric acid and dosing efficacy. The study is being conducted at New Zealand Clinical Research under the New Zealand Medicines and Medical Devices Safety Authority. Further details on the clinical trial can be found on clinicaltrials.gov and the related entry under NCT05745727.

Exhibit II – PRX-115 Trial Design



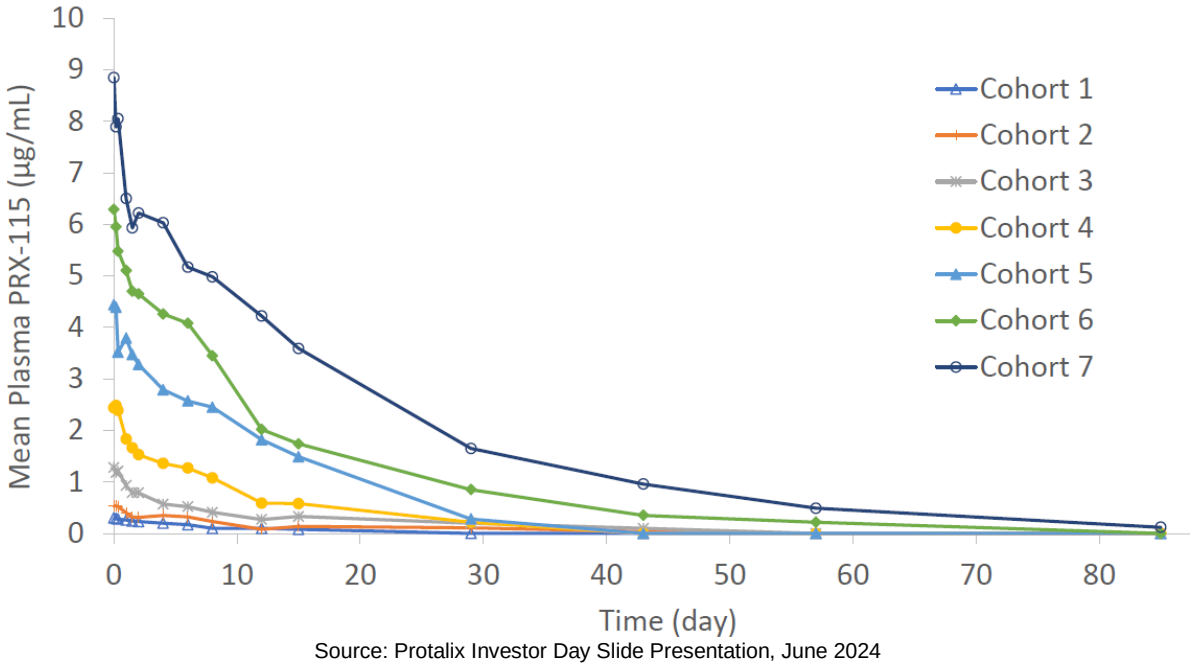
Source: Protalix Investor Day Slide Presentation, June 2024

Protalix felt that the results observed in the first seven cohorts have been sufficiently positive to expand the study by adding an 8th cohort of eight new subjects. Cohort 8 will analyze a higher dose and its potential to result in increased exposure time. Conclusions from the PK and PD study are that exposure to PRX-115:

- Increased drug systemically in a dose dependent manner;
- Reduced plasma uric acid concentrations to below 6.0 mg/dL over time;
- Was dose dependent on uric acid concentrations in the plasma;
- Was well tolerated.

26% or 11 of 42 subjects treated with PRX-115 reported a drug-related adverse event (AE), with the majority of the events being mild to moderate. One subject in cohort 2 experienced anaphylactic reaction after infusion with PRX-115, which was fully resolved. There were no other serious AEs in the trial and no AEs reported in the highest doses in cohorts 6 and 7. Protalix hopes to have a competitive product that will be superior to other leading products in the market in terms of side effects and frequency of administration.

Exhibit III – Mean PRX-115 Plasma Concentrations Are Dose Dependent



Source: Protalix Investor Day Slide Presentation, June 2024

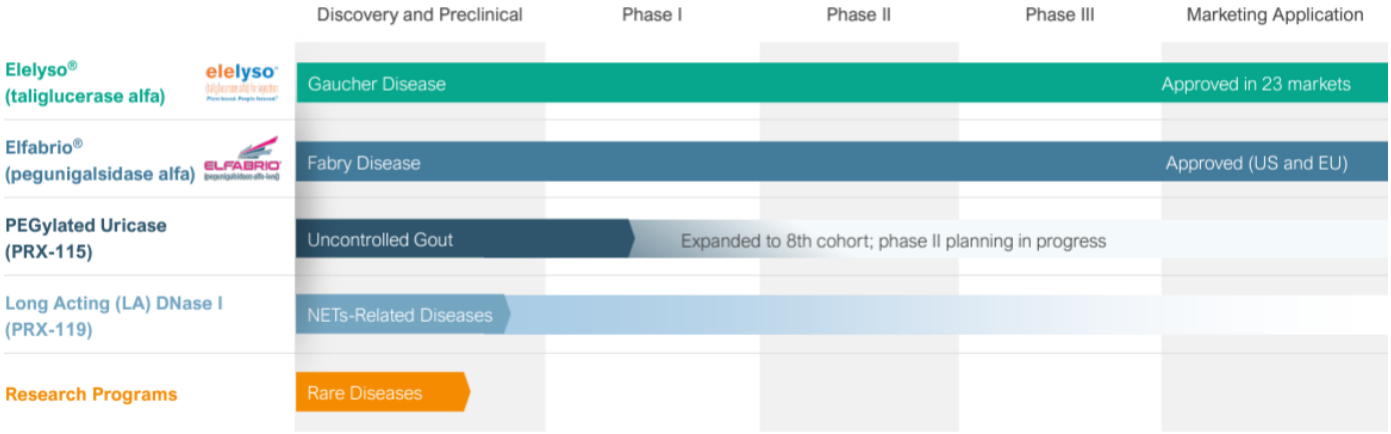
PRX-119

PRX-119 is the plant cell-expressed PEGylated recombinant human DNase I product candidate being designed to elongate half-life in the circulation of the molecule for NETs-related diseases. Protalix has conducted preclinical studies to evaluate the feasibility of the candidate and expects to continue compiling preclinical information and conducting data analysis to review with stakeholders. If signs are favorable, Protalix will conduct toxicology and Phase I studies. We expect to hear further details on the direction of the program in coming quarters.

Elfabrio Activity

Following US and EU approval of Elfabrio in May of last year, Elfabrio was further approved in Great Britain and Switzerland during the third quarter of 2023. Along with the full year report for 2023, Protalix announced that Elfabrio had also been approved in Israel. Chiesi's regulatory efforts have been successful and the partner is looking forward to other geographies and populations for further penetration of the PEGylated recombinant human α-Galactosidase-A enzyme. As disclosed in regulatory filings, Chiesi has begun the FLY study in collaboration with Protalix to assess the safety of Elfabrio in pediatric patients. While it is still in the start-up stage, the study will be a multi-center, open label trial to assess the safety, pharmacodynamics, efficacy and pharmacokinetics of Elfabrio in patients from two years to less than 18 years of age with confirmed Fabry disease to obtain a pediatric indication in the United States. Chiesi has also begun to enroll its RISE study which aims to enroll 18-20 Fabry patients in Japan. This type of study is required to bridge results to a population with a different genetic makeup and to accommodate different medical practices. RISE is expected to be complete in 2028.

Exhibit IV – Protalix Pipeline



Source: Protalix August 2024 Slide Presentation

Milestones

- Preliminary data announced from PRX-115 Phase I trial – May 2024
- Presentation at BIO International – June 2024
- Investor day presentations – June 2024
- Launch of RISE study in Japan for PRX-102 – 2024
- Repayment of convertible debt – September 2024
- Pediatric FLY study for FDA launch - 2024
- PRX-115 data publication – 2Q:24
- Plan trial design for PRX-115 Phase II study – 3Q:24
- Completion of 8th cohort of PRT-115 study – 4Q:24

Summary

Protalix reported second quarter revenues ahead of our estimates. Strong sales from lower margin Elelyso increased cost of sales relative to our estimates leading to a miss on the EPS line compared to our view. Management will pay down its convertible notes coming due in September from cash on hand and will not need to raise new capital for the foreseeable future. This removes one of the material risks for early-stage companies as the risk of shareholder dilution is minimized.

In the R&D realm, Protalix provided a first look at the Phase I data for PRX-115 for severe gout. It was mostly well tolerated and results were strong enough for the company to add an eighth cohort and plan for a Phase II study. Details on the preliminary results for PRX-115 were provided by KOL, Dr. Schlesinger, at the recent investor day.

We remain optimistic about Elfabrio's performance and have confidence that Chiesi will accomplish an effective launch. With numerous regulatory successes, we hope to see other attractive markets such as Canada, Australia and Japan be announced as having granted approval in upcoming quarters. Chiesi offers a portfolio of multiple rare disease products and is well versed in the process of commercializing assets in this niche. Protalix' low valuation, sufficient capital to repay debt and substantial revenue opportunity make this one of our most attractive names. We see Protalix as a tremendous value, holding sufficient cash to make it through the next year and providing a low risk of dilution for tenacious shareholders. Reward to risk is very favorable for equity investors. We maintain our valuation to $14 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[1]

Protalix Biotherapeutics	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US '000)	**$65,494**	**$3,748**	**$13,474**	**$16,258**	**$20,206**	**$53,686**	**$101,438**	**$167,232**
YOY Growth	37%	-61%	-62%	57%	93%	-18%	89%	65%
Cost of Revenues	$22,982	$2,602	$9,456	$4,580	$5,280	$21,918	$18,604	$25,437
Research & Development	$17,093	$2,887	$2,961	$3,800	$4,000	$13,648	$14,280	$20,250
Selling, General & Admin	$14,959	$3,115	$3,484	$3,490	$3,450	$13,539	$13,882	$16,000
Income from operations	$10,460	($4,856)	($2,427)	$4,388	$7,476	$4,581	$54,673	$105,545
Operating Margin	16%	-130%	-18%	27%	37%	9%		*63%*
Financial Expenses	$3,180	$390	$367	$300	$0	$1,057	$1,000	$1,000
Financial Income	($1,286)	($513)	($522)	($200)	($50)	($1,000)	($800)	($600)
Pre-Tax Income	$8,566	($4,733)	($2,272)	$4,288	$7,526	$4,524	$54,473	$105,145
Provision for Income Tax	$254	($138)	($69)	$0	$0	($207)	$0	$5,257
Tax Rate	3.0%	2.9%	0.0%	0.0%	0.0%	-4.6%	0.0%	5.0%
Net Income	**$8,312**	**($4,595)**	**($2,203)**	**$4,288**	**$7,526**	**$4,731**	**$54,473**	**$99,887**
Net Margin	13%	-123%	-16%	26%	37%	9%	54%	0.597297957
Reported EPS	**$0.10**	**($0.06)**	**($0.03)**	**$0.06**	**$0.10**	**$0.06**	**$0.62**	**$1.13**
Diluted Shares Outstanding	82,424	73,037	73,308	73,500	73,650	73,374	87,250	88,100

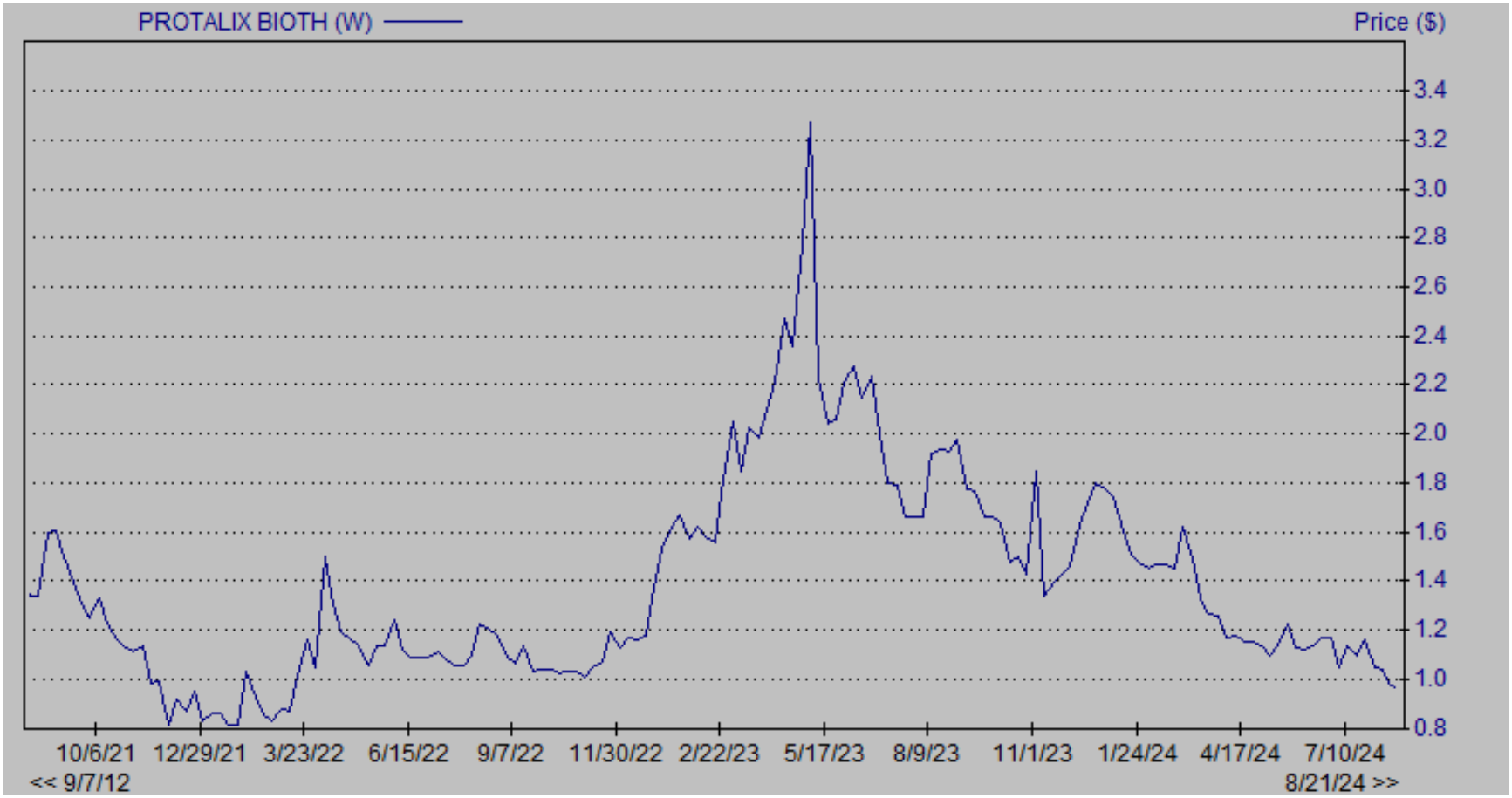
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE

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



[2] 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.

© Copyright 2024, Zacks Investment Research. All Rights Reserved.