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): February 27, 2023

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 February 27, 2023, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 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 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated February 27, 2023
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: February 27, 2023

PROTALIX BIOTHERAPEUTICS, INC.

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

PROTALIX Biotherapeutics

Protalix BioTherapeutics Reports Fiscal Year 2022 Financial and Business Results

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

CARMIEL, Israel, February 27, 2023 /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, today reported financial results for the fiscal year ended December 31, 2022 and provided a business update on recent corporate and regulatory developments.

"We are proud to have had a productive 2022 and start to 2023, culminating in the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) positive opinion recommending marketing authorization for PRX-102 for adult patients with Fabry disease," said Dror Bashan, Protalix's President and Chief Executive Officer. "We completed the pivotal parts of our PRX-102 phase III clinical program this year with the closeout of the BRIGHT and BALANCE trials, forming the basis for regulatory submissions to the EMA and U.S. Food and Drug Administration (FDA), both of which were accepted for review. Patients from the various trials remain under treatment with PRX-102 in two different open-label extension studies; 1 mg/kg every two weeks or 2 mg/kg every four weeks."

"As we move into 2023, we anticipate a significant year for the company, with potential regulatory approvals in both Europe and the United States anticipated in May 2023, as well as continued advancement of our early-stage pipeline. We are grateful for the dedication of our team and global partners who are critical in enabling us to work towards our mission of delivering new medicines to patients with high unmet needs."

2022 Full Year and Recent Business Highlights

Regulatory Advancements

- On February 24, 2023, the Company, together with its development and commercialization partner for PRX-102, Chiesi Global Rare Diseases (Chiesi), announced that the EMA's CHMP has adopted a positive opinion, recommending marketing authorization for PRX-102 (pegunigalsidase alfa) for adult patients with Fabry disease. The positive opinion was based on a marketing authorization application (MAA) submitted to the EMA on February 7, 2022. The MAA included final data from the Company's phase III BRIDGE and BRIGHT clinical trials; 12–month interim data from the Company's phase III BALANCE clinical trial; and final data from the Company's phase I/II clinical trial from naïve/untreated patients, including the related extension study, using 1 mg/kg every two weeks dosing. Data from the 24-month final analysis of the phase III BALANCE clinical trial was submitted to the EMA during the review period. The CHMP opinion is now referred for final action to the European Commission (EC). A final EC decision on the MAA is anticipated in the beginning of May 2023.

- On December 5, 2022, the Company, together with Chiesi, announced the acceptance by the FDA of a resubmitted biologics license application (BLA) for PRX-102 for the treatment of adult patients with Fabry disease. The FDA indicated in the BLA filing communication letter that the resubmitted BLA was considered a complete, class 2 response and set an action date of May 9, 2023, under the Prescription Drug User Fee Act (PDUFA). The BLA was resubmitted on November 9, 2022 and included a comprehensive set of clinical and manufacturing data compiled from all three of the Company's completed studies in its PRX-102 phase III clinical program, the BALANCE, BRIDGE and BRIGHT studies, as well as from the Company's phase I/II clinical trial of PRX-102. The

resubmission also included safety data from the ongoing phase III extension studies. If approved, the Company will be eligible to receive a milestone payment from Chiesi.

Clinical Advancements

- On August 15, 2022, the Company, together with Chiesi, announced positive final results from the BALANCE study, a phase III, 24-month, randomized, double-blind, active control study designed to evaluate the efficacy and safety of 1 mg/kg of PRX-102 administered every two weeks compared to agalsidase beta in patients previously treated with agalsidase beta for at least one year. The study met its primary endpoint and demonstrated that PRX-102 was statistically non-inferior to agalsidase beta, as measured by estimated glomerular filtration rate (eGFR) slope. In addition, results showed a favorable tolerability profile for PRX-102, consistent with results from the Company's prior trials.

- On March 18, 2022, the Company, together with Chiesi, announced positive final results from the BRIGHT study, a phase III, multicenter, multinational open-label, switch-over study designed to evaluate the safety, efficacy and pharmacokinetics of treatment with 2 mg/kg of PRX-102 administered every four weeks for 52 weeks (a total of 14 infusions) in adult patients previously treated with a commercially available enzyme replacement therapy (ERT) (agalsidase alfa or agalsidase beta). Results of the BRIGHT study indicate that PRX-102 was well tolerated, and Fabry disease assessed by eGFR slope and plasma lyso-Gb_3 was stable throughout PRX-102 treatment in adult Fabry patients.

Corporate Developments

- On December 21, 2022, the Company announced the voluntarily delisting of its common stock from the Tel Aviv Stock Exchange (TASE). The delisting will take effect on March 22, 2023, and the last trading date on the TASE is March 20, 2023.

- On December 5, 2022, the Company hosted a key opinion leader (KOL) webinar featuring Myrl D. Holida, PA C, University of Iowa Stead Family Children's Hospital, who discussed the robust PRX-102 clinical program.

- On June 30, 2022, the Company announced the appointment of Shmuel "Muli" Ben Zvi, Ph.D. to the Board of Directors. Dr. Ben Zvi is serving as the new Chairman of the Audit Committee and as a member of the Compensation Committee.

Financial Results

For the year ended December 31, 2022, compared to the year ended December 31, 2021

- The Company recorded revenues from selling goods of $25.3 million for the year ended December 31, 2022, an increase of $8.6 million, or 51%, compared to revenues of $16.7 million for the year ended December 31, 2021. The increase resulted from an increase of $2.2 million in sales to Pfizer Inc., an increase of $3.1 million in sales to Brazil and an increase of $3.3 million in sales to Chiesi.

- Revenue from licenses and R&D services for the year ended December 31, 2022 were $22.3 million, an increase of $0.7 million, or 3%, compared to revenues of $21.6 million for the year ended December 31, 2021. Revenues from license and R&D services represent mainly the revenues the Company recognized in connection with its license and supply agreements with Chiesi.

- Cost of goods sold for the year ended December 31, 2022 was $19.6 million, an increase of $3.3 million, or 20%, compared to cost of goods sold of $16.3 million for the year ended December 31, 2021. The increase in cost of goods sold was primarily the result of the increase in sales of goods.

- Total research and development expenses for the year ended December 31, 2022 were approximately $29.3 million, comprised of approximately $17.8 million in subcontractor-related expenses, approximately $7.3 million of salary and related expenses, approximately $1.4 million of materials-related expenses and approximately $2.8 million of other expenses. For the year ended December 31, 2021, the Company's total research and development expenses were approximately $29.7 million comprised of approximately $18.4 million in subcontractor-related expenses, approximately $7.4 million of salary and related expenses, approximately $1.2 million of materials-related expenses and approximately $2.7 million of other expenses. The decrease in research and developments expenses of $0.4 million, or 1%, for the year ended December 31, 2022 compared to the year ended December 31, 2021 resulted primarily from a $0.6 million decrease in subcontractor-related expenses in connection with the Company's PRX-102 clinical trials, partially offset by a $0.2 million increase in materials-related expenses.

- Selling, general and administrative expenses were $11.7 million for the year ended December 31, 2022, a decrease of $1.0 million, or 8%, from $12.7 million for the year ended December 31, 2021. The decrease resulted primarily from a decrease in professional fees and salary related expenses.

- Financial expense, net was $1.4 million for the year ended December 31, 2022, a decrease of $5.7 million, or 80%, compared to financial expenses of $7.1 million for the year ended December 31, 2021. The decrease resulted primarily from lower interest and debt amortization costs due to a decrease in the Company's outstanding notes from an aggregate principal amount of $57.92 million of convertible notes due in 2021 to an aggregate principal amount of $28.75 million of convertible notes due in 2024, and an increase in the exchange rate of New Israeli Shekels for U.S. Dollars over the period.

- For the year ended December 31, 2022, the Company recorded income taxes of approximately $530,000. The Company did not record income taxes for the year ended December 31, 2021. The income taxes were recorded for 2022 as certain sections regarding the deductibility of research and development expenses of the U.S. Tax Cuts and Jobs Act of 2017 went into effect on January 1, 2022.

- Cash, cash equivalents and short-term bank deposits were approximately $22.2 million at December 31, 2022.

- Net loss for the year ended December 31, 2022 was approximately $14.9 million, or $0.31 per share, basic and diluted, compared to a net loss of $27.6 million, or $0.62 per share, basic and diluted, for the year ended December 31, 2021.

Conference Call and Webcast Information

The Company will host a conference call today, February 27, 2023 at 8:30 am EST, to review the financial results and provide an update on recent corporate and regulatory developments, which will also be available by webcast. To participate in the conference call, please dial the following numbers or access the following websites prior to the start of the call:

Conference Call Details:

Date:	Monday, February 27, 2023
Time:	8:30 a.m. Eastern Standard Time (EST)
Toll Free (U.S.):	1-877-423-9813
International:	1-201-689-8573
Conference ID:	13736250

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: Registration – https://tinyurl.com/5n6rtnhw_
Conference ID: 13736250

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; 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: risks related to the timing, progress and likelihood of final approval by the European Medicines Agency (EMA) of the Marketing Authorization Application; the risk that the U.S. Food and Drug Administration (FDA) might not grant marketing approval for PRX-102 by the PDUFA date or at all, and other risks related to the timing, progress and likelihood of final approval by the FDA of the PRX-102 Biologics License Application (BLA); the risk that a marketing approval of PRX-102 by either the FDA or the EMA will be conditioned on significant limitations on its use; risks related to the commercial success of PRX-102, and of our other product and product candidates, if approved; the 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 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, 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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PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31, 2021	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 38,985	$ 17,111
Short-term bank deposits	-	5,069
Accounts receivable – Trade	3,442	4,586
Other assets	1,285	1,310
Inventories	17,954	16,804
Total current assets	$ 61,666	$ 44,880
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 2,077	$ 1,267
Property and equipment, net	4,962	4,553
Operating lease right of use assets	4,960	5,087
Total assets	$ 73,665	$ 55,787
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,986	$ 5,862
Other	16,433	12,271
Operating lease liabilities	1,207	1,118
Contracts liability	8,550	13,178
Total current liabilities	$ 33,176	$ 32,429
LONG TERM LIABILITIES:		
Convertible notes	$ 27,887	$ 28,187
Contracts liability	11,790	-
Liability for employee rights upon retirement	2,472	1,642
Operating lease liabilities	4,376	4,169
Total long term liabilities	$ 46,525	$ 33,998
Total liabilities	$ 79,701	$ 66,427
COMMITMENTS		
CAPITAL DEFICIENCY		
Common Stock, $0.001 par value: Authorized - as of December 31, 2021 and 2022, 120,000,000 and 144,000,000 shares, respectively; issued and outstanding - as of December 31, 2021 and 2022, 45,556,647 and 53,790,167 shares, respectively	46	54
Additional paid-in capital	368,852	379,167
Accumulated deficit	(374,934)	(389,861)
Total capital deficiency	(6,036)	(10,640)
Total liabilities net of capital deficiency	$ 73,665	$ 55,787

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

	Year Ended December 31,		
	2020	2021	2022
REVENUES FROM SELLING GOODS	$ 16,236	$ 16,749	$ 25,292
REVENUES FROM LICENSE AND R&D SERVICES	46,662	21,601	22,346
TOTAL REVENUE	62,898	38,350	47,638
COST OF GOODS SOLD	(10,873)	(16,349)	(19,592)
RESEARCH AND DEVELOPMENT EXPENSES	(38,167)	(29,734)	(29,349)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(11,148)	(12,729)	(11,711)
OPERATING INCOME (LOSS)	2,710	(20,462)	(13,014)
FINANCIAL EXPENSES	(9,671)	(7,521)	(2,529)
FINANCIAL INCOME	438	401	1,146
FINANCIAL EXPENSES, NET	(9,233)	(7,120)	(1,383)
LOSS BEFORE TAXES ON INCOME	(6,523)	(27,582)	(14,397)
TAXES ON INCOME			(530)
NET LOSS FOR THE YEAR	$ (6,523)	$ (27,582)	$ (14,927)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.22)	$ (0.62)	$ (0.31)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	29,148,047	44,140,233	48,472,159