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Protalix BioTherapeutics, Inc. (PLX: NYSE)

PLX: One Down, One to Go

The valuation employs a net present value (NPV) approach and a 15% discount rate. Our model applies 80% probability of ultimate approval and commercialization for PRX-102 in Fabry Disease in the United States, 100% to the EU and 100% to Elelyso. The model includes contributions from global commercialization.

Current Price (5/4/2023)	$3.36
Valuation	**$15.00**

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 one commercialized product, Elelyso that is marketed by Fiocruz in Brazil & Pfizer in the rest of the world for Gaucher Disease. Candidates include PRX-102 for Fabry Disease which was submitted to the EMA in February 2022 and the FDA in late 2022. If eventually approved, 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.

PRX-102 was approved in Europe 5MAY23 and has a PDUFA date of 9MAY23 IN the US. PRX-102 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	**$3.36**
52-Week Low	**$0.98**
One-Year Return (%)	**190**
Beta	**1.4**
Average Daily Volume (sh)	**1,455,374**
Shares Outstanding (mil)	**65.4**
Market Capitalization ($mil)	**219.7**
Short Interest Ratio (days)	**3.4**
Institutional Ownership (%)	**9.8**
Insider Ownership (%)	**17.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**139**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**21.0**
P/E using 2024 Estimate	**5.3**
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

First Quarter 2023 Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced 1Q:23 financial and operational results in a May 4th, 2023 press release and filing of Form 10-Q. The materials were followed by a conference call which discussed recent achievements, regulatory updates and financial performance. Protalix and its investors have been eagerly awaiting a response from the European Commission (EC) and the FDA regarding its application for PRX-102 and it has been largely quiet since the report of 2022 results on February 27th. In an early morning press release on May 5th, 2023, Protalix along with Chiesi Group Global Rare Diseases announced that the European Commission had approved PRX-102. We expect to see the FDA's response to the biologics' submission next week in line with the assigned target action date of May 9th, 2023. Regarding other assets in the pipeline, news released since the prior financial update informed stakeholders that the first patient had been dosed in the Phase I clinical trial for PRX-115 for the treatment of severe gout.

With respect to first quarter financial results, Protalix generated 1Q:23 revenues of $9.6 million compared to $16.1 million in the prior year first quarter. This resulted in net loss of ($3.1) million versus ($2.3) million in 1Q:22.

Financial results for the quarter ending March 31, 2023, compared to the quarter ending March 31, 2022:

- Revenues were $9.6 million, down 40% from $16.1 million; as declines in both goods and license fell. The decline in product sales was due to demand from Pfizer and Fiocruz being mismatched with the quarterly cycle. Revenues from license and R&D services predominantly relate to the Chiesi license and supply agreements;
- Cost of revenues was down almost 50% to $3.1 million producing a 39% gross margin on goods sold which was better than the 33% gross margin in the comparison period;
- Research and development expenses fell by one-third to $5.8 million from $8.8 million. Lower subcontractor-related expenses were partially offset by a rise in salary and related items. The overall fall in R&D was attributable to the completion of the Fabry clinical program and the regulatory process related to filing the BLA and MAA;
- Selling, general and administrative expenses fell 1% to $3.1 million vs $3.2 million. The decrease resulted primarily from a decrease salary-related expenses partially offset by a slight rise in professional fees;
- Net financial expenses were $0.5 million vs $0.4 million, on higher interest costs;
- Net loss was ($3.1) million vs ($2.3) million, or ($0.05) per share versus ($0.05) per share;

Cash and equivalents balance on March 31, 2023 totaled $33.0 million versus $22.2 million at the end of 2022. Cash burn was ($3.3) million for the first three months of the year. Financing cash flows were $14.2 million predominantly related to proceeds from issuance of common stock through an at-the-market (ATM) facility. Year to date, Protalix sold 8.2 million shares and raised gross proceeds of $14.9 million. Protalix estimates that it holds sufficient cash to fund operations until 2Q:24.

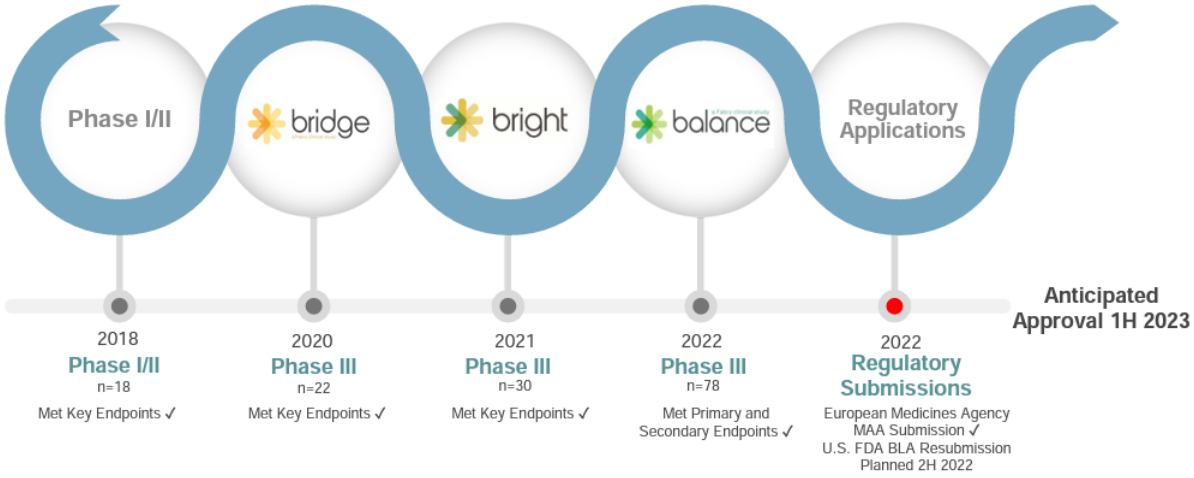
PRX-115

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]



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.

Delisting from Tel Aviv Stock Exchange

Protalix elected to delist from the Tel Aviv stock exchange in order to simplify the trading of its equity, focus on the market where the majority of its capital resides and reduce cost and complexity of listing on multiple exchanges. In a late December 2022 release, Protalix announced that its stock would no longer trade on the Tel Aviv Stock Exchange (TASE). This will allow Protalix to focus on the company's primary trading market on the NYSE American exchange. The delisting took effect on March 22, 2023.

Presentations

In late February, Protalix publicized four presentations addressing the performance of Pegunigalsidase Alfa in the BALANCE and BRIGHT studies. The documents summarized the findings of the trials, discussed the trial design, compared endpoints and reviewed the safety profile of Protalix' lead candidate. The titles were:

- First Results Of A Head-To-Head Trial Of Pegunigalsidase Alfa Vs. Agalsidase Beta In Fabry Disease: 2-Year Results Of The Phase 3 Randomized, Double-Blind, BALANCE Study
- Long-Term Safety And Efficacy Of Pegunigalsidase Alfa Administered Every 4 Weeks In Patients With Fabry Disease: 2-Year Interim Results From The Ongoing Phase 3 BRIGHT51 Open-Label Extension Study
- First Results Of A Head-To-Head Trial Of Pegunigalsidase Alfa Vs. Agalsidase Beta In Fabry Disease: 2-Year Results Of The Phase 3 Randomized, Double-Blind, BALANCE Study
- Long-Term Safety And Efficacy Of Pegunigalsidase Alfa Administered Every 4 Weeks In Patients With Fabry Disease: 2-Year Interim Results From The Ongoing Phase 3 BRIGHT51 Open-Label Extension Study

CEO Letter to Stockholders

On the first business day of 2023, Protalix CEO Dror Bashan penned a letter to shareholders highlighting the company's accomplishments over the prior year. A Marketing Authorization Application (MAA) was submitted to the European Medicines Agency (EMA) in February 2022 and a Biologics License Application (BLA) was resubmitted to the U.S. Food and Drug Administration (FDA) in November 2022. May 2023 is expected to be eventful, with marketing approval decisions expected from both entities that month.

Three Phase III studies were ongoing in 2022. This includes the BRIDGE study which analyzed 1 mg/kg of PRX–102 every two weeks dosing, the BRIGHT study which analyzed 2 mg/kg of PRX–102 every four weeks dosing and

[1] Source: Protalix September 2022 Corporate Presentation

the BALANCE study which analyzed 1 mg/kg of PRX–102 every two weeks dosing. Successful readouts for BRIGHT and BALANCE took place in 2022.

Other pipeline programs were also advanced in the prior year. PRX-115, a plant cell-expressed recombinant PEGylated uricase (urate oxidase) is undergoing preclinical work for the treatment of severe gout. Pre-clinical work has demonstrated a stable pharmacokinetic profile and long half-life, low immunogenic risk and high specific activity, supporting the potential of PRX-115 to be a safe and effective treatment for severe gout. Preliminary results for one-month multiple dosing toxicity studies of PRX-115 in two species show no indication of safety concerns, and Protalix' development plan goal is to initiate a Phase I clinical trial in 1Q:23 which is now running in New Zealand. The trial is expected to last about a year producing a clinical study report (CSR) in early 2024. Following this work, interaction with the FDA is expected provide the framework for a Phase II study. The company also holds PRX–119 in its portfolio, a plant cell-expressed long action DNase I for the treatment of NETs-related diseases.[2]

Exhibit II – Protalix Pipeline[3]

Milestones

- PRX-115 to start Phase I – 1Q:23
- EMA approval for PRX-102 –May 5th, 2023
- FDA PDUFA date 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 5th, 2023 approval of PRX-102 by the European Commission (EC) and the increase in share count as a result of the ATM-related capital raise year to date. We had applied an 80% probability of EC approval and have now increased this to 100% following EC approval. We will adjust our probability of success for FDA approval when the status of PRX-102 is clear next week. We now have an 80% chance of success with the US regulatory body. We also shift our DCF valuation forward by one year. The net of our changes results in an increase in our target from $11 per share to $15 per share.

Summary

Protalix has received approval from one regulatory agency and should see a response from the other next week. Chiesi will take over the commercialization of PRX-102 following approval and the focus for Protalix will turn to the development assets are now moving towards center stage. The Phase I trial for PRX-115 has begun and the first 9 of an anticipated 56 subjects have been enrolled. Product sales were down year over year in 1Q:23; however, this is not a surprise as ordering and delivery for Pfizer and Fiocruz are volatile. License and R&D revenues were also down, reflecting this shift away from the development stage for PRX-102. While expectations for Elelyso are low, the product has been generally improving in its revenue contribution over the last several quarters and may benefit from additional sales in Europe following the expiration of exclusivity of Vpriv. EC approval supports a valuation increase. We update our valuation to $15.00 per share.

[2] Neutrophil extracellular traps (NETs) are web-like structures that are produced by neutrophils, a type of white blood cell, as a part of the immune response to infections and inflammation. NETs are made up of DNA, histones, and antimicrobial peptides, and they function to trap and kill invading pathogens.
[3] Source: Protalix 2022 Form 10-K

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[4]

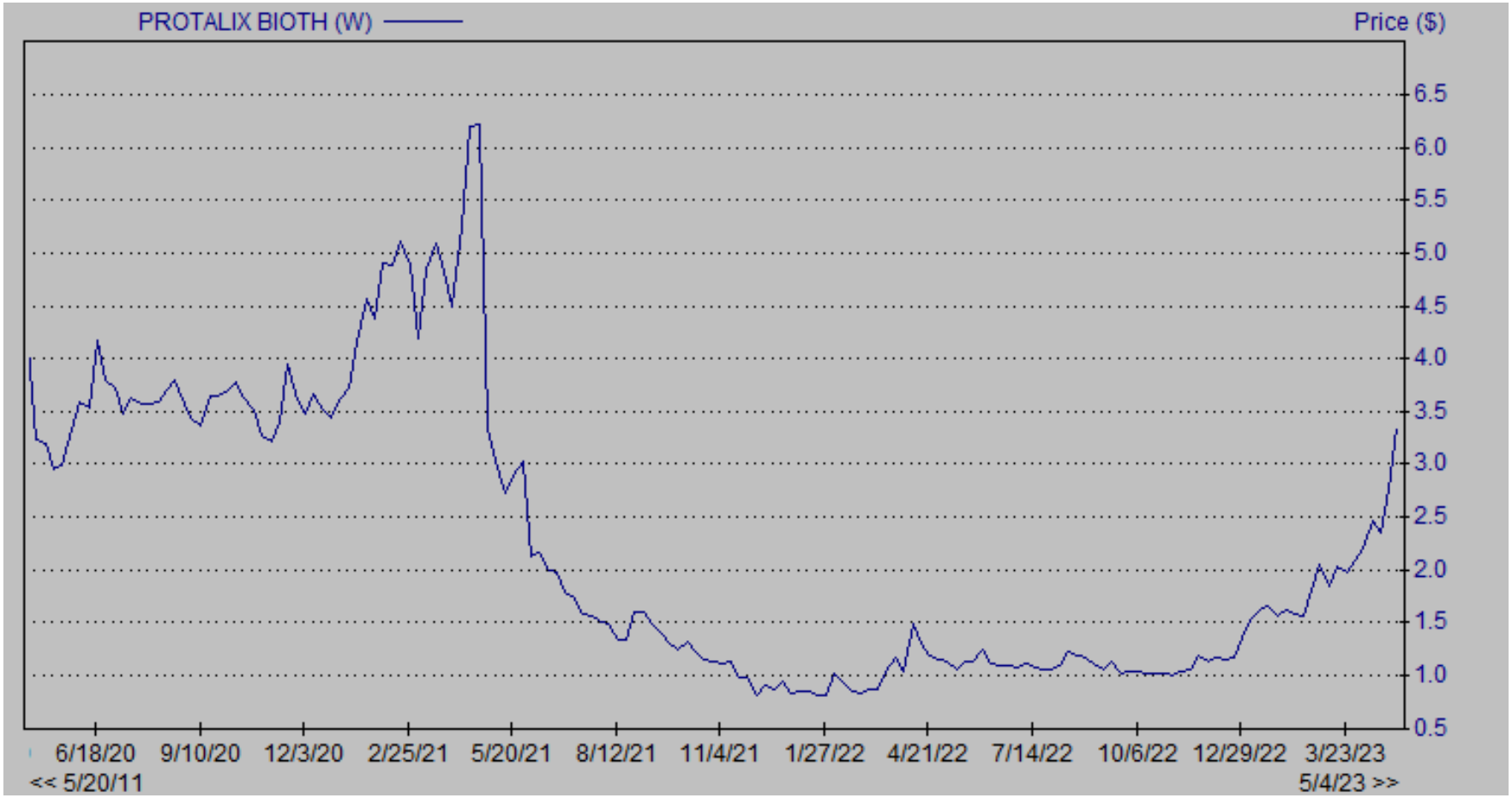
Protalix Biotherapeutics	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US '000)	**$47,638**	**$9,588**	**$10,222**	**$18,250**	**$25,166**	**$63,226**	**$94,877**	**$151,541**
YOY Growth	24%	-40%	17%	29%	192%	33%	50%	60%
Cost of Revenues	$19,592	$3,085	$3,110	$3,000	$2,850	$14,781	$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

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

HISTORICAL STOCK PRICE

Protalix BioTherapeutics, Inc. – Share Price Chart[5]



[5] Source: Zacks Research System

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