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Protalix BioTherapeutics, Inc. (PLX - NYSE)

Debt Maturities Resolved

Based on our DCF model and a 15% discount rate, Protalix is valued at approximately $12.50 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 (8/16/21)	$1.32
Valuation	**$12.50**

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 received a CRL due to the FDA's inability to perform an on-site inspection. If eventually approved, Chiesi Rare Disease will commercialize the product globally.

Protalix has additional candidates in earlier stages of development including OPRX-106 for IBD and PRX-110 for Cystic Fibrosis. The company also has a partnership with SarcoMed for development of PRX-110 in Pulmonary Sarcoidosis which was recently granted orphan drug status.

After a delay, we expect PRX-102 to be approved and sales related payments to be received in 2022. 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	**$7.02**
52-Week Low	**$1.32**
One-Year Return (%)	**-66.4**
Beta	**2.66**
Average Daily Volume (sh)	**1,705,603**
Shares Outstanding (mil)	**45.4**
Market Capitalization ($mil)	**60.1**
Short Interest Ratio (days)	**1.15**
Institutional Ownership (%)	**8.15**
Insider Ownership (%)	**24.2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**70.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 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 US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$21.6 A	$11.0 A	$10.8 A	$19.5 A	$62.9 A
2021	$11.3 A	$6.4 A	$6.9 E	$8.4 E	$33.0 E
2022					$38.4 E
2023					$110.4 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$0.10 A	-$0.13 A	-$0.14 A	$0.01 A	-$0.22 A
2021	-$0.14 A	-$0.25 A	-$0.12 E	-$0.09 E	-$0.59 E
2022					$0.04 E
2023					$1.92 E

WHAT'S NEW

Second Quarter Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced its 2Q:21 financial and operational results in an August 16, 2021 press release and filing of Form 10-Q. The reports were followed by a conference call that morning which discussed recent achievements.

Operational highlights for the quarter ended June 30th and to-date include:

- CRL issued for pegunigalsidase alfa (PRX-102) - April 2021
- Chiesi $10 million payment – May 2021
- Fireside Chat - June 2021
- Type A meeting request submitted - August 2021
- Resolution of November 2021 Convertible Note Maturity – August 2021

In the financial sphere, Protalix generated revenues of $6.4 million in 2Q:21 compared to revenue of $11.0 million in the prior year period. This resulted in net loss of ($11.2) million versus loss of ($4.2) million in 2Q:20.

Financial results for the quarter ending June 30, 2021 compared to the quarter ending June 30, 2020:

- Revenues were $6.4 million, down 41% from $11.0 million; sales from goods declined 11%, from $3.6 million to $3.2 million as decrease in Brazilian sales were offset by an increase in sales of Elelyso to Pfizer; revenues from license and R&D services declined 59% from $16.6 million to $6.8 million as revenues tied to progress of clinical trials ceased with the completion of the trials;
- Gross margin on product revenues fell to -45.9% compared with 49.9% with the negative turn attributable to one-time manufacturing costs in preparation for the anticipated approval and production of PRX-102;
- Research and development expenses declined 16% to $7.7 million from $9.2 million due to completion of two out of three Phase III clinical trials of PRX-102 and reduced costs for the BALANCE study;
- Selling, general and administrative expenses were up 45% at $3.2 million vs $2.2 million on an increase in corporate costs related to insurance and funding;
- Net financial expenses were $2.1 million vs $1.9 million, expanding due to an increase in the amortization of debt issuance costs and debt discount;
- Net loss was ($11.2) million vs net loss of ($4.2) million, or ($0.25) per share versus ($0.13) per share;

Cash and equivalents balance including short-term bank deposits on June 30, 2021 totaled $76.9 million versus $35.0 twelve months earlier. Cash burn for the first six months of the year was ($3.9) million, offset by $42.1 million in net financing cash flows generated from common stock and warrant issuance. This amount reflects the receipt of the $10 million payment from Chiesi in return for a future reduction in regulatory milestone payments. Carrying value for the convertible notes due November 2021 was $56.4 million.

Following the quarter, Protalix exchanged $54.65 million of its outstanding convertible notes for $28.75 million in newly issued convertible notes due 2024 and repaid $25.90 million of the outstanding balance in cash.

Private Note Exchange

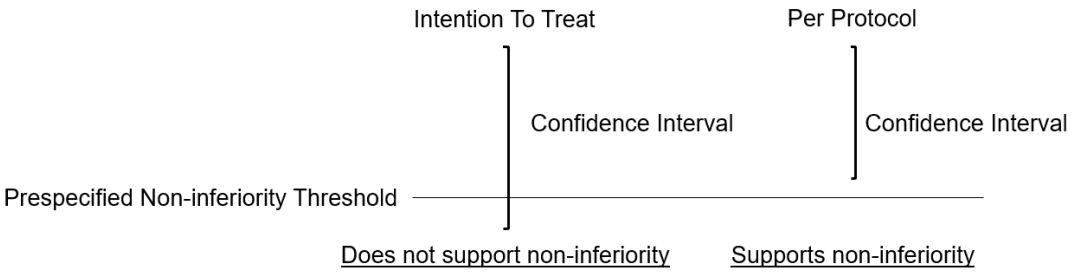
On August 13, 2021, Protalix announced an exchange of its outstanding 7.5% senior secured convertible notes due November 2021. Of the $54.65 million principal amount, $28.75 million of the total was exchanged for new 7.5% senior secured convertible notes due in August 2024. The conversion rate for the 2024 notes is 563.2216 shares of common stock for each $1,000 principal amount of the 2024 notes. This is equivalent to an equity conversion price of $1.7755, a 32.5% premium to the shares' closing price on August 13, 2021. The term of the notes is three years. $25.9 million of the obligation will be repaid in cash and an estimated $3.27 million of the aggregate principal amount of the existing notes will remain outstanding and likely settled with cash in November 2021.

BALANCE Interim Results

On June 2, 2021, Protalix and development partner, Chiesi Global Rare Diseases, provided an update regarding clinical development of Protalix' candidate pegunigalsidase alfa (PRX-102) and hosted a conference call and webcast the same morning to discuss results. Featured on the call was Dr. Ulrich Granzer, a consultant to Protalix with specialization in drug development and regulatory affairs.

Protalix' interim analysis stated that the confidence interval for the intent to treat population fell below the non-inferiority threshold while the per protocol group population confidence interval was above the threshold. No numbers were provided for the mean or range of the confidence interval as the data remains blinded.

Exhibit I - ITT and PP Confidence Intervals[1]



PRX-102 is currently being evaluated in the Phase III BALANCE trial for Fabry Disease and is Protalix' pegylated enzyme that offers enhanced longevity in the body. The pegylation provides for an extended therapeutic effect which may allow for less frequent dosing compared with current standard of care thereby reducing patient burden. The BALANCE study is a 24-month, randomized, double-blind, active control study designed to evaluate safety and efficacy of 1 mg/kg PRX-102 dosed every two weeks versus agalsidase beta (Fabrazyme). The study enrolled 78 patients who were randomized in a 2:1 ratio.

The primary endpoint evaluated in the interim analysis was comparison of mean annualized change of estimated glomerular filtration rate (eGFR) after completion of 12 months of treatment between the two arms (PRX-102 and Fabrazyme). Efficacy analysis was conducted on both Intention to Treat (ITT) and Per Protocol (PP) patient subgroups. ITT patients consisted of 77 randomized patients who received at least one dose while PP patients were those who completed at least 12 months of treatment with no major protocol violations (74 patients).

Interim results, based on analysis of the ITT population, did not achieve non-inferiority, as the lower bound of the confidence interval was below the pre-specified threshold. The confidence interval for the PP populations, however, was above the non-inferiority margin. Two patients discontinued the study due to treatment emergent adverse events (TEAE). One of the two discontinued due to related adverse events. No deaths were registered. Overall, the safety data was favorable and appears consistent with previous clinical work on PRX-102. Final data for the trial is anticipated to be unblinded in 2Q:22.

CRL Issued for PRX-102

Following the anticipated April 27th target action date for its investigational candidate, Protalix announced that the FDA had issued a Complete Response Letter (CRL) related to the submission of PRX-102.[2] Protalix and Chiesi Global Rare Disease had submitted the associated Biologics License Application (BLA) for the PEGylated enzyme and received acceptance of receipt in August 2020. Priority review was granted which normally provides for a six month appraisal of the BLA. Initially, the FDA issued a target action date of January 27, 2021, but in late November extended the date to April 27.

An ongoing outstanding item related to PRX-102 approval has been the required inspection for Protalix' manufacturing facility and that of a third party that performs fill and finish processes. Due to pandemic-related travel restrictions, inspections have been delayed, especially those performed overseas. Prior to the issuance of the CRL, it had been unclear if the agency would temporarily waive the inspection due to the unmet need for Fabry patients and the agency's backlog on account of the pandemic.

[1] Source: Created by Zacks Small Cap Research Analysts
[2] Also referred to by its generic name, pegunigalsidase alfa.

In a follow up press release on April 28th, Protalix provided additional details on the contents of the CRL. The FDA did not raise any issues related to the safety or efficacy of the drug, but rather attributed the unfortunate letter to the FDA's own inability to conduct an on-site inspection for the manufacturing facility in Israel and ongoing review of the third-party facility in Europe.

Protalix' April 28th communication indicated that primary competitor Fabrazyme was recently converted to full approval, which, for nearly 20 years, was approved based on surrogate endpoints. The change is important as it may alter PRX-102's priority review designation – a status granted to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. Priority review is provided to drug candidates that show evidence of significant improvements in safety or effectiveness when compared to standard of care. Now that Fabrazyme is fully approved, PRX-102 may no longer be eligible for expedited status, which could raise the hurdle required for approval. Despite this, we believe that the evidence presented so far strongly supports the approval of PRX-102.

Next Steps

Following the issuance of a CRL, there are several steps that are common for all candidates. The sponsor has 90 days following the issuance of a CRL to schedule a Type A meeting with the FDA to cover any questions related to the letter. When the sponsor makes the request, the FDA has 30 days to hold the meeting, after which notes from the gathering will be provided. Explained in the CRL and clarified in the meeting, the FDA outlines the steps needed to address the discrepancies presented. In general, these could include additional trials, further questions, bridging studies among other needs. When the requested deliverables are ready, the sponsor may then resubmit the application which will then be considered a Class 1 or Class 2 resubmission. A Class 1 resubmission offers a two month turnaround time and generally deals with simpler issues such as labeling, stability and safety updates, discussion of post-marketing requirements, assay validation data, minor reanalysis, final release testing or other minor issues. A Class 2 resubmission is any item that does not fall under Class 1 and/or requires presentation to an advisory committee and requires a six month turnaround time.

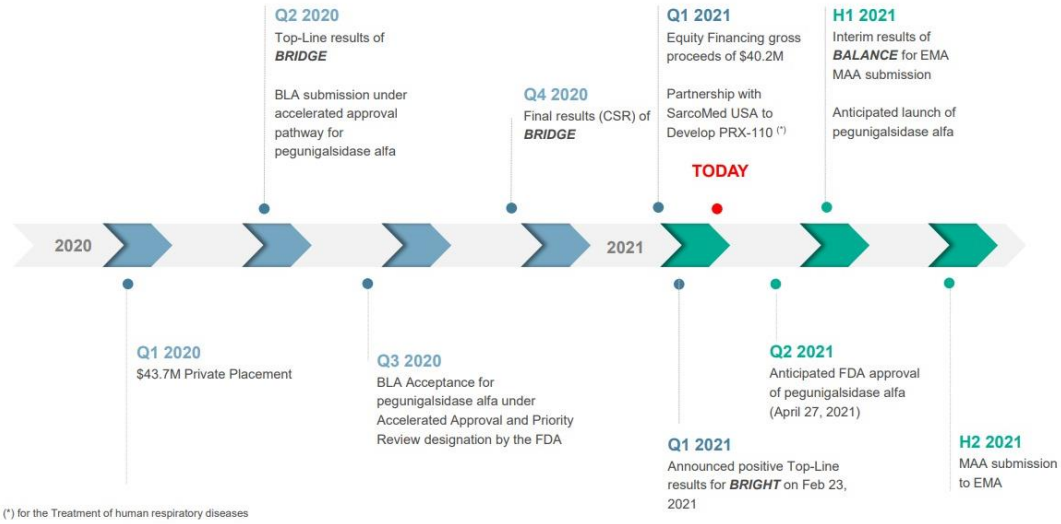
Based on our reading of the press release, it appears that the only discrepancies that exist are related to FDA inspections. Solving the discrepancies appears to be outside of the influence of Protalix and in our opinion not a justification for a CRL. In our previous report, we have noted that the FDA appears to have insufficient resources to meet its mission according to the timelines and performance benchmarks required by the Prescription Drug User Fee Act (PDUFA). Given these limitations, the agency appears to be forced to issue a CRL when it is unable to comply with the requirements for approval.

Normally, we anticipate a several month delay to the approval process when a CRL is issued. In this case it appears that addressing the defect relies on the FDA performing an on-site visit. Assuming that the inspection could take place in the next two months, followed by a resubmission the subsequent month and classification as a Class 1 resubmission, there is a minimum of five to six months before an approval could be granted. This timeline could be extended with a longer wait for an inspection and a Class 2 resubmission which could extend the timeline up to a year. We expect further clarity on this matter following the notes from an anticipated Type A meeting which is scheduled for September 9th.

Type A Meeting Granted

On August 2nd, Protalix announced that it had requested a Type A meeting from the FDA to address questions regarding the CRL. The meeting was granted and has been scheduled for September 9th, 2021. As presented in previous communications, the primary discrepancy was related to the absence of a facility inspection by the FDA. However, other issues may be discussed at the meeting. Management has indicated that they will provide further detail regarding the content after the meeting.

Exhibit II - Protalix Clinical Development Pipeline[3]



Clinical Trial Results for PRX-102

PRX–102 is a recombinant α-Galactosidase-A enzyme. Protalix uses its ProCellEx platform to express the enzyme and then chemically modifies it via surface pegylation. Protein subunits are covalently bound via chemical cross-linking using short PEG moieties, resulting in a molecule with unique therapeutic longevity in the body. In clinical studies, PRX–102 has demonstrated a circulatory half-life of approximately 80 hours. Due to the chronic nature of Fabry, patients must receive IV infusion of enzyme replacement therapy every two weeks, which is a significant burden. PRX-102, with its extended half-life, aims not only to be more effective, but also to reduce the frequency of doctors' visits by Fabry patients.

Three Phase III studies were launched to support regulatory approval of PRX-102 around the globe, designated BRIDGE, BALANCE and BRIGHT. After a release of topline results in May 2020, the BRIDGE trial provided final results on December 30, reiterating its findings of a substantial improvement in renal function. See our March 31 report for details on trial outcomes.

We expect to see interim results from the BALANCE study in the next few weeks. The data will remain blinded but safety is expected to be confirmed in the head to head, double blind study in comparison with Fabrazyme. Confirmation of safety in this 78-subject trial will provide additional support for regulatory approval and full results, if favorable, may provide justification of favoring PRX-102 over Fabrazyme. See our prior report and initiation for detailed discussion of BALANCE, BRIDGE and BRIGHT Phase III clinical trials.

Exhibit III - PRX-102 Phase III Trial Comparison[4]

	Design	Number of Patients	Next Data Read-Out	Completed
balance	1mg / kg 2 weeks Randomized Double Blind Head-to-Head vs. Fabrazyme® *24 mos.*	78 100% Enrolled	Interim results follow up expected H1 2021 (basis for EMA MAA Submission)	
bridge	1mg / kg 2 weeks Open Label Switch Over from Replagal® 12 mos.	22 100% Enrolled	Final results reported Q4 2020	✓
bright	2mg / kg 4 weeks Open Label Switch Over from Fabrazyme® and Replagal® 12 mos.	30 100% Enrolled	Announced positive Top-Line results on Feb 23, 2021	✓

[3] Protalix March 2021 Corporate Presentation
[4] Source: Protalix March 2021 Corporate Presentation

Public Offering

On February 11, 2021, Protalix both proposed a public offering of common stock and announced its pricing. The company ultimately issued 8,749,999 shares of common stock at $4.60 per share. Bank of America Securities acted as the book-running manager and Oppenheimer & Co. as the co-manager for the offering. Net proceeds will be used to fund clinical trials for Protalix' candidates, R&D activities and working capital for general corporate purposes. The completion of the raise was announced February 18, 2021, with gross proceeds totaling approximately $40.25 million and the overallotment exercised in full.

Exclusive Partnership with SarcoMed USA

Protalix announced on February 11th that it had entered into an exclusive partnership with SarcoMed USA to develop alidornase alfa for the treatment of pulmonary sarcoidosis. This is the culmination of a July 2020 non-binding term sheet between the two companies. SarcoMed USA is a private company that was formed in 2017 to support its lead product candidate, SM001, a recombinant DNase I delivered via inhalation, in pulmonary sarcoidosis. The agreement grants exclusive worldwide license for alidornase alfa (PRX-110), Protalix' Phase II recombinant DNase I, for use in the treatment of idiopathic pulmonary disorders including, but not limited to, sarcoidosis, pulmonary fibrosis and other related diseases via inhaled delivery.

Under the terms of the agreement, SarcoMed will be responsible for identifying, selecting and conducting clinical research and development of pharmaceutical candidates. In return for the license, Protalix is entitled to upfronts of $3.5 million, subject to conditions, additional payments tied to regulatory and commercial milestones and tiered royalties on product net sales commercialized through the license.

On July 21, 2020, the FDA granted Orphan Drug Designation for alidornase alfa for the treatment of sarcoidosis.

PRX-115

PRX-115 is a plant-cell expressed recombinant PEGylated uricase enzyme in development for refractory gout. This condition affects from 9.2[5] million to perhaps double[6] that level with more men than women suffering from it. While there are treatments for the disease by way of urate-lowering therapies, many do not respond to it producing an unmet need. Side effects from available medications are severe, and black box warnings for anaphylaxis and strong immunogenic reactions are present. Protalix sees an opportunity with the use of the uricase enzyme, which can convert the uric acid buildup to allantoin, which can be easily excreted from the body. This approach may provide an improved side effect profile and longer term efficacy compared with current treatments.

PRX-119

Protalix introduced PRX-119 in January 2021 as a new enzyme in preclinical work for neutrophil extracellular trap (NET)-related diseases. Excessive formation or ineffective clearance of NETs can cause pathological effects and are present in autoimmune, inflammatory and fibrotic conditions. Preclinical work has shown that DNase treatment may ameliorate NETs toxicity and Protalix anticipates advancing efforts to treat associated acute and chronic conditions with this compound.

PRX-110

Alidornase alfa is recombinant human deoxyribonuclease I (DNase I) expressed via the ProCellEx platform. Administration is via inhalation for direct application to the lungs. DNase I therapy can act as a mucus thinning agent (mucolytic) to help with clearance from the airways to improve lung function and reduce the chances of infection. Disintegrating inflammatory cells, namely neutrophils, release DNA into the sputum, which polymerizes and is present at high concentrations, contributing to the viscosity of the sputum. DNase I degrades the DNA, thus reducing the viscosity of the mucus.[7]

[5] Singh, G. *et al.* Gout and Hyperuricaemia in the USA: Prevalence and Trends. Rheumatology. 2019;58(12):2177-2180.
[6] Dehlin, M. *et al.* Global epidemiology of gout: prevalence, incidence, treatment patterns and risk factors. Nat Rev Rheumatol . 2020 Jul;16(7):380-390. doi: 10.1038/s41584-020-0441-1. Epub 2020 Jun 15.
[7] Pressler T. (2008). Review of recombinant human deoxyribonuclease (rhDNase) in the management of patients with cystic fibrosis. *Biologics: targets & therapy*, *2*(4), 611–617. https://doi.org/10.2147/btt.s3052

Milestones

- BRIDGE Final results – 4Q:20
- Partnership with Sarcomed for PRX-110 in respiratory disease – February 2021
- BRIGHT Top line results – February 2021
- PRX-102 Target Action Date – April 27, 2021
- PRX-102 CRL Announced – April 28, 2021
- Receipt of notes from FDA regarding CRL – May 2021
- Oral presentation on PRX-102 in females by Dr. Camilla Tøndel at ERA-EDTA Congress – June 2021
- BALANCE Interim results – June 2021
- ATM Agreement with HCW – July 2021
- Request Type A meeting regarding PRX-102 – August 2021
- Attend Type A meeting regarding PRX-102 – September 9, 2021
- $58 million in convertible notes due; partially extended and repaid – November 2021
- BALANCE final results – 2Q:22
- EMA submission of PRX-102 – 2022 following BALANCE final results
- EMA approval and EU commercialization of PRX-102 – 1H:23

Summary

We were unpleasantly surprised by the issuance of a complete response letter by the FDA and even more taken aback by the full approval of Fabrazyme which apparently annulled PRX-102's previous grant of accelerated approval. Based on the details provided by management, it appears that the inability of the FDA to perform an onsite inspection was the primary factor leading to the issuance of the complete response letter. The FDA has made it clear that it is behind on its audits and has issued a press release and document detailing the agency's inspection status and priorities during the pandemic. We anticipate that Protalix will follow the normal pathway travelled in response to a CRL. It will develop a briefing book, seek guidance from consultants and attend a Type A meeting to discuss the discrepancies related to the submission, all required deliverables will be addressed and a resubmission will take place. We estimate this process will take approximately one year from the issuance of the CRL. While this is an unfortunate delay for the company, investors and patients, we believe that Protalix has sufficient funds and expertise along with the help of Chiesi to address the setback.

On the European front, Protalix and Chiesi intend to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) before the end of the year. While the EMA is considering the application, BALANCE study data will be available for the agency's review. Dr. Granzer, who recently participated in an update call with investors, clarified that the EMA assesses not only results for the primary endpoint but also the totality of the data and evidence presented in the application, which will include all studies conducted by Protalix and all components of these studies. He suggested that the EMA will take a holistic view of PRX-102, including safety, efficacy and secondary endpoints and expects the EMA to also consider results from the BRIGHT and BRIDGE studies.

We are now waiting for Protalix to request, attend and provide feedback on the anticipated Type A meeting, after which we will update our estimates accordingly. We maintain our price target to $12.50 per share.

PROJECTED FINANCIALS

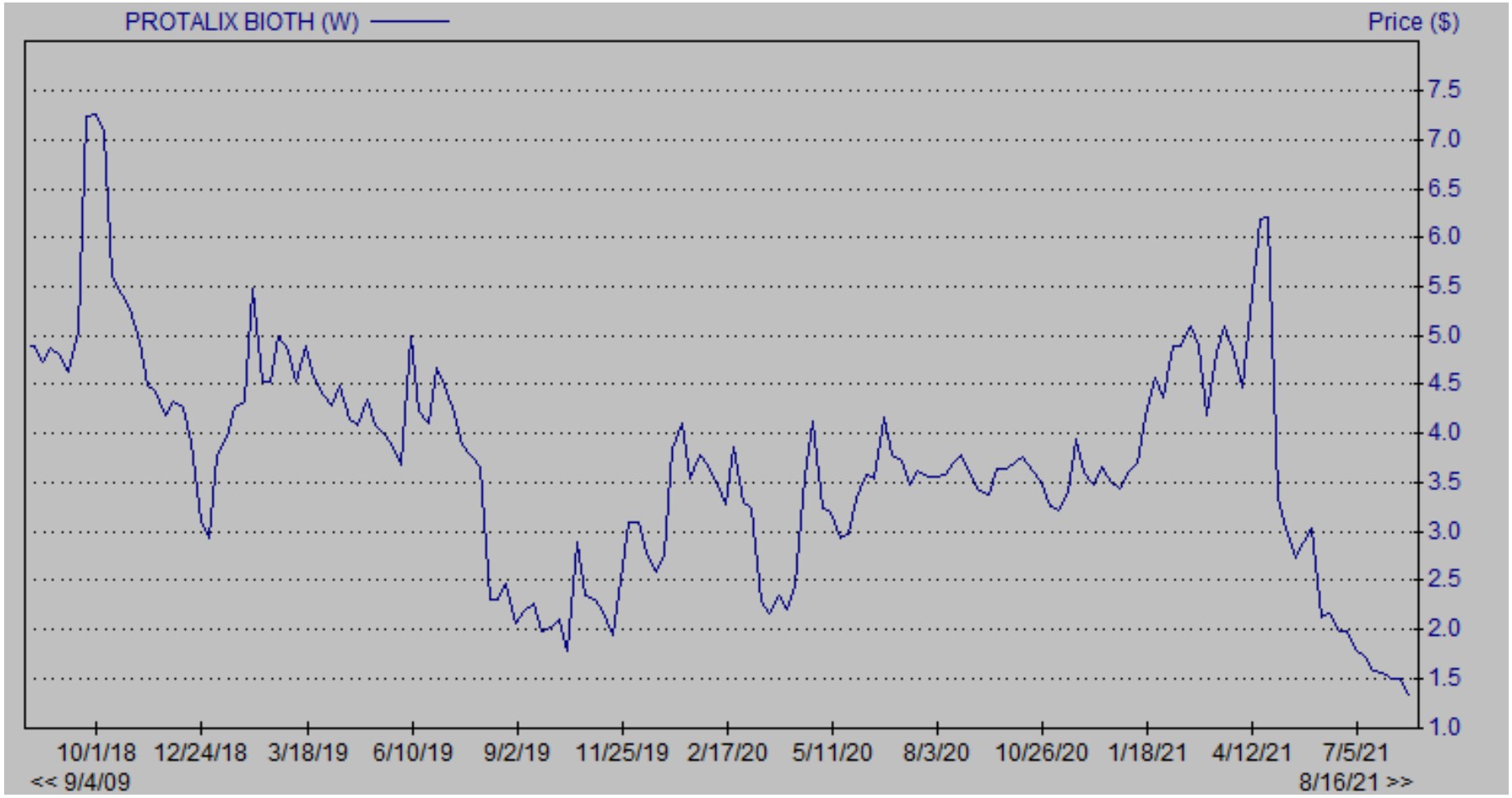
Protalix Biotherapeutics, Inc. - Income Statement

Protalix Biotherapeutics	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US '000)	**$62,898**	**$11,320**	**$6,427**	**$6,900**	**$8,396**	**$33,043**	**$38,388**	**$110,390**
YOY Growth	15%	-48%	-41%	-36%	-57%	-47%	16%	188%
Cost of Revenues	$10,873	$4,765	$4,733	$2,613	$3,716	$15,827	$11,449	$14,976
Research & Development	$38,167	$7,122	$7,689	$4,900	$4,500	$24,211	$15,000	$10,000
Selling, General & Admin	$11,148	$3,138	$3,171	$2,815	$2,787	$11,911	$10,510	$11,350
Income from operations	$2,710	($3,705)	($9,166)	($3,428)	($2,607)	($18,906)	$1,428	$74,064
Operating Margin	4%	-33%	-143%	-50%	-31%	-57%	4%	67%
Financial Expenses	$9,671	$2,156	$2,203	$1,950	$1,500	$7,809	$0	$0
Financial Income	($438)	($335)	($128)	($100)	($100)	($663)	($200)	($200)
Pre-Tax Income	($6,523)	($5,475)	($11,241)	($5,278)	($4,007)	($26,001)	$1,628	$74,264
Net Income	**($6,523)**	**($5,475)**	**($11,241)**	**($5,278)**	**($4,007)**	**($26,001)**	**$1,628**	**$74,264**
Net Margin	-10%	-48%	-175%	-76%	-48%	-79%	4%	67%
Reported EPS	**($0.22)**	**($0.14)**	**($0.25)**	**($0.12)**	**($0.09)**	**($0.59)**	**$0.04**	**$1.92**
Basic Shares Outstanding	29,148	39,934	45,437	45,600	45,800	44,193	45,000	38,582

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

HISTORICAL STOCK PRICE

Protalix Biotherapeutics, Inc. – Share Price Chart



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