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# Protalix BioTherapeutics, Inc. (PLX - NYSE)

***Target Action Date Four Weeks Away***

Based on our DCF model and a 15% discount rate, Protalix is valued at approximately $15.00 per share. Our model applies an 85% probability of ultimate approval and commercialization for PRX-102 in Fabry Disease. The model includes contributions from a global commercialization effort.

| | |
|---|---|
| Current Price (3/30/21) | $4.51 |
| **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. Other candidates include PRX-102 for Fabry Disease, now under review by the FDA with an anticipated target action date of April 27, 2021. If 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.

We expect PRX-102 to be approved and sales related payments to be received in 2021. PRX-102 can fill an unmet need with several improvements over the market leader and is expected to command a premium to existing products. Elelyso is expected to 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** | **$2.12** |
| **One-Year Return (%)** | **89.5** |
| **Beta** | **2.83** |
| **Average Daily Volume (sh)** | **822,806** |
| **Shares Outstanding (mil)** | **45.4** |
| **Market Capitalization ($mil)** | **205** |
| **Short Interest Ratio (days)** | **1.21** |
| **Institutional Ownership (%)** | **10.9** |
| **Insider Ownership (%)** | **28.2** |
| **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) |
|---|---|---|---|---|---|
| 2019 | $10.4 A | $12.2 A | $14.2 A | $17.8 A | $54.7 A |
| 2020 | $21.6 A | $11.0 A | $10.8 A | $19.5 A | $62.9 A |
| 2021 | | | | | $48.9 E |
| 2022 | | | | | $78.4 E |

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2019 | -$0.49 A | -$0.52 A | -$0.24 A | $0.02 A | -$1.23 A |
| 2020 | $0.10 A | -$0.13 A | -$0.14 A | $0.01 A | -$0.22 A |
| 2021 | | | | | -$0.00 E |
| 2022 | | | | | $0.90 E |

## WHAT'S NEW

**2020 Financial and Operational Review**

Protalix Biotherapeutics, Inc. (NYSE: PLX) announced its 2020 financial and operational results in a March 30, 2021 press release and filing of Form 10-K. The reports were followed by a conference call that morning which discussed recent achievements including results from clinical trials, proceeds from capital raises and upcoming regulatory activity. Key events in 2020 and 2021 year to date include acceptance of a biologics license application (BLA) for PRX-102 and assignment of the April 27, 2021 target action date. Top line and final results from the BRIGHT and BRIDGE studies were announced and the BALANCE study was fully enrolled. Protalix intensified its relationship with SarcoMed, which will investigate PRX-110 in pulmonary sarcoidosis. In the financial sphere, revenues of $62.9 million exceeded our estimates of $53.8 million due to greater research and development revenues from the Chiesi relationship. Loss per share of ($0.22) compared to our forecast of ($0.39).

Financial results for the year ending December 31, 2020, compared to the year ending December 31, 2019:

- Revenues were $62.8 million, up 15% from $54.7 million. Sales of Elelyso were up 2% with an improvement in year over year Pfizer sales partially offset by a decline in Brazil sales due to the impact of the pandemic. The R&D services revenues increase of 20% was primarily due to revenue recognized in connection with an updated cost estimation for the completed BRIGHT and BRIDGE studies.
- Gross margin (product sales only) rose to 33.0% from 31.3%.
- Research and development expenses declined to $38.2 million from $44.6 million, a 14% decline. The decrease was attributable to the completion of the BRIGHT and BRIDGE studies and lower costs from the BALANCE study.
- Selling, general and administrative expenses were $11.1 million, up 13% from $9.9 million due to greater share-based compensation, board of directors compensation, partially offset by lower travel, rent and utilities expenditure.
- Financial expenses were $9.7 million compared to $8.0 million which relate to interest expense for the convertible notes.
- Loss from operations was ($6.5) million compared to ($18.3) million. On a per average share balance, net loss was ($0.22) and ($1.23) respectively.

Cash and equivalents balance on December 31, 2020 was $38.5 million. Following the end of the quarter, additional funds were raised including a gross $40 million from a public equity offering and an additional $9 million from the at-the-money (ATM) program that should bring the cash balance to over $80 million in 1Q:21 after adjusting for financing costs. Cash burn was ($26.8) million, offset by $46.5 million in financing cash flows generated from common stock and warrant issuance, ATM equity offerings and warrant exercise. The strong balance sheet is sufficient to satisfy the $57.9 principal amount outstanding on the convertible notes due in November 2021.

*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.

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[1] million to perhaps double[2] 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.[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 sub-units are covalently bound via chemical cross-linking using short PEG moieties, resulting in a molecule with unique pharmacokinetic parameters. 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 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.

[1] Singh, G. *et al.* Gout and Hyperuricaemia in the USA: Prevalence and Trends. Rheumatology. 2019;58(12):2177-2180.
[2] 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.
[3] 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

**Exhibit I – 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 | ✓ |

*BRIDGE Phase III Final Results*

On December 30, 2020, Protalix announced final results of its BRIDGE Phase III open-label, switch-over clinical trial of lead candidate pegunigalsidase alfa (PRX-102) in Fabry Disease. BRIDGE was a 12-month open-label, single arm switch-over study evaluating the efficacy of 1 mg/kg of pegunigalsidase alfa infused every two weeks. The 22 Fabry patients in the trial had been previously treated with agalsidase alfa (Replagal) for at least two years and had been stable on this drug for at least six months.

The study found a mean annualized estimated glomerular filtration rate (eGFR) slope of the study participants improvement from -5.90 mL/min/1.73m$^2$/year while on agalsidase alfa to -1.19 mL/min/1.73m$^2$/year on PRX-102 in all patients. Male patients improved from -6.36 mL/min/1.73m$^2$/year to -1.73 mL/min/1.73m$^2$/year and female patients improved from -5.03 mL/min/1.73m$^2$/year to -0.21 mL/min/1.73m$^2$/year.

Lyso-GL-3 is a biomarker that indicates the status of the patient and whether or not they are improving but is not related to a patient's clinical symptoms. Baseline characteristics of the 20 completed patients, ranging from ages 28 to 60 years, were as follows: mean eGFR 75.87 in males and 86.14 in females and plasma lyso-GL-3[5] mean levels were 51.8 nM and 13.8 nM in males and females, respectively. While lyso-GL-3 levels remained somewhat high, particularly within the male cohort, continuous reduction in lyso-GL-3 levels was observed of 19.55 nM (32.35%) in males and 4.57 nM (29.81%) in females. The shift to PRX-102 resulted in a decrease of kidney disease progression and most patients were stable after the change.

PRX-102 was well tolerated during the study. All adverse events were transient without sequelae. Of the 22 patients enrolled, the majority of treatment emergent adverse events (TEAE) were mild or moderate. Two patients (9.1%) withdrew from therapy due to hypersensitivity reaction that resolved. The most common TEAEs were nasopharyngitis, headache and dyspnea.

The final results provided an immunogenic analysis, adding to the details reported in May. Over the duration of the study, patient serum was collected at monthly frequency and screened for the presence and amount of immunoglobulin (antibodies) that were active against PRX-102. An immunogenicity assessment indicated that 4 out of 20 patients (20%) developed persisting antidrug antibodies over the study period, two of which had antibodies with neutralizing activity.[6] However, two of the four patients were positive at baseline following treatment with Replagal, suggesting pre-existing antibodies that were cross-reactive with PRX-102. Furthermore, based on statistical analysis, efficacy and safety were unaffected by whether the patient was antibody positive or negative. This is likely due to remaining levels of PRX-102 that escaped antibody suppression and were sufficient to break down GL-3. Antibodies found were not anti-glycan nor anti-PEG but mostly directed toward the core of the enzyme. The 20% im-

[4] Source: Protalix 2020 Form 10-K
[5] Lyso-GL-3, also referred to as Lyso-Gb3, is a biomarker with limited correlation to symptoms, but is highly sensitive as a therapeutic monitor.
[6] Neutralizing antibodies are distinguished from binding antibodies in that neutralizing antibodies bind to sites (epitopes) directly involved in the activity of the antigen (such as a receptor), interfering with the activity of the antigen, while binding antibodies attach to non-critical portions of the antigen.

munogenicity compares to Fabrazyme and Replagal at 79%[7] and 25%-45%, respectively. Antibodies are frequently cross reactive in patients that use both Fabrazyme and Replagal[8] but do not materially impact the efficacy of the drug.

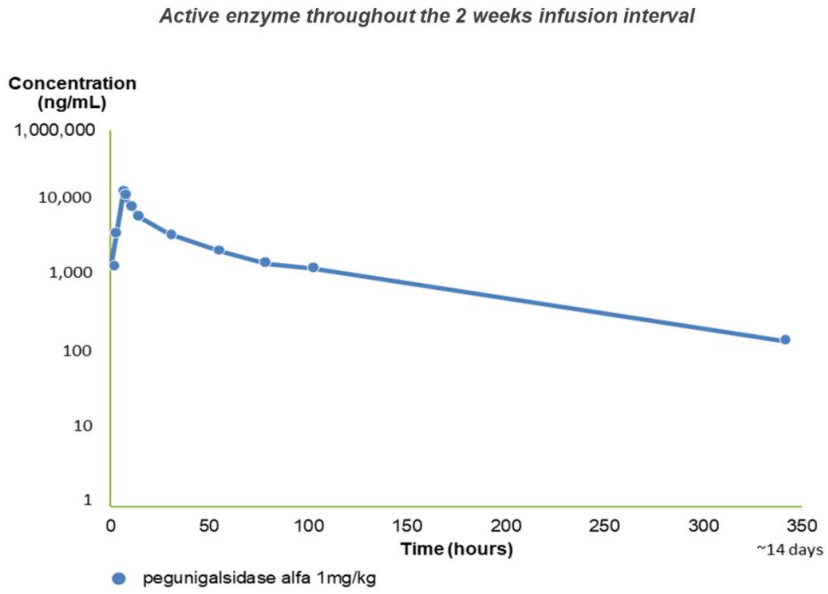
Data from the interim analysis of the BRIDGE Study was included in the PRX-102 BLA submission to the FDA under the Accelerated Approval pathway. Now that final analysis is available, the data will be used to support a Marketing Authorization Application (MAA) with the EMA. Announced on February 10, 2021, Protalix and Chiesi Global Rare Diseases presented the above key data from the final analysis of BRIDGE at the 17th Annual WORLDSymposium.

*BRIGHT Topline Results*

On February 23, 2021, Protalix announced topline results for its Phase III BRIGHT open-label, switch-over trial of PRX-102 in Fabry Disease. BRIGHT is the third Phase III clinical trial of PRX-102 for the treatment of Fabry disease. The trial was completed in July 2020. The favorable outcome from the BRIGHT trial may be used to modify the label for PRX-102 and allow for dosing every four weeks. Protalix plans to submit a clinical supplement to the FDA to obtain this modification.

BRIGHT was a 12-month, open-label switch-over study designed to assess the safety, efficacy and pharmacokinetics of PRX-102 via intravenous infusions of 2 mg/kg administered every four weeks in up to 30 patients with Fabry disease. The patients had been previously treated with ERT (Fabrazyme or Replagal). The rationale for this open-label switch-over study was based on the pharmacokinetic profile of PRX-102. Phase I/II study data suggested that 2.0 mg/kg every four weeks would be effective in mild to moderate Fabry patients. The dosing regimen served as maintenance ERT for mild to moderate Fabry patients without severe clinical symptoms and with relatively slow disease progression, with opportunity to manage. To determine eligibility for participation in the study, candidates were screened to identify and select Fabry patients with a relatively stable clinical presentation and a slow disease progression. Patients who matched the criteria were enrolled in the study and switched from their current treatment of biweekly intravenous infusions to monthly 2 mg/kg of PRX-102 for 12 months.

**Exhibit II - Plasma Drug Concentration vs. Time[9]**




Patients participating in the study were evaluated for various disease-related clinical symptoms and biomarkers, including rate of deterioration of the kidneys, while being treated with the once-monthly dosing regimen. Safety and tolerability of PRX-102 was also assessed. In February 2019, Protalix presented preliminary pharmacokinetic data from BRIGHT. The results demonstrated that PRX-102 was present and remained active in the plasma over the 4 weekly infusion intervals. The mean concentration of PRX-102 at day 28 was 138 ng/mL, showing that it was still present in the blood. In comparison, published data on Fabrazyme (1 mg/kg every 2 weeks) shows a mean con-

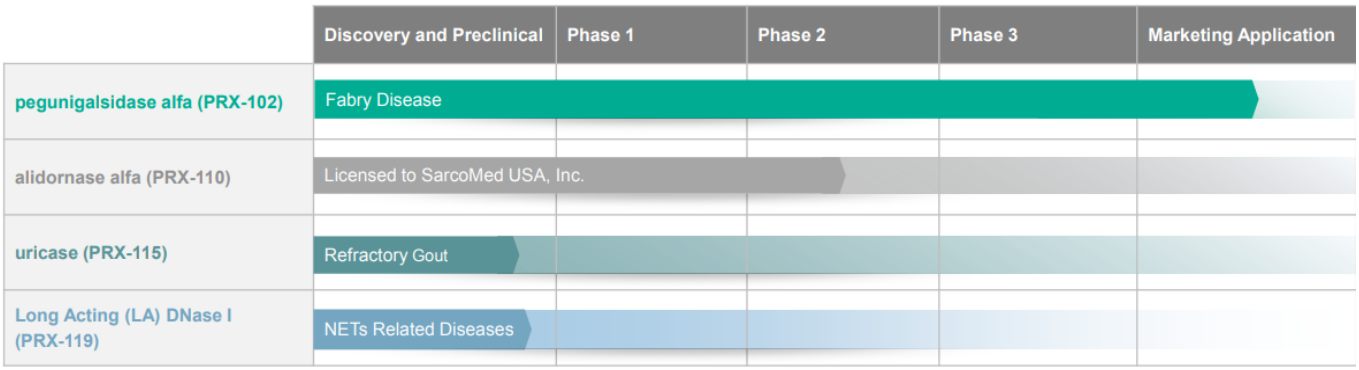
[7] Provided in FDA Label for Fabrazyme.
[8] Linthorst, G.E. *et al.* Enzyme therapy for Fabry disease: Neutralizing antibodies toward agalsidase alpha and beta. Kidney International; Volume 66, Issue 4, October 2004, Pages 1589-1595
[9] Source: Protalix Website. Accessed February 24, 2021. https://protalix.com/products/pegunigalsidase-alfa/

centration of 20 ng/mL at 10 hours post infusion. In addition, the area under the curve (AUC) for PRX-102 was measured to be approximately 2,000,000 ng hr/mL over 28 days. Based on published data, the AUC of Fabrazyme is approximately 10,000 ng hr/mL. The AUC is a measure of both the duration and magnitude that a patient is exposed to a therapy. A preliminary safety analysis of 19 patients enrolled in the BRIGHT study was also conducted and indicated that PRX-102 was well tolerated.

Topline results for BRIGHT revealed that the study had achieved key objectives in safety, efficacy and pharmacokinetics. 2 mg/kg monthly intravenous dosing was well tolerated among treated patients with 80% treated now for over two years. The enrolled patients maintained a stable clinical presentation. New patients did not develop treatment-induced anti-drug antibodies following switch to PRX-102. Of the 30 patients, 20 remained negative for anti-drug antibodies throughout the course of treatment. Four of the 10 patients who initially tested positive became negative at 12 months. All patients elected to enroll in the extension study suggesting patient satisfaction with the enzyme. The trial enrolled 30 adult patients, 26 male and six female, with 29 completing. 28 patients received the 2 mg/kg monthly as intended, with one patient switched to 1 mg/kg PRX-102 every two weeks according to protocol. The patient that withdrew from the study did so for reasons unrelated to the trial. Subjects received treatment at first under controlled conditions of the clinical site, but later at home as approved by the Investigator and Sponsor Medical Monitor. Upon completion, patients would receive 14 doses in total over the 13 four-week periods. Study outcomes revealed plasma lyso-GL-3 concentrations remained stable during the study with lyso-GL-3 concentrations increasing only 3.01 nM from baseline to week 52, 19.36 nM and 22.23 nM, respectively. Likewise, eGFR values were stable during the treatment period with mean change from baseline of -1.27 mL/min/1.73 $m^2$. Principal Investigator for the study, Dr. John Bernat, reported that patients had expressed satisfaction with the once per four-week dosing scheme, and that the treatment regimen had "potential to enable patients to maintain their clinical status while reducing their treatments by half."[10] Patients were also surveyed using the Quality of Life EQ-5D-5L questionnaire. Patient perception of their own health remained high and stable throughout the 52-week duration with overall health mean scores of 78.3 and 82.1 at baseline and week 52, respectively. The short-form Brief Pain Inventory questionnaire revealed that about 75% of participants had at least no change in average pain severity at week 52 compared to baseline. Interference items, a measure of the disease effect on daily activities, on the same questionnaire also remained stable during the study. Finally, Protalix reported that there were no Fabry clinical events during the study. Protalix expects final data on BRIGHT in 2H:21, and to present findings at an appropriate conference.

The positive data from the BRIGHT trial is supportive of the use of PRX-102 as a replacement for Fabrazyme and Replagal as it reduces the number of intravenous infusions needed while providing similar levels of efficacy and an improvement in eGFR slope.

**Exhibit III - Protalix Clinical Development Pipeline[11]**




[10] Protalix BioTherapeutics and Chiesi Global Rare Diseases Announce Positive Topline Results from BRIGHT Phase III Open-Label, Switch-Over Clinical Trial Evaluating Pegunigalsidase Alfa 2 mg/kg every Four Weeks for Treatment of Fabry Disease - Protalix BioTherapeutics
[11] Protalix Corporate Presentation March 2021

**Summary**

Since our recent initiation on Protalix, the company has provided several updates including closing almost $50 million in gross proceeds year to date, expanding a partnership with SarcoMed USA, announcing of final results from BRIDGE and providing topline data from BRIGHT. We also anticipate positive news from the FDA regarding approval of PRX-102 in the next month. Assuming FDA approval, sales of the enzyme should be underway by 2H:20. Below we summarize the key elements of our thesis:

- **PRX-102 target action date of April 27, 2021, subsequent approval and commercialization**
- **Potential for superiority vs market leader Fabrazyme**
- **Existing sales and royalty revenues from taliglucerase alfa**
- **Orphan indication for PRX-102**
- **Partnership with Chiesi for global commercialization of PRX-102 in Fabry Disease**
- **Rights to milestones and royalties**

We maintain our target price of $15.00 per share.

## PROJECTED FINANCIALS

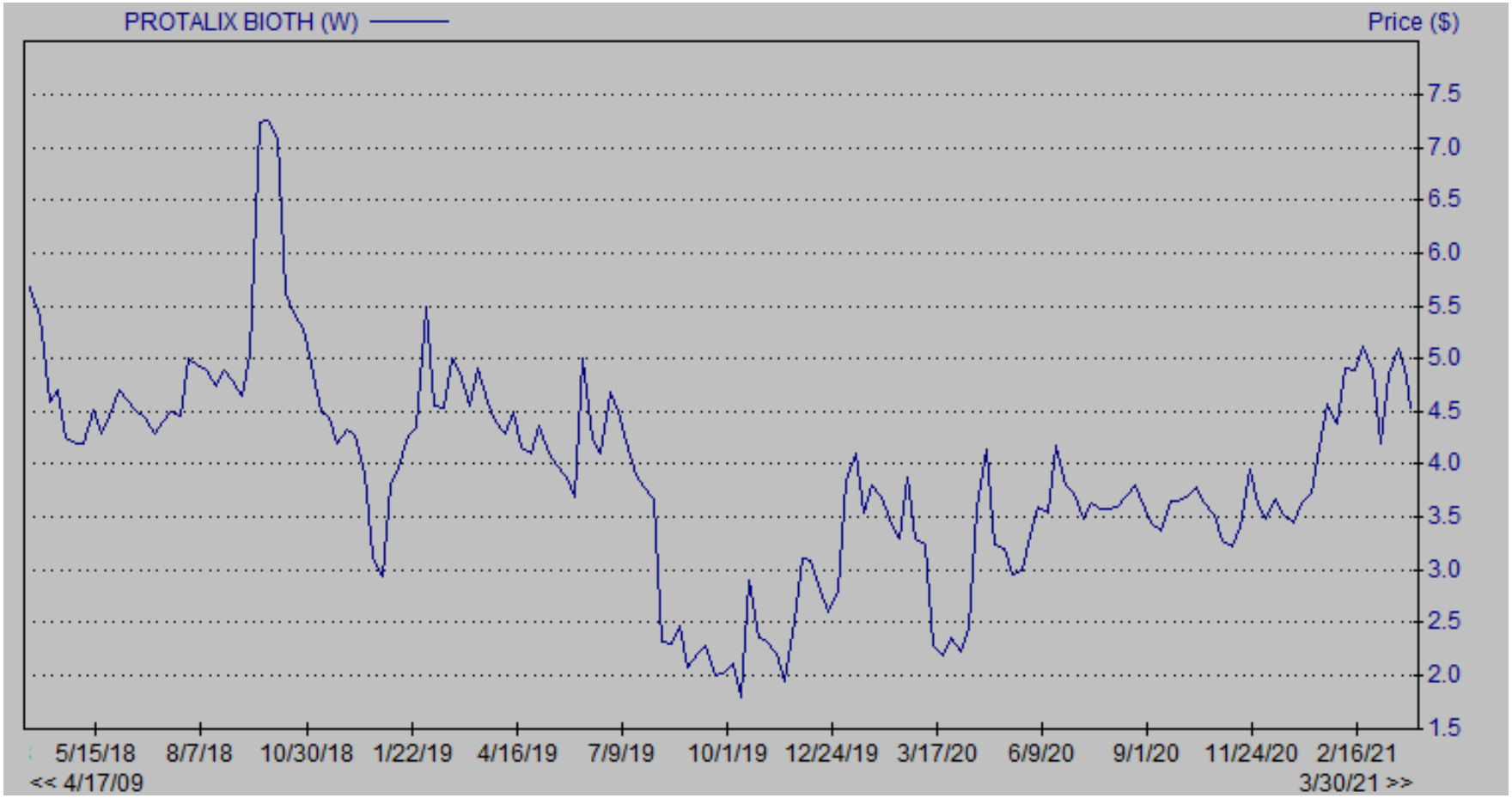
**Protalix Biotherapeutics, Inc. - Income Statement**

| Protalix Biotherapeutics | 2019 A | Q1 A | Q2 A | Q3 A | Q4 A | 2020 A | 2021 E | 2022 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues ($US '000)** | **$54,693** | **$21,646** | **$10,967** | **$10,790** | **$19,495** | **$62,898** | **$48,939** | **$78,417** |
| YOY Growth | 60% | 107% | -10% | -24% | 10% | 15% | -22% | 60% |
| Cost of Revenues | $10,895 | $3,426 | $1,827 | $2,868 | $2,752 | $10,873 | $11,339 | $12,638 |
| Research & Development | $44,616 | $10,340 | $9,186 | $7,688 | $10,953 | $38,167 | $19,400 | $15,000 |
| Selling, General & Admin | $9,899 | $3,187 | $2,194 | $2,816 | $2,951 | $11,148 | $11,457 | $10,510 |
| Income from operations | ($10,717) | $4,693 | ($2,240) | ($2,582) | $2,839 | $2,710 | $6,743 | $40,269 |
| Operating Margin | -20% | 22% | -20% | -24% | 15% | 4% | 14% | 51% |
| Financial Expenses | $7,966 | $3,229 | $1,948 | $1,973 | $2,521 | $9,671 | $7,350 | $0 |
| Financial Income | ($407) | ($203) | ($38) | ($118) | ($79) | ($438) | ($400) | ($200) |
| Pre-Tax Income | ($18,276) | $1,667 | ($4,150) | ($4,437) | $397 | ($6,523) | ($207) | $40,469 |
| **Net Income** | **($18,276)** | **$1,667** | **($4,150)** | **($4,437)** | **$397** | **($6,523)** | **($207)** | **$40,469** |
| Net Margin | -33% | 8% | -38% | -41% | 2% | -10% | 0% | 52% |
| **Reported EPS** | **($1.23)** | **$0.10** | **($0.13)** | **($0.14)** | **$0.01** | **($0.22)** | **($0.00)** | **$0.90** |
| Basic Shares Outstanding | 14,838 | 17,381 | 32,443 | 32,864 | 33,905 | 29,148 | 44,200 | 45,000 |

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

## HISTORICAL STOCK PRICE

**Protalix Biotherapeutics, Inc. – Share Price Chart**



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