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 15, 2021

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 15, 2021, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2021 and provided a financial and business update on recent corporate, clinical and regulatory 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 15, 2021
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 15, 2021

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

BioTherapeutics Reports Third Quarter 2021 Financial Results and Provides Financial and Business Update

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

CARMIEL, Israel, November 15, 2021 /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 third quarter ended September 30, 2021 and provided a financial and business update on recent corporate, clinical and regulatory developments.

"We are pleased with the progress we have made over the past few weeks with respect to the regulatory path forward with PRX-102 for the treatment of Fabry disease with both the U.S. Food and Drug Administration and the European Medicines Agency," stated Dror Bashan, Protalix's President and Chief Executive Officer. "Following our Type A meeting with the FDA, we believe there is now an established pathway to resubmit the PRX-102 BLA. We remain focused on our mission to bring to the market another important potential alternative treatment for all adult Fabry patients. We are grateful for the continued support from our team members, advocates and external partners who remain as steadfast and focused as ever; they see the value of having an alternative treatment for patients, especially one with our profile. Following the note exchange agreement we completed in August, we now have additional financial flexibility and sufficient capital to fund our operations through important milestones in 2022. We are committed to executing our strategy and are looking forward to converting the momentum of the last quarter into a successful 2022."

2021 Third Quarter and Recent Business Update

Regulatory Updates

- On October 11, 2021, the Company, together with its development and commercialization partner, Chiesi Farmaceutici S.p.A., or Chiesi, provided a regulatory update regarding PRX-102, which included the announcement of the receipt of the official Type A (End-of-Review) meeting minutes from the U.S. Food and Drug Administration (FDA) regarding the Complete Response Letter (CRL) received in April 2021 for the biologics license application (BLA) for PRX-102 for the treatment of adult patients with Fabry disease, and confirming the pathway for resubmission of a BLA for PRX-102. The PRX-102 biologics license application (BLA) resubmission to the FDA is anticipated in the second half of 2022.

- On October 8, 2021, the Company, together with Chiesi, held a meeting with the Rapporteur and Co-Rapporteur of the European Medicines Agency (EMA) regarding PRX-102. At the meeting, Chiesi and the Company discussed the scope of the anticipated Marketing Authorization Application (MAA) submission for the European Union, and the Rapporteur and Co-Rapporteur were generally supportive of a planned MAA submission for PRX-102. This is an important step in the necessary pre-submission activities leading up to a MAA submission. The Company and Chiesi expect to submit an MAA to the EMA for PRX-102 during the first quarter of 2022.

Clinical Advancements

- On October 15, 2021, the Company, together with Chiesi, announced the final dosing of the last patient in the Company's phase III *BALANCE* clinical trial, or the *BALANCE* study, for the proposed treatment of Fabry disease. The *BALANCE* study is a 24-month, randomized, double blind, active control study of PRX-102 in Fabry patients with impaired renal function. Unblinded final data is anticipated to be released in the second quarter of 2022 after all remaining patients have completed the 24-month treatment period.

- Given the changed regulatory landscape in the United States, the planned data package for the PRX-102 BLA resubmission will include the final two-year analyses of the *BALANCE* study.

Corporate & Financial Developments

- On August 25, 2021, the Company completed exchanges, or the Exchanges, of a substantial majority of the Company's outstanding 7.50% Senior Secured Convertible Notes due 2021, or the 2021 Notes, with institutional note holders. In the Exchanges, an aggregate of $54.65 million principal amount of outstanding 2021 Notes were exchanged for an aggregate of $28.75 million principal amount of newly issued 7.50% Senior Secured Convertible Notes due 2024, $25.90 million in cash, and approximately $1.1 million in cash representing accrued and unpaid interest through the closing date of the Exchanges.

  The maturity date of the 2021 Notes is November 15, 2021, on which date the Company is required to settle all of the remaining 2021 Notes then outstanding, and pay all accrued but unpaid interest thereon. On November 9, 2021, the Company delivered the necessary funds under the indenture governing the 2021 Notes to effectively discharge the remaining outstanding 2021 Notes.

Third Quarter 2021 Financial Highlights

- The Company recorded revenues from selling goods of $4.5 million during the three months ended September 30, 2021, an increase of $1.2 million, or 36%, compared to revenues of $3.3 million for the same period of 2020.

- Revenues from license and R&D services for the three months ended September 30, 2021 and September 30, 2020 were $7.5 million. 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. A revenue increase of $1.0 million recognized from the Kirin feasibility study was offset by a $1.0 million decrease in revenue generated under the Company's license and supply agreements with Chiesi.

- Cost of goods sold for the three months ended September 30, 2021 was $3.7 million, an increase of $0.8 million, or 28%, compared to $2.9 million for the same period in 2020. The increase resulted primarily from higher sales.

- Research and development expenses for the three months ended September 30, 2021 were $7.3 million, a decrease of $0.4 million, or 5%, compared to $7.7 million for the same period of 2020. The decrease was primarily the result of the completion of two out of the three phase III clinical trials of PRX-102 and reduced costs related to the *BALANCE* study. The Company expects research and development expenses to continue to be its primary expense as it enters into a more advanced stage of preclinical and clinical trials for certain product candidates.

- Selling, general and administrative expenses were $3.0 million, an increase of $0.2 million, or 7%, for the three months ended September 30, 2021 compared to $2.8 million for the same period in 2020. The increase is primarily the result of an increase of $0.4 million in corporate costs mainly related to insurance and a $0.2 million increase in sales and marketing costs, partially offset by a decrease of $0.5 million in share-based compensation.

- Financial expenses, net, were $2.3 million for the three months ended September 30, 2021 and $1.9 million for the three months ended September 30, 2020. The increase resulted primarily from loss on extinguishment related to the Exchanges of the Company's 2021 Notes.

- Cash, cash equivalents and short-term bank deposits were approximately $48.7 million at September 30, 2021.

- Net loss for the three months ended September 30, 2021 was approximately $4.2 million, or $0.09 per share, basic and diluted, compared to a net loss of $4.4 million, or $0.14 per share, basic and diluted, for the same period in 2020.

Conference Call and Webcast Information

The Company will host a conference call today, November 15, 2021, at 8:30 am Eastern Standard Time, to review the corporate, clinical and regulatory 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:

Monday, November 15, 2021, 8:30 a.m. Eastern Standard Time (EST)
Domestic: 877-423-9813
International: 201-689-8573
Conference ID: 13724767

The conference call will be webcast live from the Company's website and will be available via the following links:

Webcast Details:

Company Link: https://protalixbiotherapeutics.gcs-web.com/events0
Webcast Link: https://tinyurl.com/3c2wwhza

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

The conference call will be available for replay 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. 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 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 stabilized version of the recombinant human α-Galactosidase-A protein for the treatment of Fabry disease; alidornase alfa or PRX-110, for the treatment of various human respiratory diseases or conditions; PRX-115, a plant cell-expressed recombinant PEGylated uricase for the treatment of refractory gout; PRX-119, a plant cell-expressed long action DNase I for the treatment of NETs-related diseases; 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,” “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 timing and progress of the preparation of an updated BLA addressing the CRL for PRX-102; risks related to the timing, progress and likelihood of final approval by the FDA of a resubmitted BLA for PRX-102 and, if approved, whether PRX-102 will be commercially successful; the risk that the FDA, the EMA or other foreign regulatory authorities may not accept or approve a marketing application filed for PRX-102 or any of our other 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 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; 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 have undesirable side effects or other unexpected characteristics; risks relating to our ability to make required payments under our outstanding convertible notes or any other indebtedness as they come due and our ability to obtain additional financing and raise capital as necessary should the regulatory approval process become more extended; risks associated with the COVID-19 outbreak and variants, which may adversely impact our business, preclinical studies and clinical trials; risks relating to our evaluation and pursuit of strategic alternatives; risks relating to our ability to manage our relationship with our collaborators, distributors or partners; risks relating to changes to interim, topline or preliminary data from clinical trials that we announce or publish; 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; 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; the impact of development of competing therapies and/or technologies by other companies; risks related to our supply of drug product to Pfizer; risks related to our expectations with respect to the potential commercial value of our product and product candidates; 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; 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 the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites; 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
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Source: Protalix BioTherapeutics, Inc.

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

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,642	$ 18,265
Short-term bank deposits	38,017	20,280
Accounts receivable – Trade	5,561	2,000
Other assets	2,274	2,096
Inventories	14,730	13,082
Total current assets	$ 71,224	$ 55,723
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	1,948	$ 1,799
Property and equipment, net	5,065	4,845
Operating lease right of use assets	5,245	5,567
Total assets	$ 83,482	$ 67,934
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 8,436	$ 7,221
Other	14,694	13,926
Operating lease liabilities	1,235	1,420
Contracts liability	15,160	5,394
Convertible notes	3,239	54,427
Promissory note		4,086
Total current liabilities	$ 42,764	$ 86,474
LONG TERM LIABILITIES:		
Convertible notes	$ 27,816	$
Contracts liability	5,895	1,716
Liability for employee rights upon retirement	2,353	2,263
Operating lease liabilities	4,441	4,467
Other long term liabilities		51
Total long term liabilities	$ 40,505	$ 8,497
Total liabilities	$ 83,269	$ 94,971
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	213	(27,037)
Total liabilities and stockholders' equity (net of capital deficiency)	$ 83,482	$ 67,934

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, 2021	September 30, 2020	September 30, 2021	September 30, 2020
REVENUES FROM SELLING GOODS	$ 12,260	$ 11,975	$ 4,506	$ 3,296
REVENUES FROM LICENSE AND R&D SERVICES	17,541	31,428	7,548	7,494
TOTAL REVENUE	29,801	43,403	12,054	10,790
COST OF GOODS SOLD (1)	(13,201)	(8,121)	(3,703)	(2,868)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(22,093)	(27,214)	(7,282)	(7,688)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(9,263)	(8,197)	(2,954)	(2,816)
OPERATING LOSS	(14,756)	(129)	(1,885)	(2,582)
FINANCIAL EXPENSES	(6,613)	(7,150)	(2,410)	(1,973)
FINANCIAL INCOME	403	359	96	118
FINANCIAL EXPENSES – NET	(6,210)	(6,791)	(2,314)	(1,855)
OTHER INCOME	51			
NET LOSS FOR THE PERIOD	$ (20,915)	$ (6,920)	$ (4,199)	$ (4,437)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.48)	$ (0.25)	$ (0.09)	$ (0.14)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	43,761,769	27,758,104	45,556,647	32,863,788
(1) Includes share-based compensation	$ 217	$	$ 65	$
(2) Includes share-based compensation	$ 524	$ 635	154	562
(3) Includes share-based compensation	$ 1,216	$ 1,477	$ 344	$ 852