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

PLX: Back of the Envelope

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 following US and European approval. The model includes contributions from global commercialization.

Current Price (5/26/2023)	$2.06
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	**$1.00**
One-Year Return (%)	**87.3**
Beta	**1.4**
Average Daily Volume (sh)	**1,502,368**
Shares Outstanding (mil)	**65.4**
Market Capitalization ($mil)	**134.7**
Short Interest Ratio (days)	**2.5**
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	**12.9**
P/E using 2024 Estimate	**3.3**
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

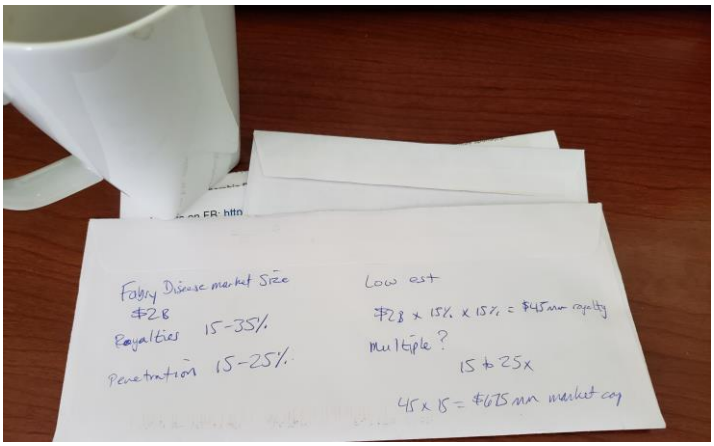
Conservative Back of the Envelope Math Suggests Dramatically Higher Valuation

We have been mystified by the reaction of Protalix Biotherapeutics, Inc's (NYSE: PLX) share price to three undeniably value-enhancing announcements over the last few weeks. On May 4th, Protalix closed at $3.36 per share, equivalent to a market capitalization of about $216 million. The next day, on May 5th, the European Commission (EC) granted marketing authorization to PRX-102 (ELFABRIO) in the European Union. On May 10th Protalix announced that FDA approval had been granted to ELFABRIO. This was followed by Protalix' announcement that a $20 million milestone would be paid in the next 30 days by commercialization partner Chiesi. Furthermore, on May 19th, Protalix was included in the new group of companies set to join the Russell 3000 Index on June 26th, a status that is associated with mandated purchases by index funds.

Closing share price and event:

- $3.36 – day before EC approval granted (May 4)
- $3.27 – EC approval announced (May 5)
- $2.92 – day before FDA approval granted (May 9)
- $2.94 – FDA approval announced (May 10)
- $2.36 – day before milestone announced (May 17)
- $2.14 - $20 million milestone announced – payable in 30 days (May 18)
- $2.06 – Friday's closing price (May 26)

Exhibit I – Back of the Envelope[1]



Obtaining regulatory clearance in the United States and European Union is a long, painstaking and uncertain process. So, when it is granted, not only does it allow the candidate to generate sales, but it also reduces the risk profile of the product. Based on our review of numerous of research efforts regarding a candidate submitted to the regulatory authorities, we estimate an approximate 85% probability of success. When approval is granted, this moves to 100% supporting a share price increase of about 18%, all else equal.

We performed a quick and conservative back of the envelope analysis to generate a base case valuation.

- Fabry Disease market size – $2 billion[2]
- Potential market share – 15% – 50%
- Royalty from Chiesi – 15% to 40%
- Applied multiple of royalty revenues – 15x – 25x
- Convertible debt – rounded up to $30 mm

[1] Zacks Analyst Work
[2] According to Evaluate Pharma, annual sales in the Fabry Disease indication were $1.9 billion in 2022 and are expected to be over $2 billion by 2024 and are expected to grow from 6-10% per annum over the next five years.

If we take the low end of each of these components and calculate a value, this produces a conservative enterprise value estimate of about $675 million. After subtracting convertible debt this gives us an equity value of $645 million or about $10 per share.

$2 billion x 15% market share x 15% royalty = $45mm. $45mm x 15x valuation multiple - $30mm debt = $645mm.

This assumes that no value is attributed to the development portfolio (PRX-115 & PRX-119), no value is attributed to Elelyso, that market share will not exceed 15% and that royalties will never rise above the bottom tier and no milestones will be paid.

We look at the following features of Elfabrio to justify our conservative back of the envelope calculation:

We believe Elfabrio will be able to take share from other enzyme replacement therapy (ERT) alternatives such as Replagal and Fabrazyme. Elfabrio offers:

- Better median reduction in the eGFR slope as demonstrated in the BALANCE study (not statistically significant);
- Reduction in eGFR slope for duration of Elfabrio treatment after previous treatment with Fabrazyme in BRIDGE study;
- Less use of infusion pre-medication and fewer infusion-related reactions;
- Reduced neutralizing antibody activity at end of study;
- Potential for periodicity of dose administration every four weeks vs. every two weeks for approved products.

Our Valuation Assumptions
Our target price and valuation are determined using a set of more realistic assumptions that produce a $16 target which we recently increased following the FDA approval of Elfabrio. These assumptions include peak penetration of 18% of US and ex-US markets, as well as a sum of royalty and milestone payments of up to 40% of product revenues.

Elfabrio Approval

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 celebrates two approvals in less than a week with the European Medicines Agency, providing its authorization for the product on May 4th, 2023.

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.

Exhibit II – Protalix Pipeline[3]

[3] Source: Protalix 2022 Form 10-K

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

Summary

Protalix has been the subject of several material and favorable news events in May 2023 including marketing approvals for Elfabrio in the United States and Europe, a $20 million milestone which is expected in the next few weeks and inclusion in the Russell 3000 index. We do a quick and dirty back of the envelope calculation which provides a conservative valuation of Protalix that is about 5x current levels. Our valuation, which takes into account performance above the bare minimum and other assets in the portfolio is well above that level at $16.00 per share. We see Protalix as a tremendous value and see no near term need to access the capital markets, eliminating the dilutive effects of such a move. Reward to risk is very favorable for equity investors in Protalix.

PROJECTED FINANCIALS

Protalix BioTherapeutics, Inc. - Income Statement[4]

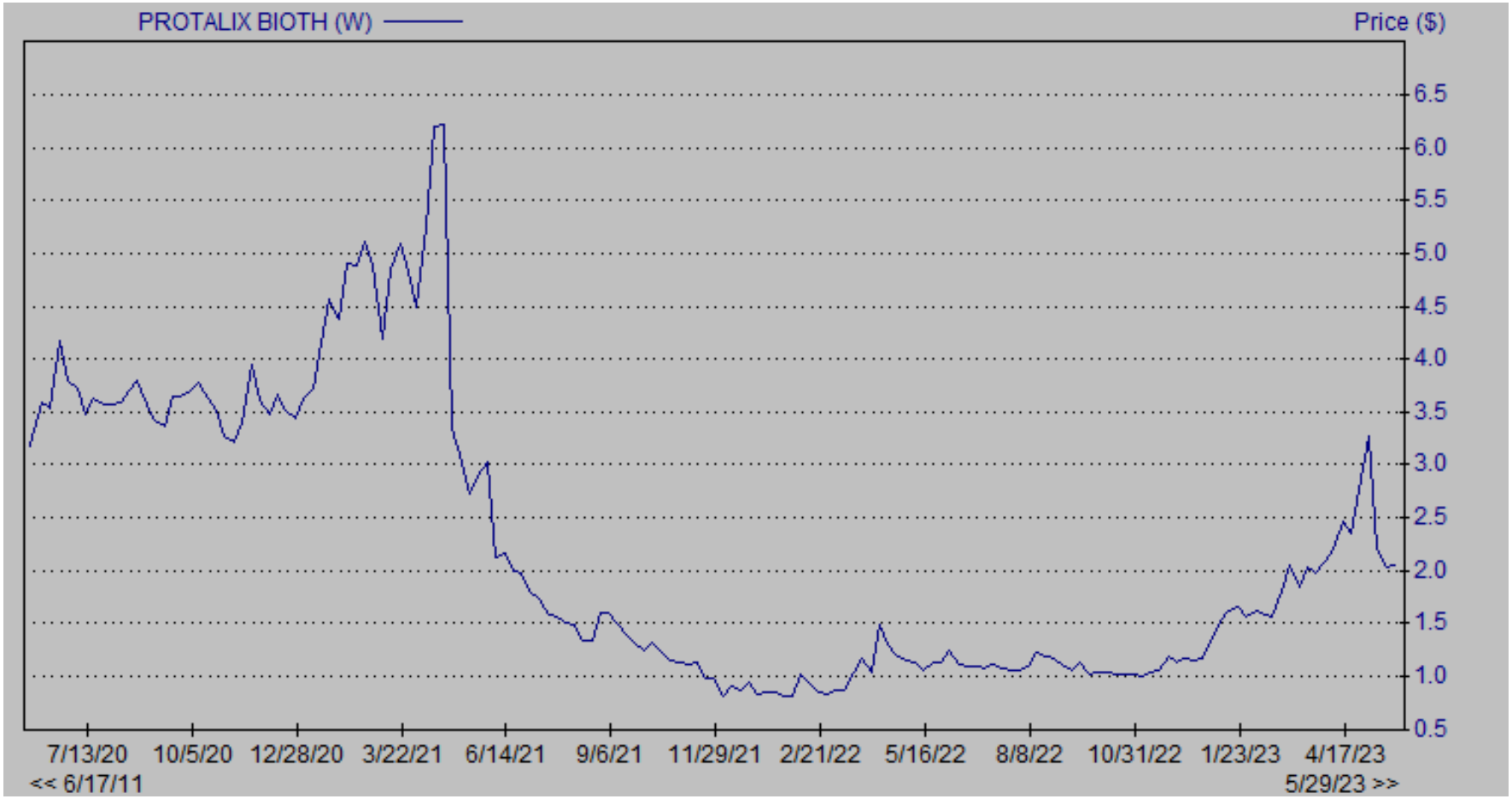
Protalix Biotherapeutics	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US '000)	**$47,638**	**$9,588**	**$10,222**	**$18,250**	**$22,601**	**$60,661**	**$90,116**	**$143,413**
YOY Growth	24%	-40%	17%	29%	162%	27%	49%	59%
Cost of Revenues	$19,592	$3,085	$3,110	$3,000	$2,850	$14,781	$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	$11,226	$10,553	$40,371	$93,924
Operating Margin	-27%	-26%	-18%	35%	50%	17%	45%	
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	$10,576	$8,154	$37,771	$91,324
Provision for Income Tax	$530	$195	$0	$0	$0	$195	$0	$0
Tax Rate	-3.7%	0.0%	0.0%	0.0%	0.0%	2.4%	0.0%	
Net Income	**($14,927)**	**($3,131)**	**($2,468)**	**$5,690**	**$10,576**	**$7,959**	**$37,771**	**$91,324**
Net Margin	-31%	-33%	-24%	31%	47%	13%	42%	0.63678683
Reported EPS	**($0.31)**	**($0.05)**	**($0.04)**	**$0.09**	**$0.16**	**$0.12**	**$0.56**	**$1.30**
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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