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Protalix BioTherapeutics, Inc. (PLX - NYSE)

1Q:21 Results & Next Steps Following CRL

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 (5/14/21)	$2.74
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.

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	**$2.61**
One-Year Return (%)	**-8.05**
Beta	**2.72**
Average Daily Volume (sh)	**1,490,544**
Shares Outstanding (mil)	**45.4**
Market Capitalization ($mil)	**124**
Short Interest Ratio (days)	**1.15**
Institutional Ownership (%)	**12.0**
Insider Ownership (%)	**28.0**
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	$8.3 E	$6.9 E	$7.5 E	$34.1 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	-$0.08 E	-$0.12 E	-$0.09 E	-$0.43 E
2022					$0.04 E
2023					$1.92 E

WHAT'S NEW

First Quarter Financial and Operational Review

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced its 1Q:21 financial and operational results in a May 14, 2021 press release and filing of Form 10-Q. The reports were followed by a conference call that morning which discussed recent achievements and the April 27th receipt of a complete response letter by the FDA for pegunigalsidase alfa (PRX-102). Key events year to date include entering into an exclusive partnership with SarcoMed to develop inhalable alidornase alfa in pulmonary sarcoidosis and related respiratory diseases, topline results from BRIGHT Phase III trial of PRX-102, raise of approximately $40 million gross through a public offer and receipt of a CRL for PRX-102 from the FDA.

In the financial sphere, Protalix generated revenues of $11.3 million in 1Q:21 compared to revenue of $21.6 million in the prior year period. This resulted in net loss of ($5.48) million versus income of $1.67 million in 1Q:20.

Financial results for the quarter ending March 31, 2021, compared to the quarter ending March 31, 2020:

- Revenues were $11.3 million, down 48% from $21.6 million; sales from goods declined 10%, from $5.0 million to $4.5 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;
- Research and development expenses declined to $7.12 million from $10.34 million, a 31% decline primarily 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 largely flat at $3.14 million vs $3.19 million;
- Financial expenses were $2.16 million vs $3.23 million, declining with a decrease in expenses related to Protalix' outstanding convertible notes;
- Net loss was ($5.48) million vs net income of $1.67 million, or ($0.14) per share versus $0.10 per share;

Cash and equivalents balance including short-term bank deposits on March 31, 2021 totaled $70.4 million versus $36.6 in the prior year period. Cash burn was ($10.2) million, offset by $42.1 million in net financing cash flows generated from common stock and warrant issuance. The strong balance sheet is sufficient to satisfy the $57.9 principal amount outstanding on the convertible notes due in November 2021.

Following the quarter, Protalix and Chiesi signed a binding term sheet on May 13, 2021 to supply Protalix with near-term capital. Chiesi agreed to make payment of $10 million before end of 2Q:21 in exchange for $25 million reduction in a longer term regulatory milestone payment in the Chiesi EX-US agreement.

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.[1] 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.

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 its

[1] Also referred to by its generic name, pegunigalsidase alfa.

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.

FDA CRLs Have Become Common

Several CRLs have been issued recently. While we have not reviewed them all, we do believe that their frequency is indicative of an FDA that has too many obligations and insufficient resources to comply with its mandate. There have been a number of delays to initial target action dates attributable to what we believe to be demands on the agency related to the pandemic and the allocation of resources to this global predicament. As COVID vaccines take their effect, the impact from the pandemic lessens and travel resumes, we anticipate the FDA will catch up. However, we believe outstanding submissions for all sponsors are at greater risk of delay independent of the safety and efficacy of the underlying drug.

We performed a quick review of Prescription Drug User Fee Act (PDUFA) calendars examining the outcomes related to the assigned PDUFA dates. We have identified 29 target action dates that occurred year-to-date with at least 38% of them either receiving a CRL or no response from the FDA on the indicated date. The trend appears to have worsened over the last 30 days with eight of ten PDUFA dates missed, CRLed or delayed.

Exhibit I - Summary of PDUFA Actions Year to Date 2021[2]

Company	PDUFA Date	Action	Company	PDUFA Date	Action
PLX	4/27/2021	CRL, travel restrictions	FGEN	3/20/2021	No response
SLGL	4/26/2021	Delayed, travel restrictions	KNSA	3/18/2021	Approved
MRK	4/18/2021	No response	GILD	3/5/2021	Approved
BMY	4/16/2021	Approved	KMPH	3/2/2021	Approved
ATXI	4/12/2021	Delayed, still reviewing	ATNX	3/1/2021	CRL, safety
ACAD	4/3/2021	CRL, stat sig	CRMD	2/28/2021	CRL, site
AVEO	3/31/2021	No response	SNY	2/22/2021	Approved
SNY	3/31/2021	Approved	GTHX	2/12/2021	Approved
MRK	3/29/2021	CRL	TGTX	2/5/2021	Approved
CYRX	3/27/2021	No response	BMY	2/5/2021	Approved
BLUE, BMY	3/26/2021	Approved	ADMS	2/1/2021	Approved
MRK	3/23/2021	Approved	AUPH	1/22/2021	Approved
ZEAL	3/22/2021	Approved	BMY	1/22/2021	Approved
PCRX	3/22/2021	Approved	MRK	1/20/2021	Approved
MNNKQ	3/22/2021	Approved			

On May 5th, 2021, the FDA delivered a press announcement addressing the inspection and assessment activities during the pandemic and providing details on how the backlog of inspections would be addressed. In March 2020, the FDA halted its domestic and foreign routine surveillance facility inspections, while continuing mission critical inspections. The agency's limited drug inspection efforts prioritized facilities that produced products presenting a shortage and COVID-related efforts.

[2] FDA Calendar – FDA Tracker, Zacks Analyst Research

A report titled Resiliency Roadmap for FDA Inspectional Oversight was also published in May providing some statistics on how the agency has performed with regard to inspections during the pandemic. During the pandemic, only mission-critical inspections have been taking place which for drugs includes products that have received breakthrough therapy or regenerative medicine advanced therapy (RMAT) designations, or for products that are used to treat a serious disease or medical condition where there is no substitute. Fabrazyme was granted accelerated approval in 2003 and recently received full approval, which precludes PRX-102 from qualifying in these categories. We anticipate that the resubmission process will add one year to our estimates for approval and ultimate commercialization.

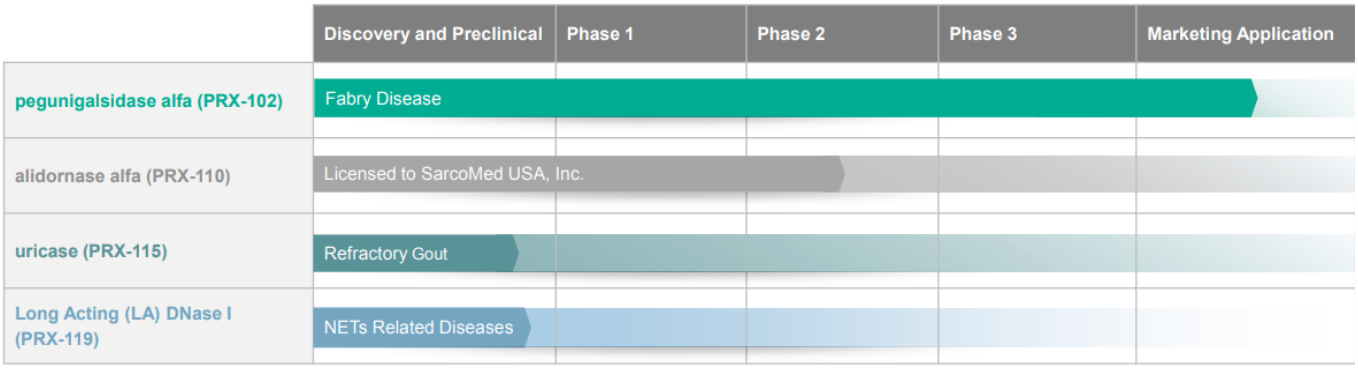
Next Steps

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. 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.

Exhibit II - Protalix Clinical Development Pipeline[3]



[3] Protalix Corporate Presentation March 2021

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 sub-units 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	Completed
balance	1mg / kg 2 weeks Randomized Double Blind Head-to-Head vs. Fabrazyme® *24 mos.*	78 100% Enrolled	
bridge	1mg / kg 2 weeks Open Label Switch Over from Replagal® 12 mos.	22 100% Enrolled	✓
bright	2mg / kg 4 weeks Open Label Switch Over from Fabrazyme® and Replagal® 12 mos.	30 100% Enrolled	✓

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 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 and R&D activities and for 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.

[4] Source: Protalix 2020 Form 10-K

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.

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]

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
- BALANCE Interim results – 2Q:21
- Request Type A meeting regarding PRX-102 – July 2021
- Attend Type A meeting regarding PRX-102 – August 2021
- $58 million in convertible notes due – November 2021
- BALANCE Final results – 1H:22
- EMA submission of PRX-102 – 2022 following BALANCE Final results
- EMA approval and EU commercialization of PRX-102 – 1H:23

[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

Valuation

We adjust our valuation to reflect the receipt of the CRL for PRX-102. While the details of the FDA's letter were not made public, we feel that there is only a small increase in risk to approval. The focus of the letter on the inability to conduct an on-site inspection rather than concerns over drug safety or efficacy justifies only a minor adjustment to our probability of success estimate. Our updated forecasts approximate an 80% likelihood of ultimate commercialization, down from 85% previously. We also forecast a one year delay in US sales based to 2H:22 on the anticipated duration of the resubmission as we discuss in an earlier section of this report. We do not change our estimates for the European approval timeline or sales trajectory. The net result of our update reduces our target price to $12.50 per share.

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 request and be granted 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. 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. Based on our assumptions provided in the valuation section we adjust our price target to $12.50 per share.

PROJECTED FINANCIALS

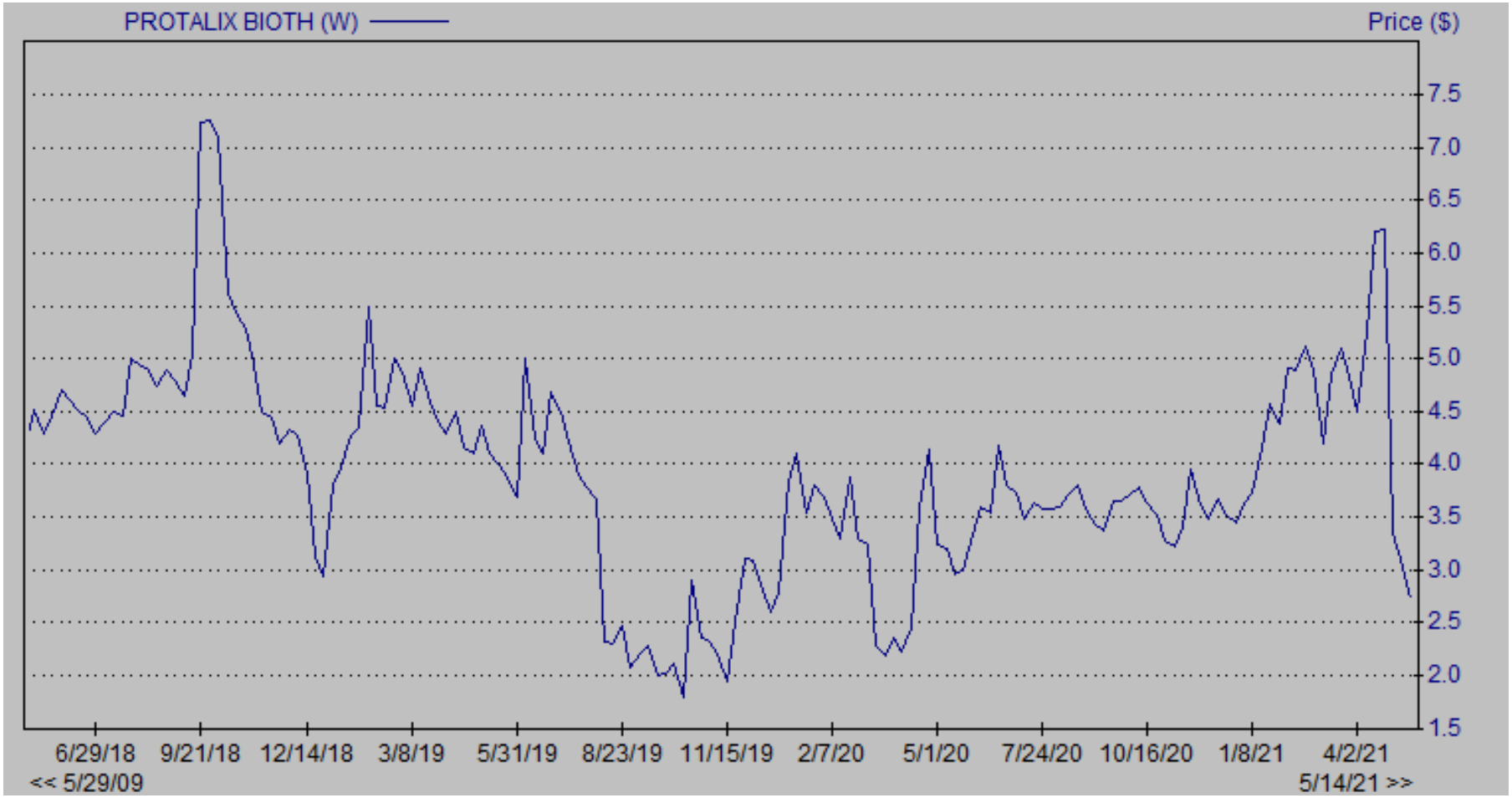
Protalix Biotherapeutics, Inc. - Income Statement

Protalix Biotherapeutics	2020 A	Q1 A	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US '000)	**$62,898**	**$11,320**	**$8,300**	**$6,900**	**$7,539**	**$34,059**	**$38,388**	**$110,390**
YOY Growth	15%	-48%	-24%	-36%	-61%	-46%	13%	188%
Cost of Revenues	$10,873	$4,765	$2,747	$2,613	$3,142	$13,267	$11,449	$14,976
Research & Development	$38,167	$7,122	$4,800	$4,900	$4,500	$21,322	$15,000	$10,000
Selling, General & Admin	$11,148	$3,138	$2,735	$2,815	$2,787	$11,475	$10,510	$11,350
Income from operations	$2,710	($3,705)	($1,982)	($3,428)	($2,890)	($12,005)	$1,428	$74,064
Operating Margin	4%	-33%	-24%	-50%	-38%	-35%	4%	67%
Financial Expenses	$9,671	$2,156	$1,950	$1,950	$1,500	$7,556	$0	$0
Financial Income	($438)	($335)	($100)	($100)	($100)	($635)	($200)	($200)
Pre-Tax Income	($6,523)	($5,475)	($3,832)	($5,278)	($4,290)	($18,875)	$1,628	$74,264
Net Income	**($6,523)**	**($5,475)**	**($3,832)**	**($5,278)**	**($4,290)**	**($18,875)**	**$1,628**	**$74,264**
Net Margin	-10%	-48%	-46%	-76%	-57%	-55%	4%	67%
Reported EPS	**($0.22)**	**($0.14)**	**($0.08)**	**($0.12)**	**($0.09)**	**($0.43)**	**$0.04**	**$1.92**
Basic Shares Outstanding	29,148	39,934	45,400	45,600	45,800	44,183	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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