UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 9, 2022

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-33357**	**65-0643773**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2 University Plaza Suite 100 Hackensack, NJ		**07601**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code 201-696-9345

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value	PLX	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On November 14, 2022, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022 and provided a business update on recent corporate and regulatory developments. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On November 14, 2022, the Company, together with its commercialization partner, Chiesi Global Rare Diseases, a business unit of the Chiesi Group, today announced the resubmission on November 9, 2022 of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for PRX-102 (pegunigalsidase alfa) for the treatment of adult patients with Fabry disease. Pegunigalsidase alfa is a purposefully-designed, long-acting recombinant, PEGylated, cross-linked α-galactosidase-A investigational product candidate. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated November 14, 2022 (Earnings Release)
99.2	Press Release dated November 14, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 14, 2022

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan
Name: Dror Bashan
Title: President and Chief Executive Officer

Protalix BioTherapeutics Reports Third Quarter 2022 Financial and Business Results

Company to host conference call and webcast today at 8:30 a.m. EST

CARMIEL, Israel, November 14, 2022 -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx® plant cell-based protein expression system, today reported financial results for the third quarter ended September 30, 2022 and provided a business update on recent corporate and regulatory developments.

"We are happy we have reached a significant milestone for our company with the recent BLA resubmission to the FDA," said Dror Bashan, Protalix's President and Chief Executive Officer. "We believe PRX-102, if approved, has the potential to significantly impact patients living with this rare, life-threatening genetic disease. As we approach potential approval and commercialization of PRX-102, we affirm our dedication to our mission of bringing new medicines to patients with serious diseases. We are grateful to our team members and external partners for their continued commitment to this program."

2022 Third Quarter and Recent Business Highlights

Regulatory Updates

- On November 9, 2022, the Company, together with its development and commercialization partner for PRX-102, Chiesi Farmaceutici S.p.A. ("Chiesi"), resubmitted a biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) for PRX-102 (pegunigalsidase alfa) for the treatment of adult patients with Fabry disease. The BLA re-submission included the final two year analyses of our phase III *BALANCE* clinical trial, which analyses were completed in July 2022, and long-term data from our open-label extension study of PRX-102 in adult patients treated with a 2 mg/kg every four weeks dosage of PRX 102. The initial BLA included a comprehensive set of preclinical, clinical and manufacturing data compiled from our completed phase I/II clinical trial of PRX 102, including the related extension study, interim clinical data from our phase III *BRIDGE* clinical trial and safety data from our on-going clinical studies of PRX 102 in adult patients receiving 1 mg/kg every two weeks.

Third Quarter 2022 Financial Highlights

- The Company recorded revenues from selling goods of $8.8 million during the three months ended September 30, 2022, an increase of $4.3 million, or 96%, compared to revenues of $4.5 million for the three months ended September 30, 2021. An increase of $3.4 million in sales to Pfizer Inc., resulting from timing differences, and an increase of $2.4 million in sales to Chiesi was partially offset by a decrease of $1.5 million in sales to Brazil resulting from timing differences.

- Revenue from licenses and R&D services for the three months ended September 30, 2022 were $5.4 million, a decrease of $2.1 million, or 28%, compared to revenues of $7.5 million for the three months ended September 30, 2021. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements.

- Cost of goods sold was $7.1 million for the three months ended September 30, 2022, an increase of $3.4 million, or 91%, from cost of goods sold of $3.7 million for the three months ended September 30, 2021. The increase in cost of goods sold was primarily the result of the increase in sales of goods.

- For the three months ended September 30, 2022, our total research and development expenses were approximately $7.4 million comprised of approximately $4.9 million in subcontractor-related expenses, approximately $1.7 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.6 million of other expenses. For the three months ended September 30, 2021, our total research and development expenses were approximately $7.3 million comprised of approximately $4.8 million in subcontractor-related expenses, approximately $1.6 million of salary and related expenses, approximately $0.1 million of materials-related expenses and approximately $0.8 million of other expenses. Total increase in research and developments expenses was $0.1 million, or 1%, for the three months ended September 30, 2022 compared to the three months ended September 30, 2021.

- Selling, general and administrative expenses were $2.8 million for the three months ended September 30, 2022, a decrease of $0.2 million, or 7%, compared to $3.0 million for the three months ended September 30, 2021. The decrease was primarily due to a decrease in salary related and selling costs.

- Financial expenses, net were $0.4 million for the three months ended September 30, 2022, compared to $2.3 million for the three months ended September 30, 2021. The decrease resulted primarily from lower interest and debt amortization costs due to a decrease in our outstanding notes from an aggregate principal amount of $57.92 million of 2021 Notes to an aggregate principal amount of $28.75 million of 2024 Notes, and an increase in the exchange rate of New Israeli Shekels for U.S. Dollars over the period.

- Cash, cash equivalents and short-term bank deposits were approximately $20.8 million at September 30, 2022.

- Net loss for the three months ended September 30, 2022 was approximately $3.6 million, or $0.07 per share, basic and diluted, compared to a net loss of approximately $4.2 million, or $0.09 per share, basic and diluted, for the same period in 2021.

Conference Call and Webcast Information

The Company will host a conference call today, November 14, 2022, at 8:30 a.m. Eastern Standard Time, to review the corporate and regulatory developments, which will also be available by webcast. To participate in the conference call, please dial the following numbers prior to the start of the call:

Conference Call Details:

Monday, November 14, 2022, 8:30 a.m. Eastern Standard Time (EST)
Domestic: 1-877-423-9813
International: 1-201-689-8573
Conference ID: 13734038

Webcast Details:

The conference will be webcast live from the Company's website and will be available via the following links:

Company Link: https://protalixbiotherapeutics.gcs-web.com/events0
Webcast Link: https://tinyurl.com/2s6sdx5e
Conference ID: 13734038

Please access the websites at least 15 minutes ahead of the conference to register, download and install any necessary audio software.

The conference call will be available for replay for two weeks on the Events Calendar of the Investors section of the Company's website, at the above link.

About Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx. Protalix was the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved by the FDA in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified stabilized version of the recombinant human α-Galactosidase-A protein for the treatment of Fabry disease; alidornase alfa or PRX-110, for the treatment of various human respiratory diseases or conditions; PRX-115, a plant cell-expressed recombinant PEGylated uricase for the treatment of severe gout; PRX-119, a plant cell-expressed long action DNase I for the treatment of NETs-related diseases; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "expect," "anticipate," "believe," "estimate," "project," "may," "plan," "will," "would," "should" and "intend," and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk and the final results of a clinical trial may be different than the preliminary findings for the clinical trial. Factors that might cause material differences include, among others: the risk that the FDA will find that the resubmitted BLA for PRX-102 is incomplete or not properly reviewable at the time of submission and, accordingly, refuse to file the resubmitted BLA or request additional information; risks related to the acceptance by the FDA of the resubmitted BLA for PRX-102, and the timing, progress and likelihood of final approval by the FDA and European Medicines Agency (EMA) of the resubmitted BLA and of a Marketing Authorization Application, respectively, for PRX-102 and, if approved, whether the use of PRX-102 will be commercially successful; likelihood that the FDA, EMA or other applicable health regulatory authorities will approve an alternative dosing regimen; risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; failure or delay in the commencement or completion of our preclinical studies and clinical trials for our other product candidates, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and inability to monitor patients adequately during or after treatment; the risk that the FDA, EMA, or other foreign regulatory authorities may not accept or approve a marketing application we file for any of our other product candidates, and other risks relating to the review process; risks associated with the novel coronavirus disease, or COVID-19, outbreak and variants, which may adversely impact our business, preclinical studies and clinical trials; risks related to any transactions we may effect in the public or private equity markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; the risk that the results of the clinical trials of our product candidates will not support the applicable claims of safety or efficacy, or that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks related to our ability to maintain and manage our relationship with our collaborators, distributors or partners; risks related to the

amount and sufficiency of our cash and cash equivalents and short-term bank deposits; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; risks relating to changes to interim, topline or preliminary data from clinical trials that we announce or publish; risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in our preparation and filing of applications for regulatory approval; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; risks related to our expectations with respect to the potential commercial value of our product and product candidates; and other factors described in our filings with the U.S. Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Investor Contact
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PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,720	$ 38,985
Short-term bank deposits	10,091	-
Accounts receivable – Trade	8,651	3,442
Other assets	1,736	1,285
Inventories	14,562	17,954
Total current assets	$ 45,760	$ 61,666
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,418	$ 2,077
Property and equipment, net	4,677	4,962
Operating lease right of use assets	4,854	4,960
Total assets	$ 56,709	$ 73,665
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,639	$ 6,986
Other	12,870	16,433
Operating lease liabilities	1,000	1,207
Contracts liability	14,793	8,550
Total current liabilities	$ 34,302	$ 33,176
LONG TERM LIABILITIES:		
Convertible notes	$ 28,111	$ 27,887
Contracts liability	-	11,790
Liability for employee rights upon retirement	1,779	2,472
Operating lease liabilities	4,031	4,376
Total long term liabilities	$ 33,921	$ 46,525
Total liabilities	$ 68,223	$ 79,701
COMMITMENTS		
CAPITAL DEFICIENCY	(11,514)	(6,036)
Total liabilities net of capital deficiency	$ 56,709	$ 73,665

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share amounts)
(Unaudited)

	Nine Months Ended		Three Months Ended	
	September 30, 2022	**September 30, 2021**	**September 30, 2022**	**September 30, 2021**
REVENUES FROM SELLING GOODS	$ 21,222	$ 12,260	$ 8,812	$ 4,506
REVENUES FROM LICENSE AND R&D SERVICES	17,799	17,541	5,371	7,548
TOTAL REVENUE	39,021	29,801	14,183	12,054
COST OF GOODS SOLD (1)	(17,195)	(13,201)	(7,074)	(3,703)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(23,732)	(22,093)	(7,386)	(7,282)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(8,613)	(9,263)	(2,848)	(2,954)
OPERATING LOSS	(10,519)	(14,756)	(3,125)	(1,885)
FINANCIAL EXPENSES	(1,879)	(6,613)	(639)	(2,410)
FINANCIAL INCOME	1,211	403	197	96
FINANCIAL EXPENSES, NET	(668)	(6,210)	(442)	(2,314)
OTHER INCOME	-	51	-	-
NET LOSS FOR THE PERIOD	$ (11,187)	$ (20,915)	$ (3,567)	$ (4,199)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.24)	$ (0.48)	$ (0.07)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	47,582,733	43,761,769	49,498,105	45,556,647
(1) Includes share-based compensation	$ 58	$ 217	$ 36	$ 65
(2) Includes share-based compensation	$ 275	$ 524	$ 114	$ 154
(3) Includes share-based compensation	$ 1,213	$ 1,216	$ 272	$ 344

Protalix BioTherapeutics and Chiesi Global Rare Diseases Announce Resubmission of Biologics License Application to U.S. Food and Drug Administration for Pegunigalsidase Alfa for the Treatment of Fabry Disease

CARMIEL, Israel and **BOSTON**, November 14, 2022 /PRNewswire/Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx® plant cell based protein expression system, and Chiesi Global Rare Diseases, a business unit of the Chiesi Group established to deliver innovative therapies and solutions for people affected by rare diseases, today announced the resubmission on November 9, 2022 of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for PRX-102 (pegunigalsidase alfa) for the treatment of adult patients with Fabry disease. Pegunigalsidase alfa is a purposefully-designed, long-acting recombinant, PEGylated, cross-linked α-galactosidase-A investigational product candidate.

The BLA resubmission includes a comprehensive set of clinical and manufacturing data. The data were compiled from studies that involved more than 140 Fabry disease patients with up to five years of follow up including all three completed studies in the PRX-102 Phase III clinical program including the BALANCE study, the BRIDGE study and the BRIGHT study, as well as the phase I/II clinical trial of PRX-102. The phase I/II data includes data compiled from the related extension study succeeding the phase I/II study. The BLA resubmission also includes safety data compiled from the ongoing phase III extension studies of PRX-102. If approved, Protalix will be eligible to receive a milestone payment from Chiesi upon BLA approval.

Protalix and Chiesi anticipate that the FDA will complete its review of the resubmission within six months of receipt.

“The resubmission of the BLA represents a significant milestone for Protalix and we believe it has meaningful potential for patients and families affected by Fabry disease. Fabry disease is a serious, life-threatening, rare genetic disorder, the ultimate consequences of which range from episodes of pain and impaired peripheral sensation to end-organ failure, particularly of the kidneys, but also of the heart and the cerebrovascular system,” said Dror Bashan, Protalix’s President and Chief Executive Officer. “Together with Chiesi, we are committed to continuing to work with the FDA toward our goal of achieving regulatory approval and making PRX-102 available to patients with this rare disease in the United States.”

The European Medicines Agency (EMA) is currently reviewing the marketing authorization application for PRX-102, and interactions with the EMA are ongoing.

“Many people who are living with Fabry disease still have existing unmet needs including access to treatment and the burden of regular infusions, and we believe it is important to deliver a potential new treatment option,” said Giacomo Chiesi, head of Chiesi Global Rare Diseases. “Together with Protalix, we thank the investigators and study participants who have made reaching this milestone possible and have supported our joint commitment to bringing this new treatment option to the Fabry patient community.”

About Fabry Disease

Fabry disease is an X-linked inherited disease that results from deficient activity of the lysosomal α-Galactosidase-A enzyme resulting in progressive accumulation of abnormal deposits of a fatty substance called

globotriaosylceramide (Gb_3) in blood vessel walls throughout a person's body. Fabry disease occurs in one person per 40,000 to 60,000. Fabry patients inherit a deficiency of the α-Galactosidase-A enzyme, which is normally responsible for the breakdown of Gb_3. The abnormal storage of Gb_3 increases with time and, accordingly, Gb_3 accumulates, primarily in the blood and in the blood vessel walls. The ultimate consequences of Gb_3 deposition range from episodes of pain and impaired peripheral sensation to end-organ failure – particularly of the kidneys, but also of the heart and the cerebrovascular system.

About PRX-102

PRX-102 (pegunigalsidase alfa) is an investigational, plant cell culture-expressed, and chemically modified stabilized version of the recombinant α-Galactosidase-A enzyme. It is a novel, PEGylated enzyme replacement therapy (ERT) under development for the treatment of Fabry disease. 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 been observed to have a circulatory half-life of approximately 80 hours. The Company designed PRX-102 to potentially address the continued unmet clinical need in Fabry patients.

About Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx. Protalix was the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved by the FDA in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified stabilized version of the recombinant human α Galactosidase A protein for the treatment of Fabry disease; alidornase alfa or PRX-110, for the treatment of various human respiratory diseases or conditions; PRX-115, a plant cell-expressed recombinant PEGylated uricase for the treatment of severe gout; PRX-119, a plant cell-expressed long action DNase I for the treatment of NETs-related diseases; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

About Chiesi Global Rare Diseases

Chiesi Global Rare Diseases is a business unit of the Chiesi Group established to deliver innovative therapies and solutions for people affected by rare diseases. As a family business, Chiesi Group strives to create a world where it is common to have a therapy for all diseases and acts as a force for good, for society and the planet. The goal of the Global Rare Diseases unit is to ensure equal access so as many people as possible can experience their most fulfilling life. The unit collaborates with the rare disease community around the globe to bring voice to underserved people in the health care system. For more information visit www.chiesirarediseases.com.

About Chiesi Group

Based in Parma, Italy, Chiesi is an international research-focused pharmaceuticals and healthcare group with over 85 years' experience, operating in 30 countries with more than 6,000 employees (Chiesi Group). To

achieve its mission of improving people's quality of life by acting responsibly towards society and the environment, the Group researches, develops and markets innovative therapeutic solutions in its three focus areas: AIR (products and services that promote respiration, from new-born to adult populations), RARE (treatment for patients with rare and ultra-rare diseases) and CARE (products and services that support specialty care and consumer-facing self-care). The Group's Research and Development center is based in Parma and works alongside 6 other important research and development hubs in France, the U.S., Canada, China, the UK, and Sweden to pursue its pre-clinical, clinical, and regulatory programs. In 2018 Chiesi has changed its legal status to a Benefit Corporation, according to the law in Italy, USA and, more recently, in France, by incorporating common benefit objectives into its bylaws, to generate value for its business, for the society and the environment. Since 2019, Chiesi has been the world's largest B Corp certified pharmaceutical group. B Corps are global leaders convinced to leverage business as a force for good. Moreover, as a Benefit Corporation, Chiesi Farmaceutici S.p.A. is required by law to report annually in a transparent way about its progress in achieving the common benefits objectives it has set forward. The Group is committed to becoming carbon neutral by the end of 2035.

For more information, please visit www.chiesi.com.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "expect," "anticipate," "believe," "estimate," "project," "may," "plan," "will," "would," "should" and "intend," and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk and the final results of a clinical trial may be different than the preliminary findings for the clinical trial. Factors that might cause material differences include, among others: risks related to the timing, progress and likelihood of final approval by the FDA and European Medicines Agency (EMA) of the resubmitted Biologics License Application (BLA) and of a Marketing Authorization Application, respectively, for PRX-102 and, if approved, whether the use of PRX-102 will be commercially successful; likelihood that the FDA, EMA or other applicable health regulatory authorities will approve an alternative dosing regimen; failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and inability to monitor patients adequately during or after treatment; delays in the approval or potential rejection of any applications we file with the FDA, EMA or other health regulatory authorities for our other product candidates, and other risks relating to the review process; risks associated with the novel coronavirus disease, or COVID-19, outbreak, which may adversely impact our business, preclinical studies and clinical trials; risks related to any transactions we may effect in the public or private equity markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; the risk that the results of the clinical trials of our product candidates will not support the applicable claims of safety or efficacy, or that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks related to our ability to maintain and manage our relationship with our collaborators, distributors or partners; risks related to the amount and sufficiency of our cash, cash equivalents and short-term deposits; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in our preparation and filing of applications for regulatory approval; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies

and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; and other factors described in our filings with the U.S. Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

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Source: Protalix BioTherapeutics, Inc.

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