**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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# FORM 8-K

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**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 7, 2019**

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**Protalix BioTherapeutics, Inc.**
**(Exact name of registrant as specified in its charter)**

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| **Delaware** | **001-33357** | **65-0643773** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **2 Snunit Street**<br>**Science Park, POB 455**<br>**Carmiel, Israel**<br>**(Address of principal executive offices)** | **20100**<br>**(Zip Code)** |

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

**(Former name or former address, if changed since last report.)**

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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 7, 2019, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the period ended September 30, 2019 and provided a corporate 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**

**(d) Exhibits**

| | |
|---|---|
| 99.1 | Press release dated November 7, 2019. |

**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 7, 2019

**PROTALIX BIOTHERAPEUTICS, INC.**

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

**Protalix BioTherapeutics Reports Third Quarter 2019 Results and Provides Corporate Update**

**CARMIEL, Israel**, November 7, 2019 -- 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 announced its third quarter 2019 financial results and provided a corporate update.

"This has been a consequential quarter for Protalix during which we continued to make solid progress on our goals to move our Fabry program toward commercialization and to pursue strategic partnerships and alliances, and we commenced efforts to improve our capital structure," said Dror Bashan, Protalix's President and Chief Executive Officer. "During the third quarter, we completed enrollment in our pivotal, head-to-head BALANCE study evaluating PRX-102 compared to Fabrazyme®. We also recently reported positive 12-month interim data from our switch-over Phase III BRIDGE study comparing PRX-102 to another standard-of-care treatment, Replagal®."

"With three, now fully enrolled Phase III clinical trials of PRX-102, we have a robust and thorough clinical program for the treatment of Fabry disease," concluded Mr. Bashan. "Our management, scientific and clinical teams are all fully committed to bringing this important treatment to the Fabry patient community."

**Third Quarter 2019 and Recent Clinical and Corporate Highlights**

- The Company, together with its development and collaboration partner, Chiesi Farmaceutici S.p.A, or Chiesi, announced the completion of enrollment in the Phase III BALANCE clinical trial of PRX-102 for the treatment of Fabry disease. The head-to-head Phase III BALANCE clinical study is designed to evaluate the safety and efficacy of PRX-102 compared to agalsidase beta (Fabrazyme®) on renal function in Fabry patients with progressing kidney disease previously treated with agalsidase beta. To date, more than 66 patients are being treated in the Company's various extension studies after opting to continue treatment with PRX-102 after completion of an original study.

- The Company announced positive 12-month interim on-treatment data from the first 16 out of the 22 adult patients (9 males and 7 females) enrolled in the BRIDGE Phase III open label switch-over study of PRX-102 for the treatment of Fabry disease. The interim data demonstrate a mean improvement in kidney function, in both male and female patients, when switched from agalsidase alfa (Replagal®) to PRX-102, and will help to support the expected U.S. Food and Drug Administration ("FDA") BLA filing under Accelerated Approval.

- The Company and Chiesi plan the submission of a BLA for PRX-102 via the FDA's Accelerated Approval pathway based on data from the completed Phase I/II clinical trials of PRX-102 and the ongoing Phase III BRIDGE clinical trial by April 2020.

**Financial Results for the Nine Months Ended September 30, 2019**

- The Company recorded revenues from selling goods of $12.1 million during the nine-month period ended September 30, 2019, an increase of $4.9 million, or 67%, compared to revenues of $7.2 million for the same period of 2018. The increase is primarily due to higher sales of Elelyso® in Brazil.

- Research and development expenses, net, were $35.0 million for the nine months ended September 30, 2019, an increase of $11.3 million, or 47%, compared to $23.8 million for the same period of 2018. The increase resulted primarily from an increase of $8.5 million in clinical trial related costs as well as a decrease of $1.8 million in grants received from the Israeli Innovation Authority.

- Selling, general and administrative expenses for the nine months ended September 30, 2019 were $6.9 million, a decrease of $1.9 million, or 21%, compared to $8.7 million for the same period in 2018. The decrease is primarily due to costs related to the Chiesi US Agreement we entered into in the third quarter of 2018, which were not incurred in the third quarter of 2019.

- Net loss for the nine months ended September 30, 2019 was $18.6 million, or $0.13 per share, basic and diluted, compared to a net loss of $21.0 million, or $0.14 per share, basic and diluted, for the nine months ended September 30, 2018.

- At September 30, 2019, the Company had $21.4 million in cash and cash equivalents.

- The Company received a communication from NYSE American LLC stating that the Company is not in compliance with the continued listing standards as set forth in the NYSE American Company Guide as it has reported a stockholders' equity deficiency as of June 30, 2019 and net losses in its five most recent fiscal years ended December 31, 2018. Subsequently, in accordance with the NYSE American Company Guide, the Company submitted to the NYSE American a plan to regain compliance with the continued listing standards.

- The Company has engaged a first-tier financial advisory firm to assist in evaluating and pursuing strategic alternatives to maximize stakeholder value and address the foregoing.

- As part of the Company's efforts to advance its clinical development program and to realize future benefits of commercial success, the Company's Board of Directors, along with the management team, has determined that it is in the Company's best interest to seek to address to its capital structure.

- Accordingly, the Company convened a Special Meeting of Stockholders to seek approval for the following:

  - A reverse stock split at a ratio of not less than 1-for-10 and not greater than 1-for-20, with the exact ratio to be set within that range at the discretion of the Board of Directors before the day prior to the Special Meeting of Stockholders without further approval or authorization of the stockholders; and to reduce the total number of shares of the Company's common stock that the Company is authorized to issue from 350 million to 120 million shares.

- The Special Meeting of Stockholders of Protalix BioTherapeutics, Inc. to vote on the proposal will be held at 1:00 p.m., Israel time, on December 9, 2019 at the offices of the Company's Israeli counsel, Horn & Co., Law Offices, Amot Investments Tower, 2 Weizmann Street, 24th Floor, Tel Aviv 6423902, Israel.

**Conference Call and Webcast Information**

The Company will host a conference call on Thursday, November 7, 2019, at 8:30 am, Eastern Standard 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 (USA): 888-224-1005
International: 323-994-2093
Conference ID: 1931108
Webcast: http://bit.ly/2BSCaiY

The conference call will also be broadcast live and 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. Our pipeline consists of proprietary, potentially clinically superior versions of recombinant therapeutic proteins that target established pharmaceutical markets.

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 includes the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease, in phase III clinical trials (BALANCE, BRIDGE and BRIGHT studies); and OPRX-106, an orally delivered anti-inflammatory treatment, and alidornase alfa, both in phase II clinical trials. 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 related to our ability to identify and complete strategic alternatives on attractive terms or at all within the time period required to regain compliance with the continued listing standards of the NYSE American; risks related to our ability to continue as a going concern absent a refinancing or restructuring; risks related to any transactions we may effect in the public or private equity markets to raise capital to finance future research and development, general and administrative expenses and working capital activities; failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: 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; 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; 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 ultimate purchase by Fundação Oswaldo Cruz of alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase generally; risks related to the amount of our future revenues and expenditures; the risk that despite the FDA's grant of fast track designation for pegunigalsidase alfa for the treatment of Fabry disease, 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; 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)

| | September 30, 2019 (Unaudited) | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 21,442 | $ 37,808 |
| Accounts receivable – Trade | 8,716 | 4,729 |
| Other assets | 2,756 | 1,877 |
| Inventories | 7,525 | 8,569 |
| Total current assets | $ 40,439 | $ 52,983 |
| **NON-CURRENT ASSETS:** | | |
| **FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT** | $ 1,953 | $ 1,758 |
| **PROPERTY AND EQUIPMENT, NET** | 5,573 | 6,390 |
| **OPERATING LEASE RIGHT OF USE ASSETS** | 5,764 | - |
| Total assets | $ 53,729 | $ 61,131 |
| **LIABILITIES NET OF CAPITAL DEFICIENCY** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable and accruals: | | |
| Trade | $ 7,755 | $ 5,211 |
| Other | 12,730 | 10,274 |
| Operating lease liabilities | 1,222 | - |
| Contracts liability | 11,612 | 9,868 |
| Total current liabilities | $ 33,319 | $ 25,353 |
| **LONG TERM LIABILITIES:** | | |
| Convertible notes | $ 50,163 | $ 47,966 |
| Contracts liability | 28,586 | 33,027 |
| Liability for employee rights upon retirement | 2,606 | 2,374 |
| Operating lease liabilities | 4,532 | - |
| Other long term liabilities | 5,372 | 5,292 |
| Total long term liabilities | $ 91,259 | $ 88,659 |
| Total liabilities | $ 124,578 | $ 114,012 |
| **COMMITMENTS** | | |
| **CAPITAL DEFICIENCY** | $ (70,849) | $ (52,881) |
| Total liabilities net of capital deficiency | $ 53,729 | $ 61,131 |

**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, 2019 | September 30, 2018 | September 30, 2019 | September 30, 2018 |
| **REVENUES FROM SELLING GOODS** | $ 12,086 | $ 7,222 | $ 5,126 | $ 663 |
| **REVENUES FROM LICENSE AND R&D SERVICES** | 24,848 | 16,665 | 9,122 | 11,672 |
| **COST OF GOODS SOLD** | (7,945) | (7,024) | (3,205) | (1,917) |
| **RESEARCH AND DEVELOPMENT EXPENSES, NET (1)** | (35,021) | (23,755) | (10,000) | (10,071) |
| **SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)** | (6,885) | (8,744) | (2,587) | (4,088) |
| **OPERATING LOSS** | (12,917) | (15,636) | (1,544) | (3,741) |
| **FINANCIAL EXPENSES** | (5,877) | (5,824) | (2,050) | (1,811) |
| **FINANCIAL INCOME** | 227 | 437 | 34 | 230 |
| **FINANCIAL EXPENSES, NET** | (5,650) | (5,387) | (2,016) | (1,581) |
| **NET LOSS FOR THE PERIOD** | $ (18,567) | $ (21,023) | (3,560) | $ (5,322) |
| **NET LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED** | $ (0.13) | $ (0.14) | (0.02) | $ (0.04) |
| **WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED** | 148,382,299 | 146,752,355 | 148,382,299 | 148,187,513 |
| **(1) Includes share-based compensation** | $ 426 | $ 54 | $ 110 | $ 14 |
| **Includes grants** | $ (55) | $ (1,810) | (52) | $ (732) |
| **(2) Includes share-based compensation** | $ 173 | $ 42 | $ 86 | $ 8 |

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