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): August 7, 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 August 7, 2023, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 7, 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: August 7, 2023

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Second Quarter 2023 Financial and Business Results

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

CARMIEL, Israel, August 7, 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 second quarter ended June 30, 2023 and provided a business update on recent regulatory, clinical and corporate developments.

“2023 has been a transformational year for Protalix thus far,” said Dror Bashan, Protalix’s President and Chief Executive Officer. “We are very proud to have received regulatory approval for Elfabrio® in both the United States and the European Union, a significant milestone for adult Fabry disease patients and their families alike. Our commercial partner, Chiesi Global Rare Diseases, has the expertise and global reach to maximize the potential of Elfabrio, and Chiesi has already launched the product in the United States. As the second approved drug from our proprietary platform, this approval not only validates our recombinant protein expression platform but also our strong clinical and regulatory expertise in rare diseases. We now turn our focus to strengthening our rare disease pipeline programs and building a sustainable portfolio. We extend our gratitude to our team and dedicated partners for their commitment to our programs and more importantly to patients in need.”

2023 Second Quarter and Recent Business Highlights

Regulatory Advancements

The Company, together with its development and commercialization partner, Chiesi Global Rare Diseases (Chiesi), a business unit of the Chiesi Group, announced that Elfabrio® (pegunigalsidase alfa) received regulatory approval in both the United States (U.S.) and European Union (EU) for the treatment of adult patients with Fabry disease in the 1 mg\kg every two weeks dosage. Elfabrio, a PEGylated enzyme replacement therapy (ERT), is a recombinant human α–Galactosidase–A enzyme expressed in plant-cell culture that is designed to provide a long half-life.

- On May 5, 2023, the European Commission (EC) granted marketing authorization to Elfabrio (pegunigalsidase alfa) in the European Union.
- On May 10, 2023, the U.S. Food and Drug Administration (FDA) approved Elfabrio (pegunigalsidase alfa-iwxj) in the U.S. for the treatment of adult patients with Fabry disease.

Clinical Developments

- The Company’s First in Human (FIH) phase I clinical trial of PRX–115, a recombinant PEGylated uricase product candidate under development as a potential treatment for severe gout, continues to advance. To date, 16 patients have been dosed in the trial. 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

- During the three months ended June 30, 2023, the Company announced that it is eligible to receive a $20 million milestone payment from Chiesi Global Rare Diseases. The milestone payment was triggered by the FDA's approval of Elfabrio for the treatment of adult patients with Fabry disease.

- On June 26, 2023, the Company was included in the broad-market Russell 3000® Index at the conclusion of the 2023 Russell indexes annual reconstitution. Annual Russell indexes reconstitution captures the 4,000 largest US stocks as of April 28, 2023 ranked by total market capitalization. Membership in the US all-cap Russell 3000® Index, which remains in place for one year, means automatic inclusion in the large-cap Russell 1000® Index or small-cap Russell 2000® Index as well as the appropriate growth and value style indexes.

- On June 27, 2023, the Company hosted a key opinion leader (KOL) event highlighting the recent FDA approval of Elfabrio in the United States. The event featured presentations from Ankit Mehta, MD, FASN (Baylor University Medical Center), who discussed the opportunity for Elfabrio to address unmet needs in Fabry disease, and Giacomo Chiesi, Head of Chiesi Global Rare Diseases, who discussed Chiesi's commercial capabilities. Protalix leadership also provided insight into the Company's strategy and future plans. Access to a replay of the event is available at the following site: https://lifescievents.com/event/protalix/.

Second Quarter 2023 Financial Highlights

- The Company recorded revenues from selling goods of $15.1 million during the three months ended June 30, 2023, an increase of $11.7 million, or 344%, compared to revenues of $3.4 million for the three months ended June 30, 2022. The increase resulted primarily from an increase of $11.7 million in sales to Chiesi, following the approvals by the FDA and the European Medicines Agency (EMA) of Elfabrio.

- The Company recorded revenues from license and R&D services of $20.0 million for the three months ended June 30, 2023, an increase of $14.6 million, or 270%, compared to revenues of $5.4 million for the three months ended June 30, 2022. The increase resulted from the $20.0 million regulatory milestone payment from Chiesi in connection with the FDA approval of Elfabrio. 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 $6.1 million for the three months ended June 30, 2023 an increase of $2.0 million, or 49%, from cost of goods sold of $4.1 million for the three months ended June 30, 2022. The increase in cost of goods sold was primarily the result of the increase in sales of Elfabrio drug substance to Chiesi and royalties payable to the Israel Innovation Authority in connection with the Chiesi agreements.

- For the three months ended June 30, 2023, the Company's total research and development expenses were approximately $4.5 million comprised of approximately $1.7 million in subcontractor-related expenses, approximately $2.0 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 June 30, 2022, our total research and development expenses were approximately $7.6 million comprised of approximately $4.4 million in subcontractor-related expenses, approximately $1.6 million of salary and related expenses, approximately $0.7 million of materials-related expenses and approximately $0.9 million of other expenses. Total decrease in research and developments expenses was $3.1 million, or 41%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. The decrease in research and development expenses primarily resulted from the completion of our Fabry clinical program and the regulatory processes related to the Biologics License Application (BLA) and Marketing Authorization Application (MAA) review of Elfabrio by the applicable regulatory agencies.

- Selling, general and administrative expenses were $4.0 million for the three months ended June 30, 2023, an increase of $1.4 million, or 54%, compared to $2.6 million for the three months ended June 30, 2022. The increase resulted primarily from an increase of approximately $1.2 million in salary and related expenses due to one-time cash bonuses.

- Financial expenses, net were $0.8 million for the three months ended June 30, 2023, compared to financial income, net of $0.2 million for the three months ended June 30, 2022. The increase resulted primarily from an increase of $0.6 million in costs related to exchange rates as well as an increase in our convertible notes related expenses of $0.3 million net of a gain recognized due to conversions of a portion of the 2024 Notes of $0.4 million.

- In the three months ended June 30, 2023, the Company recorded income taxes of approximately $0.3 million which were primarily the result of the provision for current taxes in respect of Section 174 of the U.S. Tax Cuts and Jobs Act of 2017 which went into effect on January 1, 2022. Section 174 eliminated the option to immediately deduct research and development expenses in the year incurred and requires the Company to capitalize and amortize these expenditures over 15 years (for out of U.S.-based research and development). In addition, during the three months ended June 30, 2023, the Company released a valuation allowance related to deferred tax assets of the U.S. jurisdiction that resulted in a net benefit to tax expense of $3.1 million.

- Cash and cash equivalents were approximately $48.2 million at June 30, 2023.

- Net income for the three months ended June 30, 2023 was approximately $19.3 million, or $0.29 per share, basic, and $0.21 per share, diluted, compared to a net loss of $5.3 million, or $0.11 per share, basic and diluted, for the same period in 2022.

Conference Call and Webcast Information
The Company will host a conference call today, August 7, 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:	Monday, August 7, 2023
Time:	8:30 am EDT
Toll Free:	1-877-423-9813
International:	1-201-689-8573
Conference ID:	13740122

The Call me™ feature, which avoids having to wait for an operator, may be accessed at the following link: https://tinyurl.com/2v682k5m.

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/348f738e
Conference ID:	13740122

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

A replay of the call will be available 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 a 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 for the treatment of Gaucher disease, Protalix's first product manufactured through ProCellEx, excluding in Brazil, where Protalix retains full rights. Protalix's second product, Elfabrio®, was approved by both the FDA and the European Medicines Agency in May 2023. Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of Elfabrio.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: 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.

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 commercialization of Elfabrio, our approved product for the treatment of adult patients with Fabry disease; risks relating to Elfabrio's market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product; risks related to our commercialization partner's ability to obtain and maintain reimbursement for Elfabrio, 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 Elfabrio; risks related to the regulatory approval and commercial success of our other product and product candidates, if approved; 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; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials; 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 associated with global conditions and developments such as supply chain challenges, the inflationary environment and tight labor market, and instability in the banking industry, which may adversely impact our business, operations and ability to raise additional financing if and as required and on terms acceptable to us; 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; risks relating to our evaluation and pursuit of strategic partnerships; the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy and that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks relating to our ability to manage our relationship with our collaborators, distributors or partners, including, but not limited to, Pfizer and Chiesi; risks related to the amount and sufficiency of our

cash and cash equivalents; 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 the compliance by Fiocruz with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement; 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; 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; risks related to our supply of drug products to Pfizer; potential product liability risks, and risks of securing adequate levels of related insurance coverage; the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties; risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of certain regulatory authorities and of certain of our suppliers, collaborative partners, licensees, clinical trial sites, distributors and customers; 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.

Investor Contact
Chuck Padala, Managing Director
LifeSci Advisors
646-627-8390
chuck@lifesciadvisors.com

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

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 48,184	$ 17,111
Short-term bank deposits	—	5,069
Accounts receivable – Trade	4,049	4,586
Other assets	1,708	1,310
Inventories	19,635	16,804
Total current assets	$ 73,576	$ 44,880
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,268	$ 1,267
Property and equipment, net	4,637	4,553
Deferred income tax asset	3,130	—
Operating lease right of use assets	5,806	5,087
Total assets	$ 88,417	$ 55,787
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,304	$ 5,862
Other	18,545	12,271
Operating lease liabilities	1,260	1,118
Contracts liability	—	13,178
Total current liabilities	$ 23,109	$ 32,429
LONG TERM LIABILITIES:		
Convertible notes	$ 20,132	$ 28,187
Liability for employee rights upon retirement	1,598	1,642
Operating lease liabilities	4,577	4,169
Total long term liabilities	$ 26,307	$ 33,998
Total liabilities	$ 49,416	$ 66,427
COMMITMENTS		
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	39,001	(10,640)
Total liabilities and stockholders' equity (net of capital deficiency)	$ 88,417	$ 55,787

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

	Six Months Ended		Three Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
REVENUES FROM SELLING GOODS	$ 20,141	$ 12,410	$ 15,075	$ 3,382
REVENUES FROM LICENSE AND R&D SERVICES	24,522	12,428	20,000	5,371
TOTAL REVENUE	44,663	24,838	35,075	8,753
COST OF GOODS SOLD (1)	(9,233)	(10,121)	(6,148)	(4,087)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(10,322)	(16,346)	(4,475)	(7,579)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(7,146)	(5,765)	(4,031)	(2,611)
OPERATING INCOME (LOSS)	17,962	(7,394)	20,421	(5,524)
FINANCIAL EXPENSES	(2,169)	(1,242)	(1,305)	(623)
FINANCIAL INCOME	918	1,016	531	813
FINANCIAL INCOME (EXPENSES), NET	(1,251)	(226)	(774)	190
INCOME (LOSS) BEFORE TAXES ON INCOME	16,711	(7,620)	19,647	(5,334)
TAXES ON INCOME	(503)	-	(308)	-
NET INCOME (LOSS) FOR THE PERIOD	$ 16,208	$ (7,620)	$ 19,339	$ (5,334)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ 0.26	$ (0.16)	$ 0.29	$ (0.11)
DILUTED	$ 0.18	$ (0.16)	$ 0.21	$ (0.11)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	62,378,745	46,589,976	67,158,628	47,327,952
DILUTED	78,896,220	46,589,976	83,200,641	47,327,952
(1) Includes share-based compensation	$ 104	$ 22	$ 46	$ 28
(2) Includes share-based compensation	$ 324	$ 161	$ 144	$ 85
(3) Includes share-based compensation	$ 556	$ 941	$ 248	$ 175