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Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: FDA Approval of Elfabrio

The valuation employs a net present value (NPV) approach and a 15% discount rate. Our model recognizes the approval Elfabrio in Fabry Disease in the United States and the EU and assigns 100% probability of success to it and Elelyso. The model includes contributions from global commercialization.

Current Price (5/10/2023)	$2.94
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 the product 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. 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	**$0.98**
One-Year Return (%)	**185**
Beta	**1.4**
Average Daily Volume (sh)	**1,771,374**
Shares Outstanding (mil)	**65.4**
Market Capitalization ($mil)	**192.3**
Short Interest Ratio (days)	**4.8**
Institutional Ownership (%)	**9.1**
Insider Ownership (%)	**12.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**126**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**18.4**
P/E using 2024 Estimate	**2.1**
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	$10.2 E	$18.3 E	$25.2 E	$63.2 E
2024					$94.9 E
2025					$151.5 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	-$0.04 E	$0.09 E	$0.20 E	$0.16 E
2024					$0.63 E
2025					$1.42 E

WHAT'S NEW

FDA Grants Approval to Elfabrio

The FDA announced approval of Elfabrio, effective May 9, 2023, making it the 15th approved drug for the year from the US agency. Elfabrio, previously designated PRX-102, is indicated for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase). Protalix Biotherapeutics, Inc. (NYSE: PLX) celebrates two approvals in less than a week with the European Medicines Agency, providing its authorization for the product on May 4th, 2023. We expect milestones to be due upon approval from partner Chiesi; however, these amounts have not been disclosed.

We update our valuation to reflect the approval of Elfabrio, increasing our probability of success to 100%. Along with sharecount modifications, this generates a price target of $16.00 per share, a greater than 5x upside from the latest closing price.

We are looking forward to an investor day in June that will identify the pathway forward for development candidates and we hope provide an early look at Chiesi's early commercialization efforts. We are interested to see how the relationship with Chiesi will evolve and how new in-development candidates PRX-115 and PRX-119 will advance.

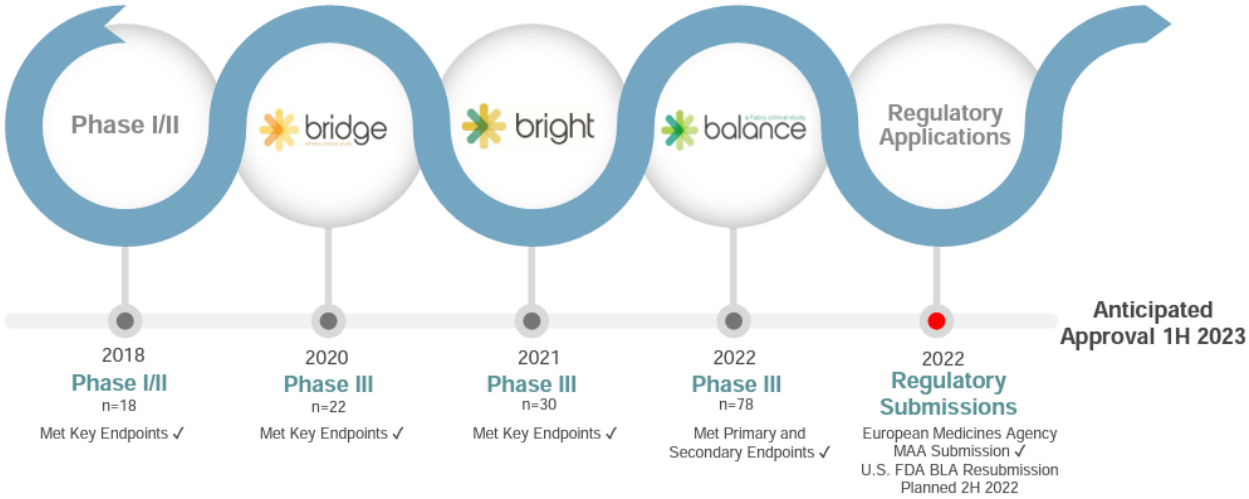
PRX-115

Protalix announced that it had dosed its first patient in the Phase I clinical trial for PRX-115 in the treatment of severe gout. The study is designed as a double-blind, placebo-controlled, single ascending dose study designed to evaluate the safety and pharmacokinetics, pharmacodynamics and immunogenicity of PRX-115 in up to 56 patients. The single ascending dose study will have up to 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. As of the date of the first quarter earnings call, nine patients have been dosed. The trial is being run in New Zealand, which was selected due to the Contract Research Organization (CRO) having a presence there and its positive outlook for enrollment in the country.

PRX-102

Protalix has submitted its BLA and MAA to the US and European regulatory authorities. On May 5th, 2023, Protalix and Chiesi announced that the European Commission had approved PRX-102. The companies are now waiting for a response from the FDA which is expected next week.

Exhibit I – Regulatory Submission Timeline[1]



[1] Source: Protalix September 2022 Corporate Presentation

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. We expect to hear additional details regarding PRX-119 at the investor day planned for June 2023.

Exhibit II – Protalix Pipeline[2]

Milestones

- PRX-115 to start Phase I – 1Q:23
- EMA authorization for PRX-102 – May 5th, 2023
- FDA approval for PRX-102 – May 9th, 2023
- Investor event: Protalix Strategy – late June 2023
- PRX-115 Clinical Study Report – 1Q:24

Valuation

We update our valuation to reflect the May 9th, 2023 approval of Elfabrio by the Food and Drug Administration (FDA), the increase in share count as a result of the ATM-related capital raise year to date and recognition of the potential need for capital to support development projects. Prior to the EMA and FDA approvals, we had applied an 80% probability to Elfabrio for regulatory success and have now increased this to 100%. The net of our changes results in an increase in our target to $16 per share.

Summary

Protalix has received approval from the two most important global regulatory agencies for Elfabrio which provides a new option for a population of around 15,000 Fabry patients in the associated regions. Chiesi will assume the commercialization responsibilities for Elfabrio and Protalix' focus will turn towards development assets. The Phase I trial for PRX-115 has begun and the first 9 of an anticipated 56 subjects have been enrolled. Based on the approval of Elfabrio by the FDA, we update our valuation to $16.00 per share.

[2] Source: Protalix 2022 Form 10-K

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[3]

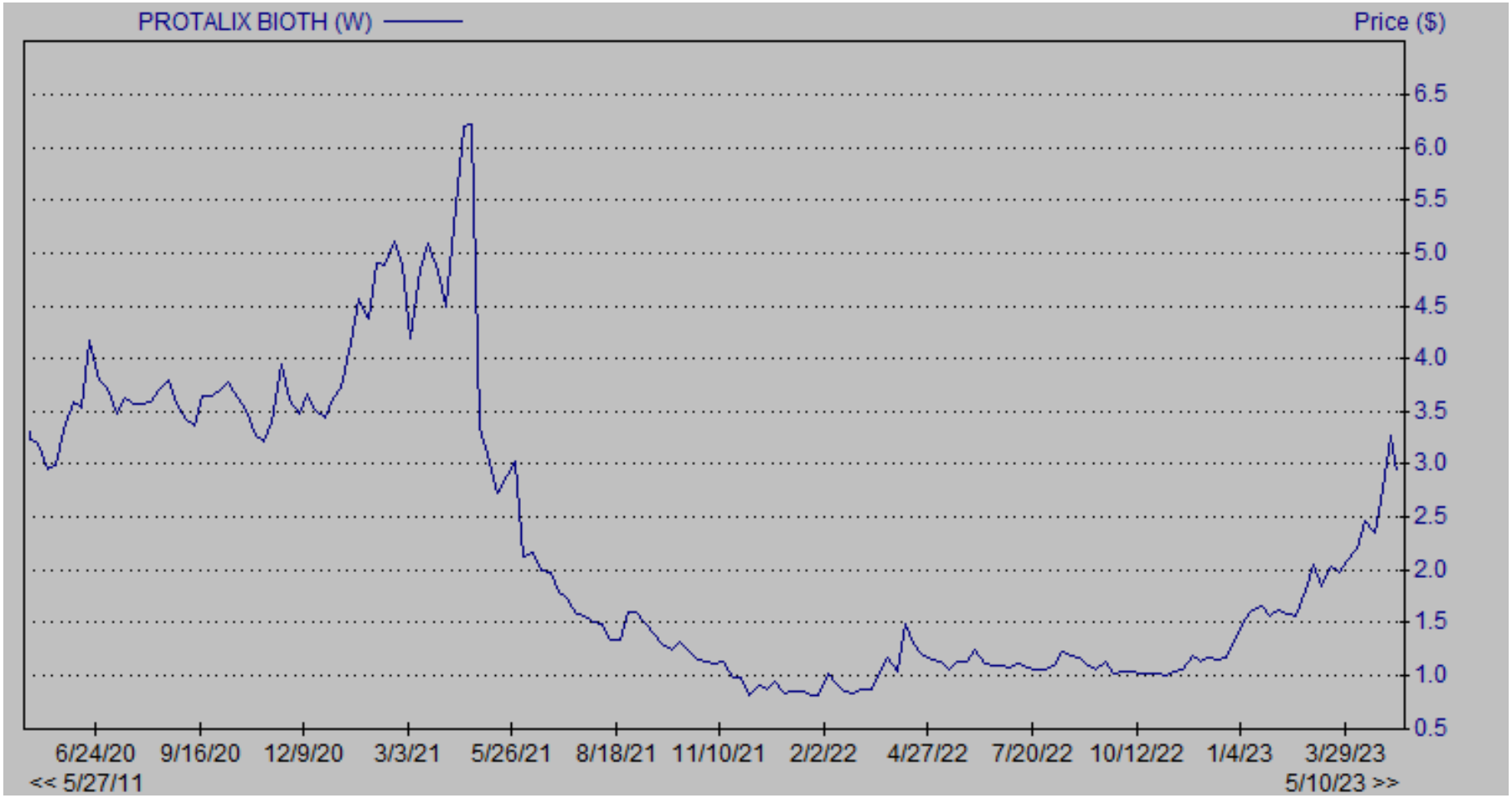
Protalix Biotherapeutics	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US '000)	**$47,638**	**$9,588**	**$10,222**	**$18,250**	**$25,166**	**$63,226**	**$94,877**	**$151,541**
YOY Growth	24%	-40%	17%	29%	192%	33%	50%	60%
Cost of Revenues	$19,592	$3,085	$3,110	$3,000	$2,850	$14,781	$16,725	$16,888
Research & Development	$29,349	$5,847	$5,920	$5,710	$5,500	$22,977	$20,300	$19,500
Selling, General & Admin	$11,711	$3,115	$3,010	$3,200	$3,025	$12,350	$12,721	$13,102
Income from operations	($13,014)	($2,459)	($1,818)	$6,340	$13,791	$13,118	$45,131	$102,052
Operating Margin	-27%	-26%	-18%	35%	55%	21%	48%	
Financial Expenses	$2,529	$649	$650	$650	$650	$2,599	$2,600	$2,600
Financial Income	($1,146)	($172)	$0	$0	$0	($200)	$0	$0
Pre-Tax Income	($14,397)	($2,936)	($2,468)	$5,690	$13,141	$10,719	$42,531	$99,452
Provision for Income Tax	$530	$195	$0	$0	$0	$195	$0	$0
Tax Rate	-3.7%	0.0%	0.0%	0.0%	0.0%	1.8%	0.0%	
Net Income	**($14,927)**	**($3,131)**	**($2,468)**	**$5,690**	**$13,141**	**$10,524**	**$42,531**	**$99,452**
Net Margin	-31%	-33%	-24%	31%	52%	17%	45%	0.656267679
Reported EPS	**($0.31)**	**($0.05)**	**($0.04)**	**$0.09**	**$0.20**	**$0.16**	**$0.63**	**$1.42**
Basic Shares Outstanding	48,472	57,480	65,500	65,900	66,450	63,833	68,000	70,000

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

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