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): October 29, 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**		**2161401**
(Address of principal executive offices)		**(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 October 29, 2020, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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 October 29, 2020
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: October 29, 2020

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

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

Announced FDA acceptance of BLA filing of PRX-102 for the treatment of Fabry disease

Top-line data from the BRIGHT study expected by end of first quarter, 2021

Management to host conference call and live webcast today, October 29, at 8:30 am ET

CARMIEL, Israel, October 29, 2020 – 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 third quarter ended September 30, 2020, and provided a business update on recent corporate and clinical developments.

"This quarter, we delivered on another important milestone for the Company with the FDA's acceptance of, and grant of Priority Review designation to, the biologics license application (BLA) submitted for PRX-102 for the treatment of Fabry disease," said Dror Bashan, Protalix's President and Chief Executive Officer. "We continue to build-out our clinical data profile for PRX-102. The last patient has completed treatment in the *BRIGHT* study, and we expect to report top-line data from the study by the end of the first quarter, 2021. We remain focused on advancing our earlier stage pipeline as well. We are proud of our team's continued dedication and collaboration in progressing on our corporate mission during these challenging times of the pandemic."

Recent Business Highlights

- Announced U.S. Food and Drug Administration (FDA) acceptance of the BLA submitted for PRX-102 (pegunigalsidase alfa) for the treatment of adult patients with Fabry disease and grant of Priority Review designation to the BLA. The BLA was submitted under the FDA's accelerated approval pathway in collaboration with the Company's development and commercialization partner, Chiesi Global Rare Diseases. The FDA indicated in its communications that it is not currently planning to hold an advisory committee meeting to discuss the application.

- The FDA set an action date of January 27, 2021 under the Prescription Drug User Fee Act (PDUFA) for the BLA. The FDA advised that, as part of its review of the BLA application, it requires an inspection of the Company's manufacturing facility and that of a third party in Europe that performs fill and finish processes for PRX-102. Due to COVID-19 related FDA travel restrictions, the FDA has advised that it may be unable to conduct the inspections prior to the PDUFA date. Together with Chiesi, the Company is diligently exploring potential alternatives that would enable the FDA to meet its timeline. As part of such efforts, Chiesi submitted a request to the FDA for a Type A meeting. The

Company anticipates an FDA response to this request during the first week of November 2020.

- Disclosed the completion of the patient treatment period for the Company's phase III *BRIGHT* clinical trial of PRX-102 for the treatment of Fabry disease. The trial was designed to evaluate the safety and efficacy of 2 mg/kg PRX-102 infused every four weeks, in Fabry patients. The Company expects to report top-line results from the trial by the end of the first quarter, 2021.

- Announced the launch of an Expanded Access Program in the United States for PRX-102 allowing a broader group of physicians and patients, beyond those in the Company's phase III clinical program, access to PRX-102.

- Launched an at-the-market equity offering program with BofA Securities enabling the Company to sell up to $30 million shares of common stock according to the terms and conditions set forth in its agreement with BofA Securities. The program provides the Company with greater capital-raising flexibility as it executes on its commercialization and development plans.

Third Quarter 2020 Financial Highlights

The Company recorded revenues from selling goods of $3.3 million during the three months ended September 30, 2020, a decrease of $1.8 million, or 36%, compared to revenues of $5.1 million for the same period of 2019. The decrease resulted primarily from a timing difference in sales to Brazil in 2020 compared to 2019, which was partially offset by an increase in sales to Pfizer Inc.

Revenues from license and R&D services for the three months ended September 30, 2020 were $7.5 million, a decrease of $1.6 million, or 18%, compared to $9.1 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 for the three months ended September 30, 2020 was $2.9 million, a decrease of $0.3 million, or 11%, compared to $3.2 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 for the three months ended September 30, 2020 were $7.7 million, a decrease of $2.3 million, or 23%, compared to $10.0 million 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 *BALANCE* study 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 for the three months ended September 30, 2020 were $2.8 million, an increase of $0.2 million, or 9%, compared to $2.6 million for the same period of 2019.

Financial expenses net for the three months ended September 30, 2020 were $1.9 million, a decrease of $0.1 million, or 8%, compared to $2.0 million for the same period of 2019.

Cash, cash equivalents and short-term bank deposits were approximately $41.3 million at September 30, 2020.

Conference Call and Webcast Information:

The Company will host a conference call on Thursday, October 29, 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: 13711708

The conference call 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/y2z676dk
Conference ID: 13711708

Please access the websites 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; and others. Protalix has partnered with Chiesi Global Rare Diseases, 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 related to the timing, progress and likelihood of final approval by the FDA of the BLA for PRX-102, by the PDUFA date or at all, which was accepted by the FDA and granted Priority Review designation in August 2020 and, if approved, whether the use of 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 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 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 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; 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; 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.

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

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,533	$ 17,792
Short-term bank deposits	27,760	-
Accounts receivable – Trade	3,146	4,700
Other assets	2,612	1,832
Inventories	13,281	8,155
Total current assets	$ 60,332	$ 32,479
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	1,639	$ 1,963
Property and equipment, net	4,639	5,273
Operating lease right of use assets	5,700	5,677
Total non-current assets	$ 11,978	$ 12,913
Total assets	$ 72,310	$ 45,392
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 8,351	$ 6,495
Other	13,347	11,905
Operating lease liabilities	1,176	1,139
Contracts liability	16,720	16,335
Promissory note	4,301	4,301
Total current liabilities	$ 43,895	$ 40,175
LONG TERM LIABILITIES:		
Convertible notes	$ 53,505	$ 50,957
Contracts liability	1,533	16,980
Liability for employee rights upon retirement	2,088	2,565
Operating lease liabilities	4,558	4,528
Other long term liabilities	46	509
Total long term liabilities	$ 61,730	$ 75,539
Total liabilities	$ 105,625	$ 115,714
COMMITMENTS		
CAPITAL DEFICIENCY	(33,315)	(70,322)
Total liabilities net of capital deficiency	$ 72,310	$ 45,392

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

	Nine Months Ended		Three Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 20
REVENUES FROM SELLING GOODS	$ 11,975	$ 12,086	$ 3,296	$ 5,12
REVENUES FROM LICENSE AND R&D SERVICES	31,428	24,848	7,494	9,12
TOTAL REVENUE	43,403	36,934	10,790	14,24
COST OF GOODS SOLD	(8,121)	(7,945)	(2,868)	(3,20
RESEARCH AND DEVELOPMENT EXPENSES, NET (1)	(27,214)	(35,021)	(7,688)	(10,00
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(8,197)	(6,885)	(2,816)	(2,58
OPERATING LOSS	(129)	(12,917)	(2,582)	(1,54
FINANCIAL EXPENSES	(7,150)	(5,877)	(1,973)	(2,05
FINANCIAL INCOME	359	227	118	3
FINANCIAL EXPENSES - NET	(6,791)	(5,650)	(1,855)	(2,01
NET LOSS FOR THE PERIOD	$ (6,920)	$ (18,567)	$ (4,437)	$ (3,56
NET LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED	$ (0.25)	$ (1.25)	$ (0.14)	$ (0.2
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	27,758,104	14,838,213	32,863,788	14,838,21
(1) Includes share-based compensation	$ 635	$ 426	$ 562	$ 11
(2) Includes share-based compensation	$ 1,477	$ 173	$ 852	$ 8