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 6, 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 November 6, 2023, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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 November 6, 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: November 6, 2023

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Third Quarter 2023 Financial and Business Results

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

CARMIEL, Israel, November 6, 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 third quarter ended September 30, 2023 and provided a business update on recent regulatory, clinical and corporate developments.

“We continued our efforts this quarter towards turning Protalix into a fully-sustainable biopharmaceutical company with a growing pipeline of differentiated proprietary assets. With the approval of Elfabrio® by the U.S. FDA and the European Medicines Agency earlier this year, we are pleased to see our commercial partner Chiesi Global Rare Diseases hit the ground, both in the United States and the European Union. Additionally, Chiesi is continuing to position Elfabrio for future growth with additional approvals worldwide,” said Dror Bashan, Protalix’s President and Chief Executive Officer. “Our strong balance sheet coupled with our growing revenue stream allows us to focus on the continued development of our growing pipeline of assets, including PRX-115, our recombinant PEGylated uricase in development for the potential treatment of severe gout. We are continuing to enroll patients in our Phase I clinical trial evaluating the safety, pharmacokinetics, pharmacodynamics and immunogenicity of PRX-115, and look forward to continuing to progress this product candidate forward, Mr. Bashan continued. “We are proud of our achievements and look forward to an exciting future as a company with a proven platform and two approved drugs, a rich pipeline of product candidates in lucrative markets, a world-class team of dedicated employees, strong financial support with a solid balance sheet and an increasing stream of revenues.”

2023 Third 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, continued to attain marketing authorizations around the world for Elfabrio (pegunigalsidase alfa) for the treatment of adult patients with Fabry disease. 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 August 15, 2023, Chiesi announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorization for Elfabrio in Great Britain for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease.

- On September 11, 2023, Swissmedic, the national authorization and supervisory authority for drugs and medical products in Switzerland, announced the approval of Elfabrio in Switzerland for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease.

Clinical Developments

The Company continued to advance its 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. To date, 32 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 up to 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. We expect to announce top-line results from this study in mid-2024.

Corporate Developments

On September 14, 2023, Eliot Richard Forster, Ph.D. joined the Company's Board of Directors as its Chairman, replacing former Chairman Zeev Bronfeld, who retired for personal reasons. In addition to his role as Chairman, Dr. Forster is serving as an independent director on the Company's Nominating Committee.

Third Quarter 2023 Financial Highlights

- The Company recorded revenues from selling goods of $10.2 million during the three months ended September 30, 2023, an increase of $1.4 million, or 16%, compared to revenues of $8.8 million for the three months ended September 30, 2022. The increase resulted primarily from an increase of $3.0 million in sales to Chiesi, following the approvals by the FDA and the EMA of Elfabrio, and of $0.6 million in sales to Brazil, partially offset by a $2.2 million decrease in sales to Pfizer.

- The Company recorded revenues from license and R&D services of $0.2 million for the three months ended September 30, 2023, a decrease of $5.2 million, or 96%, compared to revenues of $5.4 million for the three months ended September 30, 2022. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. As of March 1, 2023, sponsorship of the extension studies was transferred to Chiesi, and Chiesi is now administering all open label extension studies.

- Cost of goods sold was $4.9 million for the three months ended September 30, 2023, a decrease of $2.2 million, or 31%, from cost of goods sold of $7.1 million for the three months ended September 30, 2022. The decrease in cost of goods sold was primarily the result of the decrease in sales to Pfizer, partially offset by an increase in sales of Elfabrio to Chiesi and of Elelyso to Brazil.

- For the three months ended September 30, 2023, the Company's total research and development expenses were approximately $3.7 million comprised of approximately $1.0 million of subcontractor-related expenses, approximately $1.9 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, 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. Total decrease in research and developments expenses was $3.7 million, or 50%, compared to the three months ended September 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 $3.7 million for the three months ended September 30, 2023, an increase of $0.9 million, or 32%, compared to $2.8 million for the three months ended September 30, 2022. The increase resulted primarily from an increase of approximately $0.6 million in salary and related expenses due to one-time cash bonuses and an increase in share-based compensation.

- Financial income, net was $0.2 million for the three months ended September 30, 2023, compared to financial expenses, net of $0.4 million for the three months ended September 30, 2022. The change resulted primarily from an increase of $0.3 million in interest income.

- In the three months ended September 30, 2023, the Company recorded income taxes of approximately $0.1 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, which was enacted in December 2017.

- Cash, cash equivalents and short term bank deposits were approximately $41.0 million at September 30, 2023.

- Net loss for the three months ended September 30, 2023 was approximately $1.9 million, or $0.03 per share, basic, and $0.04 per share, diluted, compared to a net loss of $3.6 million, or $0.07 per share, basic and diluted, for the same period in 2022.

Conference Call and Webcast Information
The Company will host a conference call today, November 6, 2023, at 8:30 a.m. EST, 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, November 6, 2023
Time:	8:30 a.m. Eastern Standard Time (EST)
Toll Free:	1-877-423-9813
Israeli Toll Free:	1-809-406 247
International:	1-201-689-8573
Conference ID:	13741587
Call me™:	https://tinyurl.com/2tsadwma

The Call me™ feature allows you to avoid the wait for an operator; you enter your phone number on the platform and the system calls you right away.

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/362f74wx
Conference ID:	13741587

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 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 possible disruption of our operations due to the war declared by Israel's security cabinet against the Hamas terrorist organization located in the Gaza Strip, the military campaign against the Hezbollah and other 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; 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 changes to interim, topline or preliminary data from clinical trials that we announce or publish; 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; 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)

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 20,408	$ 17,111
Short-term bank deposits	20,567	5,069
Accounts receivable – Trade	8,935	4,586
Other assets	1,125	1,310
Inventories	21,583	16,804
Total current assets	$ 72,618	$ 44,880
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,260	$ 1,267
Property and equipment, net	4,684	4,553
Deferred income tax asset	3,092	—
Operating lease right of use assets	5,915	5,087
Total assets	$ 87,569	$ 55,787
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,114	$ 5,862
Other	18,740	12,271
Operating lease liabilities	1,313	1,118
Contracts liability	—	13,178
Convertible notes	20,192	—
Total current liabilities	$ 43,359	$ 32,429
LONG TERM LIABILITIES:		
Convertible notes		$ 28,187
Liability for employee rights upon retirement	$ 1,461	1,642
Operating lease liabilities	4,502	4,169
Total long term liabilities	$ 5,963	$ 33,998
Total liabilities	$ 49,322	$ 66,427
COMMITMENTS		
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	38,247	(10,640)
Total liabilities and stockholders' equity (net of capital deficiency)	$ 87,569	$ 55,787

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

	Nine Months Ended		Three Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
REVENUES FROM SELLING GOODS	$ 30,309	$ 21,222	$ 10,168	$ 8,812
REVENUES FROM LICENSE AND R&D SERVICES	24,699	17,799	177	5,371
TOTAL REVENUE	55,008	39,021	10,345	14,183
COST OF GOODS SOLD (1)	(14,126)	(17,195)	(4,893)	(7,074)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(13,991)	(23,732)	(3,669)	(7,386)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(10,816)	(8,613)	(3,670)	(2,848)
OPERATING INCOME (LOSS)	16,075	(10,519)	(1,887)	(3,125)
FINANCIAL EXPENSES	(2,406)	(1,879)	(460)	(639)
FINANCIAL INCOME	1,323	1,211	628	197
FINANCIAL INCOME (EXPENSES), NET	(1,083)	(668)	168	(442)
INCOME (LOSS) BEFORE TAXES ON INCOME	14,992	(11,187)	(1,719)	(3,567)
TAXES ON INCOME	(636)	—	(133)	—
NET INCOME (LOSS) FOR THE PERIOD	$ 14,356	$ (11,187)	$ (1,852)	$ (3,567)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ 0.22	$ (0.24)	$ (0.03)	$ (0.07)
DILUTED	$ 0.16	$ (0.24)	$ (0.04)	$ (0.07)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	65,811,506	47,582,733	72,281,681	49,498,105
DILUTED	81,040,281	47,582,733	83,782,679	49,498,105
(1) Includes share-based compensation	$ 299	$ 58	$ 195	$ 36
(2) Includes share-based compensation	$ 506	$ 275	$ 182	$ 114
(3) Includes share-based compensation	$ 1,276	$ 1,213	$ 720	$ 272