Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive
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Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: First Quarter Update

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 (3/14/2024)	$1.16
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	**$2.51**
52-Week Low	**$1.03**
One-Year Return (%)	**-47.5**
Beta	**0.9**
Average Daily Volume (sh)	**428,550**
Shares Outstanding (mil)	**73.3**
Market Capitalization ($mil)	**85.0**
Short Interest Ratio (days)	**18.2**
Institutional Ownership (%)	**13.1**
Insider Ownership (%)	**14.6**
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	**13.7**
P/E using 2023 Estimate	**13.7**
P/E using 2024 Estimate	**6.5**
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	$12.5 E	$16.3 E	$20.2 E	$52.7 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	$0.02 E	$0.06 E	$0.10 E	$0.12 E
2025					$0.63 E
2026					$1.13 E

WHAT'S NEW

First Quarter 2024 Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced first quarter 2024 financial and operational results in a May 10th, 2024 press release and in the filing of Form 10-Q. The reports were followed by a conference call which discussed recent achievements, regulatory 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.

Revenues for 1Q:24 were $3.7 million, which consisted almost entirely of product sales which produced a net loss of ($4.6) million or ($0.06) per share.

Financial results for the quarter ending March 31st, 2024, compared to prior year comparable period:

- Revenues were $3.7 million, down 61% from $9.6 million on lower revenues from both Pfizer and Brazil. Research and development revenues were also down sharply as responsibility for further development and commercialization of Elfabrio has shifted to Chiesi;
- Cost of revenue was down 16% to $2.6 million reflecting the decline in sales to Pfizer and Brazil. Gross margin was 29%; however, we note that there are many moving parts in this number and gross margin excludes previously recognized costs that will be recognized in future batches of product;
- Research and development expenses fell 51% to $2.9 million from $5.8 million. Completion of the Fabry clinical program and related regulatory efforts in 2023 led to the decline. These expenditures were partially offset by spending on the PRX-115, PRX-119 and other early-stage research and development programs;
- Selling, general and administrative expenses were flat at $3.1 million for both measurement periods;
- Net financial income was $123,000 compared to a net financial expense of ($477,000) due to higher interest income on bank deposits and lower notes interest expense related to notes conversions executed in 2023;
- Income tax benefit of $138,000 compares to income tax expense of ($195,000);
- Net loss was ($4.6) million vs ($3.1) million, or ($0.06) per share versus ($0.05) per share;

The cash and equivalents balance on March 31, 2024 totaled $48.5 million versus $44.6 million at the end of 2023. The increase was mostly attributable to cash payments from Chiesi for product not yet released which was not offset by operating expenses. Free cash flow was $3.6 million for 1Q: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. Following the end of the quarter, Protalix announced receipt of $3.7 million from partners for Elelyso sales.

PRX-102 Activity

Following US and EU approval of Elfabrio in May of last year, the compound 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. Chesi'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, Chesi 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.

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. Now that almost a year has passed, Protalix has enrolled 56 patients and anticipates publishing the preliminary results from the trial in 2Q:24. The 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.

In conjunction with the report of first quarter 2024 results, Protalix announced that it will pursue an eighth cohort to its Phase I trial and begin planning for a Phase II study. Seven cohorts have been completed and 42 subjects were treated with PRX-115 and 14 with placebo.

Protalix felt that the results observed so far in the first seven cohorts were sufficiently positive to expand the study by adding an eighth 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:

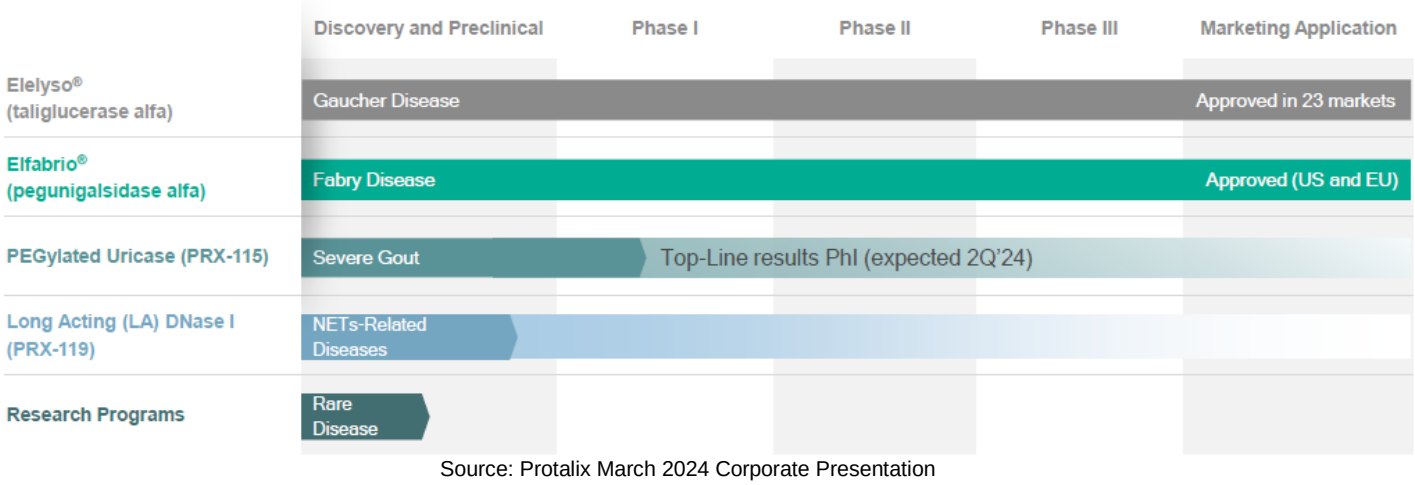
- Increased drug systemically in a dose dependent manner;
- Reduced plasma uric acid concentrations to below 6.0 mg/dL over time;
- Was dose dependent on uric acid concentrations in the plasma;
- Was well tolerated.

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.

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 2024.

Exhibit I – Protalix Pipeline



Source: Protalix March 2024 Corporate Presentation

Milestones

- PRX-115 starts Phase I – 1Q:23
- EMA authorization for PRX-102 – May 5th, 2023
- FDA approval for PRX-102 – May 9th, 2023
- Elfabrio approval in Switzerland – August 2023
- Elfabrio approval in Great Britain – September 2023
- Appointment of Richard Forster, Ph.D. as Chairman – September 2023
- Elfabrio approved by the Israeli Ministry of Health – January 2024
- Launch of RISE study in Japan for PRX-102 - 2024
- Pediatric FLY study for FDA launch - 2024
- PRX-115 data publication –2Q:24

Valuation

We adjust our estimates to reflect a slower ramp in Elfabrio sales and later recognition of a second milestone payment related to the product. We also reduce R&D and SG&A below our previous estimates as costs for earlier stage trials will be lower than our previous estimates and to reflect the several compensation-related payments in 2023 will not recur in 2024. The net result of our adjustments yields a valuation of $14 per share.

Summary

Protalix reported first quarter results that were behind our estimates. However, Elelyso sales are historically irregular and Elfabrio sales are still in their very early stages with the initial focus on building inventories. Therefore, we are not materially concerned with the lower year on year revenues as we anticipate that it will be made up in subsequent periods. Management has made it clear that it will be able to pay down its convertible notes coming due in September out of 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.

We adjust our valuation to reflect lower operating expenses and a slower than expected revenue ramp, which may be in part related to the delay in revenue recognition by Protalix. Partner Chiesi has been busy obtaining new regulatory approvals and conducting new studies to obtain additional approvals for Elfabrio with several new geographies added over the last several months. 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.

We remain optimistic about Elfabrio's performance and have confidence that Chiesi will accomplish an effective launch. With regulatory successes in five different jurisdictions so far, 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 adjust our valuation to $14 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[1]

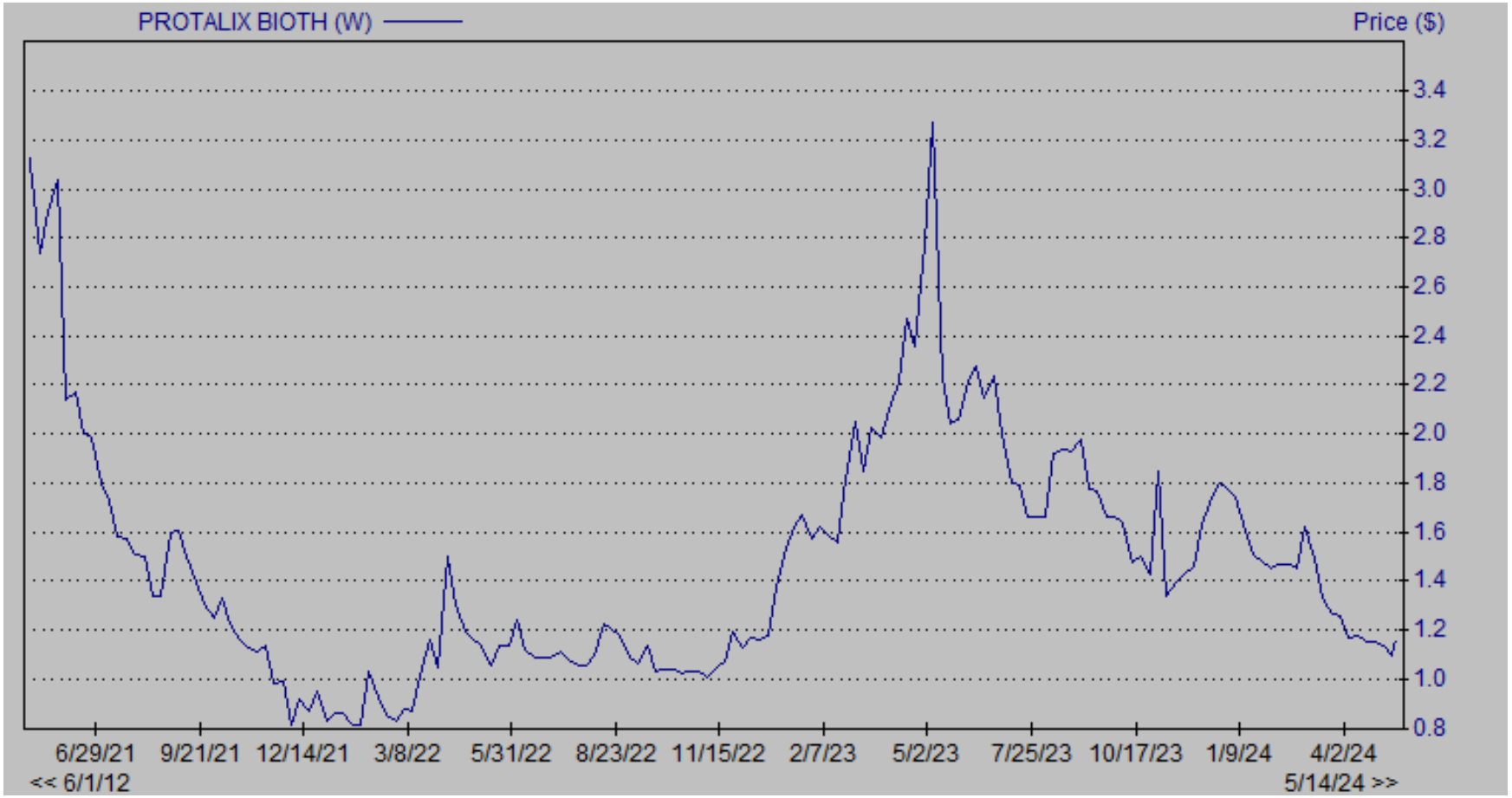
Protalix Biotherapeutics	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US '000)	**$65,494**	**$3,748**	**$12,500**	**$16,258**	**$20,206**	**$52,712**	**$101,438**	**$167,232**
YOY Growth	37%	-61%	-64%	57%	93%	-20%	92%	65%
Cost of Revenues	$22,982	$2,602	$3,900	$4,580	$5,280	$16,362	$18,604	$25,437
Research & Development	$17,093	$2,887	$3,500	$3,800	$4,000	$14,187	$14,280	$20,250
Selling, General & Admin	$14,959	$3,115	$3,366	$3,490	$3,450	$13,421	$13,761	$16,000
Income from operations	$10,460	($4,856)	$1,734	$4,388	$7,476	$8,742	$54,794	$105,545
Operating Margin	16%	-130%	14%	27%	37%	17%		63%
Financial Expenses	$3,180	$390	$300	$300	$0	$990	$1,000	$1,000
Financial Income	($1,286)	($513)	($400)	($200)	($50)	($1,000)	($800)	($600)
Pre-Tax Income	$8,566	($4,733)	$1,834	$4,288	$7,526	$8,752	$54,594	$105,145
Provision for Income Tax	$254	($138)	$0	$0	$0	($138)	$0	$5,257
Tax Rate	3.0%	2.9%	0.0%	0.0%	0.0%	-1.6%	0.0%	5.0%
Net Income	**$8,312**	**($4,595)**	**$1,834**	**$4,288**	**$7,526**	**$8,890**	**$54,594**	**$99,887**
Net Margin	13%	-123%	15%	26%	37%	17%	54%	0.597297957
Reported EPS	**$0.10**	**($0.06)**	**$0.02**	**$0.06**	**$0.10**	**$0.12**	**$0.63**	**$1.13**
Diluted Shares Outstanding	82,424	73,037	73,400	73,500	73,650	73,397	87,250	88,100

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

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

HISTORICAL STOCK PRICE

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



[2] Source: Zacks Research System

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