Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive

November 15, 2022
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)

BLA & MAA: 1H:23 Responses

Based on our DCF model and a 15% discount rate, Protalix is valued at approximately $11.00 per share. Our model applies an 80% probability of ultimate approval and commercialization for PRX-102 in Fabry Disease. The model includes contributions from a global commercialization effort.

Current Price (11/14/2022)	$1.07
Valuation	**$11.00**

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 expected to be resubmitted to the FDA in 2H:22. 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.

We expect PRX-102 to be approved in Europe and the US and sales related payments to be received in 2023. 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	**$2.00**
52-Week Low	**$0.70**
One-Year Return (%)	**-7.0**
Beta	**1.6**
Average Daily Volume (sh)	**106,334**
Shares Outstanding (mil)	**50.7**
Market Capitalization ($mil)	**54.2**
Short Interest Ratio (days)	**16.2**
Institutional Ownership (%)	**4.9**
Insider Ownership (%)	**17.9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**33.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
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)
2021	$11.3 A	$6.4 A	$12.0 A	$8.5 A	$38.4 A
2022	$16.1 A	$8.8 A	$14.2 A	$6.1 E	$45.1 E
2023					$63.2 E
2024					$94.9 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.14 A	-$0.25 A	-$0.09 A	-$0.15 A	-$0.63 A
2022	-$0.05 A	-$0.11 A	-$0.07 A	-$0.15 E	-$0.39 E
2023					$0.16 E
2024					$0.69 E

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Third Quarter Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced its 3Q:22 financial and operational results in a November 14, 2022 press release and filing of Form 10-Q. The materials were followed by a conference call which discussed recent achievements, regulatory updates and drivers for financial performance. News was dominated by the resubmission of the biologics license application (BLA) for PRX-102. Since the previous quarterly update in mid-August, Protalix has participated in an investor conference and continued its efforts to advance the Phase I trial for PRX-115 in gout which should start in 1Q:23.

Other important events year to date include the report of topline data from the BALANCE clinical trial, final results from the BRIGHT clinical trial and the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for PRX-102.

In the financial sphere, Protalix generated third quarter revenues of $14.2 million compared to $12.1 million in the prior year period. This resulted in net loss of ($3.6) million versus ($4.2) million in 3Q:21.

Financial results for the quarter ending September 30, 2022, compared to the quarter ending September 30, 2021:

- Revenues were $14.2 million, up 18% from $12.1 million; sales from goods rose 96% to $8.8 million, which included growth from Pfizer and recognition of material revenues from Chiesi. Revenues from license and R&D services, which are related to Chiesi license and supply agreements, fell 23% to $5.4 million from $7.5 million;
- Cost of revenues was up 20% to $7.1 million producing a 20% gross margin, slightly improved over prior year levels;
- Research and development expenses rose to $7.4 million from $7.3 million, a 1% increase. Other, unallocated expenses rose, with the increase partially offset by lower subcontractor and salary costs;
- Selling, general and administrative expenses fell 4% to $2.8 million vs $3.0 million;
- Financial expenses were a net $442,000 vs $2.3 million, on lower interest and debt amortization costs;
- Net loss was ($3.6) million vs ($4.2) million, or ($0.07) per share versus ($0.09) per share;

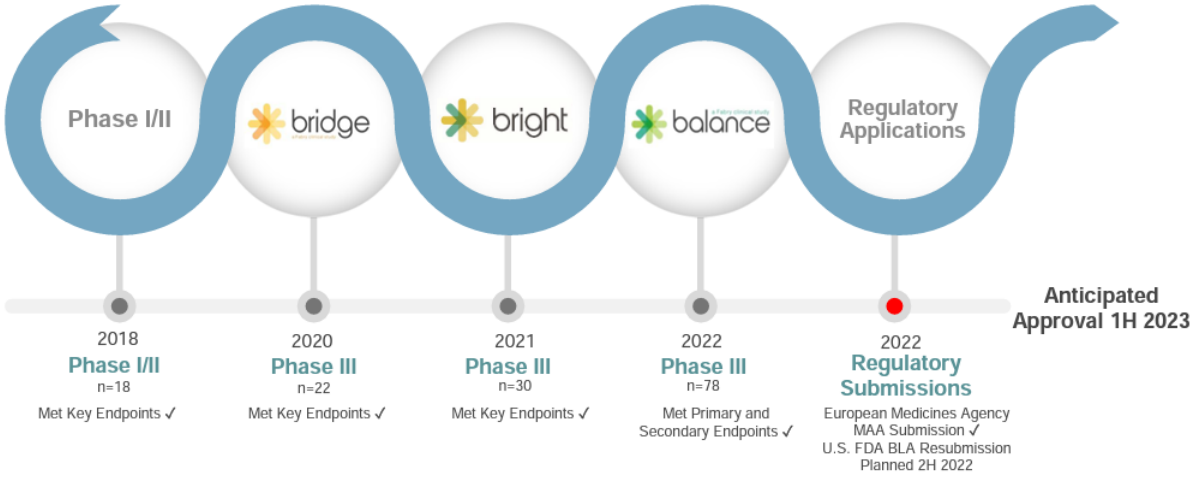
Cash and equivalents balance on September 30, 2022 totaled $20.8 million versus $39.0 million at the end of 2021. Cash burn was ($22.4) million for the first nine months of the year. Financing cash flows of $4.2 million related to proceeds from issuance of common stock. Protalix holds sufficient cash to fund operations for at least 12 months, which extends beyond the expected regulatory approval of PRX-102.

Following the end of the quarter, 507,000 shares were sold under the ATM program for proceeds of $530,000. Other cash inflows following the end of the third quarter include approximately $5.2 million from Pfizer, Fiocruz and Chiesi related to the various licensing and collaboration agreements.

PRX-102

Protalix has now submitted a BLA and MAA to the US and EU regulatory authorities. Based on the submission timelines, we expect a response from the FDA in May 2023 and from the EMA in late March or early April. Prior to the third quarter earnings release, Protalix announced the resubmission of the BLA to the FDA which included clinical and manufacturing data and results from BALANCE, BRIDGE and BRIGHT studies along with other materials, including long term open label extension data. Based on the November 9th acceptance date and an anticipated 6-month review, we expect a response from the FDA in May 2023. The EMA application, which was originally submitted in February 2022, proceeded to the day 120 list of questions in June 2022. Protalix responded to the questions and submitted a response package to the agency in September 2022 following a three-month clock stop. The response package included the results from the BALANCE study and the interim analysis of the PRX-102 open label extension study. Based on the EMA timeline, we expect a response regarding approval in late March or early April.

Exhibit I – Regulatory Submission Timeline[1]



Milestones

- MAA submission of PRX-102 to the EMA – February 2022
- BRIGHT final results – March 2022
- BALANCE topline results – April 2022
- BALANCE final data – August 2022
- BLA submission to the FDA – November 2022
- PRX-115 to start Phase I – 1Q:23
- EMA approval for PRX-102 – 1H:23
- FDA approval for PRX-102 – 1H:23

Exhibit II – Protalix Pipeline[2]



Summary

Protalix has now resubmitted its BLA in to the FDA and can expect to see a response from two regulatory agencies in the first half of 2023. It should also see the start of its Phase I trial for PRX-115 early next year, which is intended for gout. Revenues have shown an increase in the quarter due to strength at Pfizer and early PRX-102 sales to Chiesi. While expectations for Elelyso are low, the product has been generally improving in its revenue contribution over the last several quarters. We are optimistic on approval chances for PRX-102 at both the FDA and EMA and expect to receive a response from the agencies in the March to May time period. We maintain our valuation of $11.00 per share.

[1] Source: Protalix September 2022 Corporate Presentation
[2] Source: Protalix September 2022 Corporate Presentation

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[3]

Protalix Biotherapeutics	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US '000)	**$38,350**	**$16,085**	**$8,753**	**$14,183**	**$6,120**	**$45,141**	**$63,226**	**$94,877**
YOY Growth	-39%	42%	36%	18%	-28%	18%	40%	50%
Cost of Revenues	$16,349	$6,034	$4,087	$7,074	$2,848	$20,043	$14,781	$16,725
Research & Development	$29,734	$8,767	$7,579	$7,386	$7,950	$31,682	$28,000	$28,000
Selling, General & Admin	$12,729	$3,154	$2,611	$2,848	$2,988	$11,601	$12,350	$11,920
Income from operations	($20,462)	($1,870)	($5,524)	($3,125)	($7,666)	($18,185)	$8,095	$38,232
Operating Margin	-53%	-12%	-63%	-22%	-125%	-40%	13%	40%
Financial Expenses	$7,521	$618	$623	$639	$0	$1,880	$0	$0
Financial Income	($401)	($202)	($813)	($197)	($50)	($1,262)	($200)	($200)
Pre-Tax Income	($27,582)	($2,286)	($5,334)	($3,567)	($7,616)	($18,803)	$8,295	$38,432
Net Income	**($27,582)**	**($2,286)**	**($5,334)**	**($3,567)**	**($7,616)**	**($18,803)**	**$8,295**	**$38,432**
Net Margin	-72%	-14%	-61%	-25%	-124%	-42%	13%	41%
Reported EPS	**($0.63)**	**($0.05)**	**($0.11)**	**($0.07)**	**($0.15)**	**($0.39)**	**$0.16**	**$0.69**
Basic Shares Outstanding	44,121	45,844	47,328	49,498	50,700	48,342	51,000	55,968

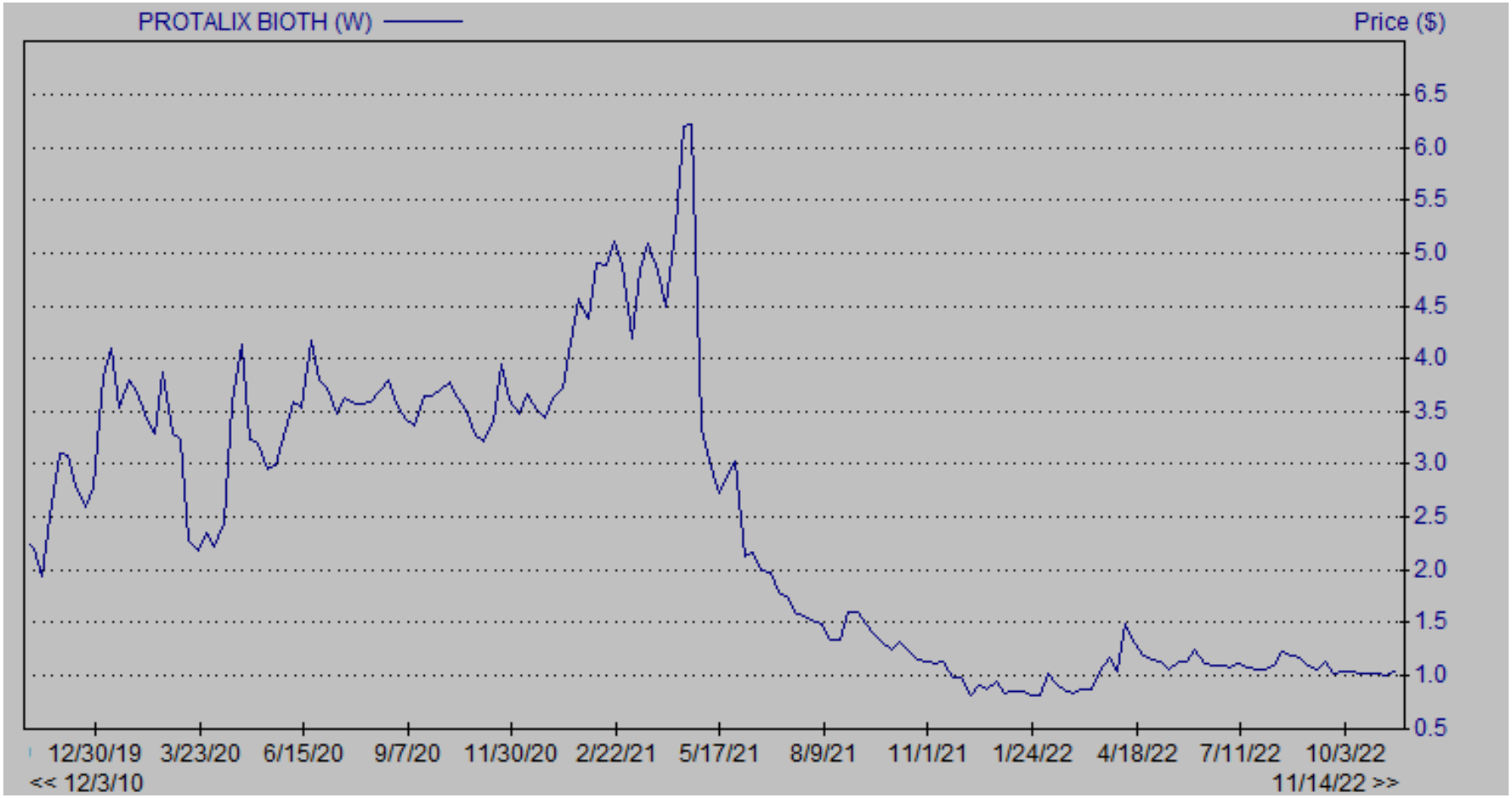
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

© Copyright 2022, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE

Protalix BioTherapeutics, Inc. – Share Price Chart[4]



[4] 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 2022, Zacks Investment Research. All Rights Reserved.