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): May 4, 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 May 4, 2023, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023 and provided a business update on recent regulatory, clinical and corporate 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 May 4, 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: May 4, 2023

PROTALIX BIOTHERAPEUTICS, INC.

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

PROTALIX Biotherapeutics

Protalix BioTherapeutics Reports First Quarter 2023 Financial and Business Results

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

CARMIEL, Israel, May 4, 2023 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: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 first quarter ended March 31, 2023 and provided a business update on recent regulatory, clinical and corporate developments.

"While we are awaiting for the European Commission and the U.S. Food and Drug Administration decisions, we and our partner, Chiesi, remain committed to bringing PRX-102 to market and improving the lives of patients with Fabry disease," said Dror Bashan, Protalix's President and Chief Executive Officer. "In addition, we are making progress in our early stage PRX-115 program in severe gout with the initiation of our first-in-human Phase I clinical trial."

2023 First Quarter 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 Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) had 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 was referred for final action to the European Commission.

Clinical Developments

- On March 27, 2023, the Company announced that the first patient was dosed in a First in Human (FIH) phase I clinical trial of PRX-115, the Company's recombinant PEGylated uricase product candidate under development as a potential treatment for severe gout. The FIH trial is a double-blind, placebo-controlled, single ascending dose study designed to evaluate the safety, pharmacokinetics, pharmacodynamics and immunogenicity of PRX-115 in approximately 56 patients with elevated uric acid levels (>6.0 mg/dL) and no previous exposure to PEGylated uricase. The study is being conducted at New Zealand Clinical Research (NZCR) under the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) and the Health and Disability Ethics Committee (HDEC) guidelines.

Corporate Developments

- On March 22, 2023, the Company's request for a voluntary delisting of the Company's common stock from the Tel Aviv Stock Exchange ("TASE") took effect. The last trading day on the TASE was March 20, 2023.

First Quarter 2023 Financial Highlights

- The Company recorded revenues from selling goods of $5.1 million during the three months ended March 31, 2023, a decrease of $3.9 million, or 43%, compared to revenues of $9.0 million for the three months ended March 31, 2022. The decrease resulted primarily from a decrease of $2.7 million in sales to Brazil and a decrease of $1.1 million in sales to Pfizer, both resulting from timing differences.

- The Company recorded revenues from license and R&D services of $4.5 million for the three months ended March 31, 2023, a decrease of $2.6 million, or 37%, compared to revenues of $7.1 million for the three months ended March 31, 2022. Revenues from license and R&D services are comprised primarily of revenues the Company recognized in connection with the Chiesi Agreements.

- Cost of goods sold was $3.1 million for the three months ended March 31, 2023, a decrease of $2.9 million, or 48%, from cost of goods sold of $6.0 million for the three months ended March 31, 2022. The decrease in cost of goods sold was primarily the result of the decrease in sales of goods.

- For the three months ended March 31, 2023, the Company's total research and development expenses were approximately $5.8 million comprised of approximately $3.5 million in subcontractor-related expenses, approximately $1.5 million of salary and related expenses, approximately $0.1 million of materials-related expenses and approximately $0.7 million of other expenses. For the three months ended March 31, 2022, the Company's total research and development expenses were approximately $8.8 million comprised of approximately $5.8 million in subcontractor-related expenses, approximately $2.0 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.8 million of other expenses. Total decrease in research and developments expenses was $3.0 million, or 34%, for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. The decrease in research and development expenses primarily resulted from the completion of the Company's Fabry clinical program and of a substantial portion of the regulatory processes related to the Biologics License Application resubmission (BLA) and MAA submission for PRX-102.

- Selling, general and administrative expenses were $3.1 million for the three months ended March 31, 2023, a decrease of $0.1 million, or 3%, compared to $3.2 million for the three months ended March 31, 2022. A decrease of approximately $0.4 million in salary and related expenses was partially offset by an increase of $0.3 million in professional fees.

- Financial expenses, net were $0.5 million for the three months ended March 31, 2023, compared to financial expenses, net of $0.4 million for the three months ended March 31, 2022.

- In the three months ended March 31, 2023, the Company recorded income taxes of approximately $0.2 million. Income taxes were recorded as Section 174 of the U.S. Tax Cuts and Jobs Act of 2017 went into effect on January 1, 2022.

- Cash and cash equivalents were approximately $33.0 million at March 31, 2023.

- Net loss for the three months ended March 31, 2023 was approximately $3.1 million, or $0.05 per share, basic and diluted, compared to a net loss of $2.3 million, or $0.05 per share, basic and diluted, for the same period in 2022.

Conference Call and Webcast Information

The Company will host a conference call today, May 4, 2023 at 8:30 am EDT, to review the regulatory, clinical and corporate 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:

Date:	Thursday, May 4, 2023
Time:	8:30 a.m. Eastern Daylight Time (EDT)
Toll Free (U.S.):	1-800-954-0653
International:	1-212-231-2918
Conference ID:	22026736

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/4ye3uhu5
Conference ID: 22026736

Please access the websites at least 15 minutes ahead of the conference call 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. It is 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. This unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa, Protalix's first product manufactured through ProCellEx, excluding in 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 EMA of the PRX-102 MAA or by the FDA of the resubmitted PRX-102 BLA by the PDUFA action date, if at all, and, if approved, whether either the EMA or the FDA will impose significant limitations on the use of PRX-102; risks related to, if approved, the commercialization of PRX-102 or that PRX-102's revenue, expenses and costs may not be as expected; risks relating to PRX-102's market acceptance, competition, reimbursement and regulatory actions, if approved; risks related to our commercialization partner's ability to obtain and

maintain reimbursement for PRX-102 if approved, and the extent to which patient assistance programs and co-pay programs are utilized; the likelihood that the FDA, EMA or other applicable health regulatory authorities will approve an alternative dosing regimen for PRX-102; risks related to the commercial success of Protalix's other product and product candidates, if approved; failure or delay in the commencement or completion of our preclinical studies and clinical trials of 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; delays in the approval or potential rejection of any applications we file with the FDA, EMA or other health regulatory authorities for our 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 the amount and sufficiency of our cash and cash equivalents; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	March 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,036	$ 17,111
Short-term bank deposits	—	5,069
Accounts receivable – Trade	1,304	4,586
Other assets	758	1,310
Inventories	20,303	16,804
Total current assets	$ 55,401	$ 44,880
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,252	$ 1,267
Property and equipment, net	4,704	4,553
Operating lease right of use assets	5,202	5,087
Total assets	$ 66,559	$ 55,787
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,105	$ 5,862
Other	13,471	12,271
Operating lease liabilities	1,149	1,118
Contracts liability	11,790	13,178
Total current liabilities	$ 31,515	$ 32,429
LONG TERM LIABILITIES:		
Convertible notes	$ 28,267	$ 28,187
Liability for employee rights upon retirement	1,617	1,642
Operating lease liabilities	4,152	4,169
Total long term liabilities	$ 34,036	$ 33,998
Total liabilities	$ 65,551	$ 66,427
COMMITMENTS		
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	1,008	(10,640)
Total liabilities and stockholders' equity (net of capital deficiency)	$ 66,559	$ 55,787

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

	Three Months Ended	
	March 31, 2023	**March 31, 2022**
REVENUES FROM SELLING GOODS	$ 5,066	$ 9,028
REVENUES FROM LICENSE AND R&D SERVICES	4,522	7,057
TOTAL REVENUE	9,588	16,085
COST OF GOODS SOLD (1)	(3,085)	(6,034)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(5,847)	(8,767)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(3,115)	(3,154)
OPERATING LOSS	(2,459)	(1,870)
FINANCIAL EXPENSES	(649)	(618)
FINANCIAL INCOME	172	202
FINANCIAL EXPENSES, NET	(477)	(416)
LOSS BEFORE TAXES ON INCOME	(2,936)	(2,286)
TAXES ON INCOME	(195)	-
NET LOSS FOR THE PERIOD	$ (3,131)	$ (2,286)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.05)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	57,480,009	45,843,563
(1) Includes share-based compensation	$ 58	$ (6)
(2) Includes share-based compensation	$ 180	$ 76
(3) Includes share-based compensation	$ 308	$ 766