Zacks Small-Cap Research
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Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: Elfabrio Geographic Expansion

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)	$1.37
Valuation	**$16.00**

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	**$3.55**
52-Week Low	**$1.21**
One-Year Return (%)	**-31.2**
Beta	**0.9**
Average Daily Volume (sh)	**323,161**
Shares Outstanding (mil)	**73.1**
Market Capitalization ($mil)	**100.1**
Short Interest Ratio (days)	**22.0**
Institutional Ownership (%)	**14.1**
Insider Ownership (%)	**9.8**
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)
2022	$16.1 A	$8.8 A	$14.2 A	$8.6 A	$47.6 A
2023	$9.6 A	$35.1 A	$10.3 A	$10.5 A	$65.5 A
2024					$74.1 E
2025					$127.4 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.05 A	-$0.11 A	-$0.07 A	-$0.07 A	-$0.31 A
2023	-$0.05 A	$0.21 A	-$0.02 A	-$0.07 A	$0.10 A
2024					$0.21 E
2025					$0.81 E

WHAT'S NEW

Full Year 2023 Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced full year 2023 financial and operational results in a March 14th, 2024 press release and filing of Form 10-K. The reports were followed by a conference call which discussed recent achievements, regulatory updates and financial performance. Since the end of the third quarter, 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 2023 were $65.5 million, which consisted of $40.4 million of product sales and $25.1 of million license and research and development revenues. This produced a net income of $8.3 million compared to a loss of ($14.9) million in the prior year.

Financial results for the year ending December 31st, 2023, compared to prior year comparable period:

- Revenues were $65.5 million, up 37% from $47.6 million; as milestones, stronger sales of Elelyso and first royalty revenues from Elfabrio were generated. Pfizer sales were up 1% and sales in Brazil increased 10% to $12.5 and $10.4 million respectively. Chiesi revenues from R&D reimbursements and the $20 million milestone payment related to Elfabrio approval totaled $21.6 million while Chiesi product revenue reached $17.5 million;
- Cost of revenue was up 17% reflecting additional costs from manufacturing of Elelyso and greater volumes of Elelyso sales. Gross margin was 43%; 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 42% to $17.1 million from $29.3 million. Substantial reductions in subcontractor related expenses were partially offset by a slight rise in salary and related expenses. Materials and other expenses were generally lower for the full year;
- Selling, general and administrative expenses rose 28% to $15.0 million vs $11.7 million. The increase was related to higher salary and related expenses due to one-time cash bonuses as well as an increase in travel, conferences and employee training;
- Net financial expense was ($1.9) million compared to a net financial expense of ($1.4) million due to increases in interest expense;
- Income taxes of $0.3 million compare to $0.5 million;
- Net income was $8.3 million vs a loss of ($14.9) million, or $0.10 per share versus ($0.31) per share;

The cash and equivalents balance on December 31, 2023 totaled $44.6 million versus $22.2 million at the end of 2022. Cash burn was ($2.6) million for the year. Financing cash flows were $24.7 million predominantly related to proceeds from issuance of common stock through an at-the-market (ATM) facility. 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 year, Protalix announced receipt of an additional ~$5 million from partners for expense reimbursements and 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 the 10-K regulatory filing, Chesi has begun the FLY study in collaboration with Protalix. 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. A study such as this is usually required to bridge results to a population with a different genetic makeup and to accommodate different medical practices. The study is expected to be complete in 2028.

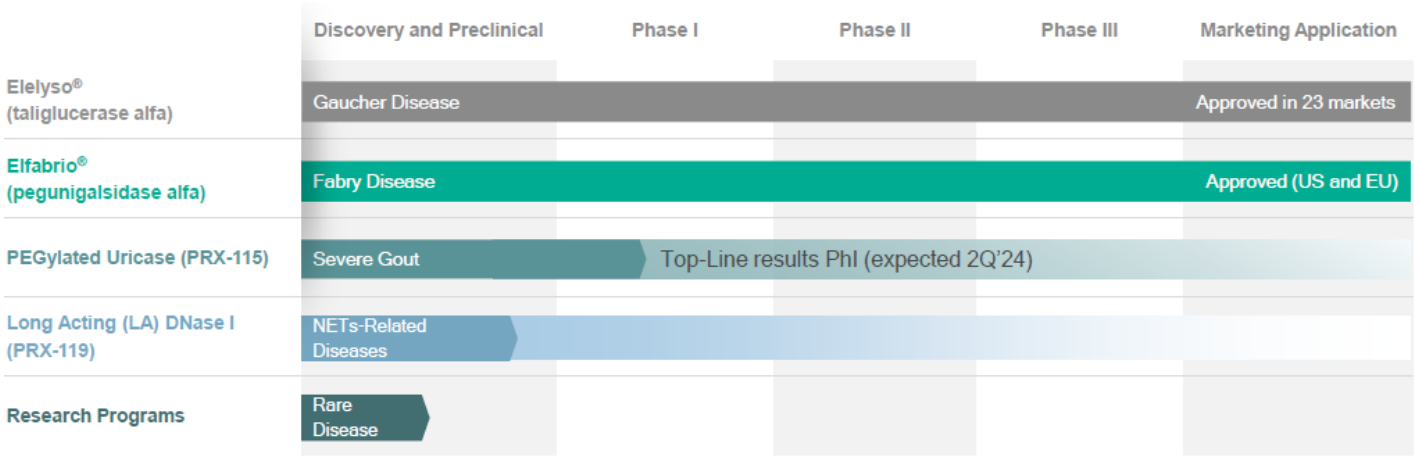
PRX-115

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.

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[1]



Appointment of New Chairman

Protalix announced the appointment of a new Chairman of its Board of Directors in October, Dr. Eliot Richard Forster. Dr. Forster serves on other boards as well including that of Avacta Group, Immatics NV and Ochre Bio. He was previously CEO of F-Star Therapeutics which was acquired by inovoX in March 2023. He has also been CEO of Immunocure, Creabilis and Solace Pharmaceuticals. Dr. Forster's big pharma background includes Pfizer and GlaxoWellcome.

Dr. Forster replaces Zeev Bronfeld who had served as Chairman of Protalix' board since August 2019. Mr. Bronfeld had served as a director of Protalix since 1996 and will retire as Dr. Forster assumes the post.

[1] Source: Protalix Corporate Presentation, February 2024

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

Summary

Protalix reported full year results that matched our revenue estimates and slightly exceeded our profitability estimates. Better gross margin and lower R&D were partially offset by higher SG&A to produce earnings several cents ahead of our forecasts. We are still in the early days of ramp up for Elfabrio and it is difficult to determine which revenues are ongoing and which are related to inventory building, so we expect lumpy topline results as we move towards equilibrium. Partner Chiesi has been busy obtaining new regulatory approvals and conducting new studies to obtain additional approvals for Elfabrio. In the R&D realm, Protalix soon expects to publish data for PRX-115 for severe gout. The Phase I study is investigating safety and early signs of efficacy in a New Zealand trial that we hope to assess in the next few weeks. PRX-119 remains in the consideration stage with ongoing work identifying support for moving into the clinic. We sense that management's attention may have shifted from PRX-119 to other as yet unidentified programs which we expect to hear about in a subsequent press release or earnings call.

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, low need for capital infusion 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 of $16 per share.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[2]

Protalix Biotherapeutics	2022 A	Q1 A	Q2 E	Q3 A	Q4 A	2023 A	2024 E	2025 E
Total Revenues ($US '000)	**$47,638**	**$9,588**	**$35,075**	**$10,345**	**$10,486**	**$65,494**	**$74,060**	**$127,350**
YOY Growth	24%	-40%	301%	-27%	22%	37%	13%	72%
Cost of Revenues	$19,592	$3,085	$6,148	$4,893	$8,856	$22,982	$18,605	$19,300
Research & Development	$29,349	$5,847	$4,475	$3,669	$3,102	$17,093	$19,800	$19,300
Selling, General & Admin	$11,711	$3,115	$4,031	$3,670	$4,143	$14,959	$15,367	$15,756
Income from operations	($13,014)	($2,459)	$20,421	($1,887)	($5,615)	$10,460	$20,288	$72,994
Operating Margin	-27%	-26%	58%	-18%	-54%	16%	27%	
Financial Expenses	$2,529	$649	$1,305	$460	$766	$3,180	$2,600	$2,600
Financial Income	($1,146)	($172)	($531)	($628)	$45	($1,286)	$0	$0
Pre-Tax Income	($14,397)	($2,936)	$19,647	($1,719)	($6,426)	$8,566	$17,688	$70,394
Provision for Income Tax	$530	$195	$308	$133	($382)	$254	$0	$0
Tax Rate	-3.7%	0.0%	0.0%	0.0%	0.0%	3.0%	0.0%	
Net Income	**($14,927)**	**($3,131)**	**$19,339**	**($1,852)**	**($6,044)**	**$8,312**	**$17,688**	**$70,394**
Net Margin	-31%	-33%	55%	-18%	-58%	13%	24%	55%
Reported EPS	**($0.31)**	**($0.05)**	**$0.21**	**($0.02)**	**($0.07)**	**$0.10**	**$0.21**	**$0.81**
Diluted Shares Outstanding	48,472	57,480	83,201	83,783	85,220	82,424	86,000	87,250

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

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