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 10, 2020

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 Snunit Street **Science Park, POB 455** **Carmiel, Israel** **(Address of principal executive offices)**	**2161401** **(Zip Code)**

Registrant's telephone number, including area code +972-4-988-9488

(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 10, 2020, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2020, and provided a business update on recent corporate and clinical 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

(d) Exhibits

99.1	Press release dated August 10, 2020

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 10, 2020

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Second Quarter 2020 Financial Results and Provides Business Update

Announced positive top-line data in its Phase III BRIDGE study of PRX-102 for the Treatment of Fabry disease

Submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration for PRX-102 for the treatment of Fabry disease

Conference call and live webcast scheduled for Monday, August 10, 2020 at 8:30 am ET

CARMIEL, Israel, August 10, 2020 /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 second quarter ended June 30, 2020, and provided a business update on recent corporate and clinical developments.

"This quarter, we delivered on two very important milestones for the company: announcing positive topline results in our *BRIDGE* phase III clinical trial of PRX-102 for the treatment of Fabry disease and subsequent BLA submission to the U.S. Food and Drug Administration (FDA). We were able to accomplish these goals even as we faced the challenging headwinds from the global COVID-19 pandemic, and I am very proud of our entire team for their commitment and dedication," said Dror Bashan, Protalix's President and Chief Executive Officer. "As we look towards an exciting second half of the year, we are continuing to build Protalix for the long term. We augmented our research and development team with highly qualified and seasoned veterans to support and enhance our pipeline, and we announced a new partnership to explore the development of PRX-110." Mr. Bashan concluded, "We are gratified to have a balance sheet supporting our strategic plans and look forward to continuing to execute as we move towards the anticipated commercial launch of PRX-102 for the treatment of Fabry disease."

Recent Business Highlights

- Submitted a Biologics License Application (BLA) to the FDA for PRX-102 (pegunigalsidase alfa) for the treatment of adult patients with Fabry disease on May 27, 2020. The BLA was submitted under the FDA's accelerated approval pathway in collaboration with the Company's development and commercialization partner, Chiesi Farmaceutici S.p.A. On July 28, 2020, the FDA informed Chiesi that the BLA had been filed for review and that the FDA was working on the 74-day letter. In addition, the FDA informed Chiesi that no "Refuse To File" will be issued for the PRX-102 BLA.

- Announced positive topline results from our *BRIDGE* Phase III clinical trial of PRX-102 for the treatment of Fabry disease. The study was an open-label, switch-over trial designed to evaluate the safety and efficacy of 1 mg/kg PRX-102 infused every two weeks, in Fabry patients. The trial met its main objectives for safety and efficacy, and topline analysis indicated substantial improvement in renal function as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope) in patients switched from agalsidase alfa to PRX-102.

- Enhanced the executive management team with the appointment of Yael Hayon, Ph.D. as Vice President, Research and Development. Dr. Hayon brings over a decade of pharmaceutical research and development experience in both the scientific operations and administrative functions.

- Entered into a non-binding term sheet with SarcoMed USA, Inc. to explore the development and commercialization of PRX-110 (alidornase alfa) in the treatment of Pulmonary Sarcoidosis and related diseases. SarcoMed USA was formed in 2017 to investigate if a novel DNase 1 compound could influence the chronic pulmonary inflammation seen in Pulmonary Sarcoidosis patients.

Second Quarter 2020 Financial Highlights

The Company recorded revenues from selling goods of $3.6 million during the three months ended June 30, 2020, an increase of $0.2 million, or 6%, compared to revenues of $3.4 million for the same period of 2019.

Revenues from license and R&D services for the three months ended June 30, 2020, were $7.3 million, a decrease of $1.5 million, or 17%, compared to revenues of $8.8 million for the same period of 2019. Revenues from license and R&D services are comprised primarily of revenues the Company recognized in connection with its license and supply agreements with Chiesi. The decrease is primarily due to the completion of two out of the three phase III clinical trials of PRX-102 as well as lower costs related to the Company's phase III BALANCE clinical trial of PRX-102 for the treatment of Fabry disease.

Cost of goods sold was $1.8 million for the three months ended June 30, 2020, a decrease of $0.9 million, or 32%, from cost of goods sold of $2.7 million for the same period of 2019. The decrease is primarily due to a change in the cost structure as well as lower royalties paid to the Israeli Innovation Authority.

Research and development expenses were $9.2 million for the three months ended June 30, 2020, a decrease of $4.1 million, or 31%, compared to $13.3 million of research and development expenses for the same period of 2019. The decrease is primarily due to the completion of two out of the three phase III clinical trials of PRX-102 and reduced costs related to the Company's phase III BALANCE clinical trial as well as a decrease in costs related to manufacturing of the Company's drug in development as some of the manufactured drug product and related costs have been recorded as inventory.

Selling, general and administrative expenses were $2.2 million for the three months ended June 30, 2020, an increase of $0.1 million, or 6%, compared to $2.1 million for the same period of 2019.

Cash and cash equivalents at June 30, 2020 was $4.8 million, with $35.2 million in bank deposits.

Conference Call and Webcast Information

The Company will host a conference call on Monday, August 10, 2020, at 8:30 am, Eastern Daylight Time, to review the clinical, corporate, and financial highlights. To participate in the conference call, please dial the following numbers prior to the start of the call:

Domestic:	877-423-9813
International:	201-689-8573
Conference ID:	13706783
Webcast:	https://tinyurl.com/y3cuc7gw

The conference call will be broadcast live and also available for replay for two weeks on the Company's website, www.protalix.com, in the Events Calendar of the Investors section. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

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 for marketing 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 version of the recombinant human α-Galactosidase-A protein for the proposed treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; PRX-115, a plant cell-expressed recombinant PEGylated Uricase for the treatment of gout; 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,” “plan,” “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 that the FDA will not accept an application for accelerated approval of PRX-102 with the data generated to date or will request additional data or other conditions of our submission of any application for accelerated approval of PRX-102 and, if approved, whether PRX-102 will be commercially successful; failure or delay in the commencement or completion of our preclinical 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 monitor patients adequately during or after treatment; and inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; risks associated with the novel coronavirus disease (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 our claims of safety or efficacy, 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 Chiesi Farmaceutici and any other collaborator, distributor or partner; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of BioManguinhos alfataliglicerase generally; risks related to our commercialization efforts for BioManguinhos alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; risks related to the amount and sufficiency of our cash and cash equivalents; the risk that despite the FDA’s grant of fast track designation for PRX-102, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA’s ability to withdraw the fast track designation at any time; 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; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities, and other risks relating to the review process; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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.

Investor Contact
Chuck Padala, Managing Director
LifeSci Advisors
+1-646-627-8390
chuck@lifesciadvisors.com

Media Contact
Brian Pinkston
LaVoieHealthScience
+1-857-588-3347
bpinkston@lavoiehealthscience.com

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

	June 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,843	$ 17,792
Short-term bank deposits	30,147	-
Accounts receivable – Trade	5,262	4,700
Other assets	2,893	1,832
Inventories	11,065	8,155
Total current assets	$ 54,210	$ 32,479
NON-CURRENT ASSETS:		
Long-term bank deposits	$ 5,025	-
Funds in respect of employee rights upon retirement	2,005	$ 1,963
Property and equipment, net	4,793	5,273
Operating lease right of use assets	5,677	5,677
Total non-current assets	$ 17,500	$ 12,913
Total assets	$ 71,710	$ 45,392
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,707	$ 6,495
Other	11,910	11,905
Operating lease liabilities	1,145	1,139
Contracts liability	18,352	16,335
Promissory note	4,301	4,301
Total current liabilities	$ 42,415	$ 40,175
LONG TERM LIABILITIES:		
Convertible notes	$ 52,622	$ 50,957
Contracts liability	4,122	16,980
Liability for employee rights upon retirement	2,665	2,565
Operating lease liabilities	4,526	4,528
Other long term liabilities	124	509
Total long term liabilities	$ 64,059	$ 75,539
Total liabilities	$ 106,474	$ 115,714
COMMITMENTS		
CAPITAL DEFICIENCY	(34,764)	(70,322)
Total liabilities net of capital deficiency	$ 71,710	$ 45,392

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

	Six Months Ended		Three Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Revenues from selling goods	$ 8,679	$ 6,960	$ 3,648	$ 3,430
Revenues from license and R&D services	23,934	15,726	7,319	8,817
Total revenue	32,613	22,686	10,967	12,247
Cost of goods sold	(5,253)	(4,740)	(1,827)	(2,695)
Research and development expenses, net (1)	(19,526)	(25,021)	(9,186)	(13,323)
Selling, general and administrative expenses (2)	(5,381)	(4,298)	(2,194)	(2,068)
Operating income (loss)	2,453	(11,373)	(2,240)	(5,839)
Financial expenses	(5,177)	(3,827)	(1,948)	(1,907)
Financial income	241	193	38	3
Financial expenses, net	(4,936)	(3,634)	(1,910)	(1,904)
Net loss for the period	$ (2,483)	$ (15,007)	$ (4,150)	$ (7,743)
Loss per share of common stock - basic and diluted	$ (0.12)	$ (1.01)	$ (0.13)	$ (0.52)
Weighted average number of shares of common stock used in computing loss per share – basic and diluted	19,923,935	14,838,213	32,442,636	14,838,213
(1) Includes share-based compensation	$ 73	$ 316	$ (5)	$ 138
(2) Includes share-based compensation	$ 625	$ 87	$ 272	$ (25)