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 14, 2024

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 14, 2024, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2024 and provided a business update. 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 14, 2024
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 14, 2024

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Second Quarter 2024 Financial and Business Results

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

CARMIEL, Israel, August 14, 2024 /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 quarter ended June 30, 2024, and provided a business update.

"In the second quarter, Protalix has made meaningful progress on our early-stage pipeline," said Dror Bashan, Protalix's President and Chief Executive Officer. "Results from the first seven cohorts of the phase I clinical trial of PRX-115 for the treatment of uncontrolled gout are encouraging, and we anticipate topline results from all eight cohorts to be available in the third quarter of 2024. Based on the safety results to date, we have initiated preparations for a phase II clinical trial of PRX-115 in uncontrolled gout patients. Our strong balance sheet enables repayment of our convertible notes due September 2024 while maintaining ongoing operations and executing on our corporate strategy."

Second Quarter 2024 and Recent Business Highlights

Pipeline Developments

- In May 2024, the Company announced positive topline results from the First-in-Human (FIH) Phase I clinical trial of PRX-115, the Company's a recombinant PEGylated uricase product candidate in development as a potential treatment for uncontrolled gout.
    - Results from the first seven dosing cohorts demonstrated that single administration of PRX-115 induced rapid, long-lasting reduction of plasma uric acid concentrations, a dose-dependent increase in exposure, and a favorable tolerability profile.
    - Dosing of the eighth and highest dose cohort is complete, and topline results from the full trial are expected in the third quarter of 2024.
- In June 2024, the Company hosted an Investor Day highlighting current treatment landscapes and clinical results for Fabry disease and uncontrolled gout. The event featured presentations from key opinion leaders (KOLs) Aleš Linhart, D.Sc., FESC (Charles University, Prague) and Naomi Schlesinger, M.D. (University of Utah). The Company's leadership also provided insight into its strategy and future plans. A replay of the event can be accessed here: https://ir.protalix.com/events/event-details/person-investor-day-discuss-current-treatment-landscapes-and-clinical-results.

Second Quarter 2024 Financial Highlights

- The Company recorded revenues from selling goods of $13.3 million during the three months ended June 30, 2024, a decrease of $1.8 million, or 12%, compared to revenues of $15.1 million for the three months ended June 30, 2023. The decrease resulted primarily from a decrease of $10.0 million in sales to Chiesi, partially offset by an increase of $4.7 million in sales to Brazil and an increase of $3.5 million in sales to Pfizer. Sales to Chiesi in the three months ended June 30, 2023 were in connection with the commercial launch and inventory buildup of Elfabrio® after its approval for marketing in the United States and the European Union. The increases in sales to Brazil and Pfizer during the three months ended June 30, 2024 resulted primarily from the timing of delivery.

- The Company recorded revenues from license and R&D services of $0.2 million for the three months ended June 30, 2024, a decrease of $19.8 million, or 99%, compared to revenues of $20.0 million for the three months ended June 30, 2023. Revenues from license and R&D services are comprised primarily of revenues the Company recognized in connection with the Chiesi Agreements. The revenues from license and R&D services for the three months ended June 30, 2023 were the result of the $20.0 million regulatory milestone payment from Chiesi in connection with the FDA approval of Elfabrio granted during that period.

- Cost of goods sold was $9.5 million for the three months ended June 30, 2024, an increase of $3.4 million, or 56%, from cost of goods sold of $6.1 million for the three months ended June 30, 2023. The increase in cost of goods sold was primarily the result of an increase in sales to Pfizer and to Brazil. In addition, during the three months ended June 30, 2023, a significantly higher portion of the costs for certain drug substance sold, as compared to the three months ended June 30, 2024, were recognized as research and development expenses, not cost of goods sold, as such drug substance was produced as part of the Company's research and development activities.

- For the three months ended June 30, 2024, the Company's total research and development expenses were approximately $3.0 million comprised of approximately $0.5 million in subcontractor-related expenses, approximately $1.6 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.7 million of other expenses. 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 of 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. Total decrease in research and developments expenses for the three months ended June 30, 2024 was $1.5 million, or 33%, compared to the three months ended June 30, 2023. The decrease in research and development expenses resulted primarily from the completion of the Company's Fabry clinical program and the regulatory processes related to the review of the Elfabrio Biologics License Application (BLA) in the United States and the

Marketing Authorization Application (MAA) in the European Union by the applicable regulatory agencies.

- Selling, general and administrative expenses were $3.5 million for the three months ended June 30, 2024, a decrease of $0.5 million, or 13%, compared to $4.0 million for the three months ended June 30, 2023. The decrease resulted primarily from a decrease of $0.5 million in salary and related expenses.

- Financial income, net were $0.2 million for the three months ended June 30, 2024, compared to financial expenses, net of $0.8 million for the three months ended June 30, 2023. The difference resulted primarily from higher interest income on bank deposits and lower notes interest expenses due to notes conversions executed in 2023.

- For the three months ended June 30, 2024, the Company recorded a tax benefit of approximately $0.1 million, compared to income taxes of $0.3 million for the three months ended June 30, 2023. Income taxes recorded are 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 $45.0 million at June 30, 2024.

- Net loss for the three months ended June 30, 2024 was approximately $2.2 million, or $0.03 per share, basic and diluted, compared to a net income of $19.3 million, or $0.29 per share, basic, and $0.21 per share, diluted, for the same period in 2023.

- Since the end of the quarter ended June 30, 2024, the Company collected approximately $4.6 million in the aggregate from sales to Pfizer Inc., and approximately $2.3 million from sales to Brazil.

Conference Call and Webcast Information

The Company will host a conference call today, August 14, 2024 at 8:30 am EDT, to review the financial results and provide a business update. To participate in the conference call, please dial the following numbers prior to the start of the call:

Conference Call Details:

Date:	Wednesday, August 14, 2024
Time:	8:30 a.m. Eastern Daylight Time (EDT)
Toll Free:	1-877-423-9813
International:	1-201-689-8573
Israeli Toll Free:	1-809-406-247
Conference ID:	13747744
Call me™:	https://tinyurl.com/2n9fhumh

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:
Company Link: https://ir.protalix.com/news-events/events
Webcast Link: https://tinyurl.com/yb6bu7vs
Conference ID: 13747744

Participants are requested to access the websites at least 15 minutes ahead of the conference 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 uncontrolled 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® (pegunigalsidase alfa-iwxj), 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; 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; risks related to the regulatory approval and commercial success of our other product and product candidates, if approved; risks related to our expectations with respect to the potential commercial value of our products and product candidates; 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 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 Inc., or Pfizer, and Chiesi Farmaceutici S.p.A.; 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; risks relating to the compliance by Fundação Oswaldo Cruz, an arm of the Brazilian Ministry of Health, 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; and 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)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 23,399	$ 23,634
Short-term bank deposits	21,630	20,926
Accounts receivable – Trade	10,126	5,272
Other assets	1,493	1,055
Inventories	20,719	19,045
Total current assets	$ 77,367	$ 69,932
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 535	$ 528
Property and equipment, net	4,609	4,973
Deferred income tax asset	3,299	3,092
Operating lease right of use assets	5,730	5,909
Total assets	$ 91,540	$ 84,434
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,064	$ 4,320
Other	19,343	19,550
Operating lease liabilities	1,450	1,409
Contracts liability	12,695	-
Convertible notes	20,420	20,251
Total current liabilities	$ 57,972	$ 45,530
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 705	$ 714
Operating lease liabilities	4,282	4,621
Total long term liabilities	$ 4,987	$ 5,335
Total liabilities	$ 62,959	$ 50,865
COMMITMENTS		
STOCKHOLDERS' EQUITY	28,581	33,569
Total liabilities and stockholders' equity	$ 91,540	$ 84,434

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, 2024	June 30, 2023	June 30, 2024	June 30, 2023
REVENUES FROM SELLING GOODS	$ 16,981	$ 20,141	$ 13,304	$ 15,075
REVENUES FROM LICENSE AND R&D SERVICES	241	24,522	170	20,000
TOTAL REVENUE	17,222	44,663	13,474	35,075
COST OF GOODS SOLD	(12,058)	(9,233)	(9,456)	(6,148)
RESEARCH AND DEVELOPMENT EXPENSES	(5,848)	(10,322)	(2,961)	(4,475)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(6,599)	(7,146)	(3,484)	(4,031)
OPERATING INCOME (LOSS)	(7,283)	17,962	(2,427)	20,421
FINANCIAL EXPENSES	(757)	(2,169)	(367)	(1,305)
FINANCIAL INCOME	1,035	918	522	531
FINANCIAL INCOME (EXPENSES), NET	278	(1,251)	155	(774)
INCOME (LOSS) BEFORE TAX BENEFIT (TAXES ON INCOME)	(7,005)	16,711	(2,272)	19,647
TAX BENEFIT (TAXES ON INCOME)	207	(503)	69	(308)
NET INCOME (LOSS) FOR THE PERIOD	$ (6,798)	$ 16,208	$ (2,203)	$ 19,339
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ (0.09)	$ 0.26	$ (0.03)	$ 0.29
DILUTED	$ (0.09)	$ 0.18	$ (0.03)	$ 0.21
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	73,172,980	62,378,745	73,308,281	67,158,628
DILUTED	73,172,980	78,896,220	73,308,281	83,200,641