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): May 6, 2019

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**		**20100**
(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))

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. ☐

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

Item 2.02 Results of Operations and Financial Condition

On May 6, 2019, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 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 May 6, 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: May 6, 2019

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Yossi Maimon
Name: Yossi Maimon
Title: Vice President and Chief Financial Officer

Exhibit 99.1

Protalix BioTherapeutics Reports 2019 First Quarter Results and Provides Corporate Update

CARMIEL, Israel, May 6, 2019 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®, today announced its financial results for the three months ended March 31, 2019 and provided a corporate update.

"In the first three months of 2019, we have continued to execute on enrollment in our PRX-102 studies and have worked to prepare ourselves for a potential accelerated approval path," said Mr. Moshe Manor, Protalix's President and Chief Executive Officer. "In addition, we are encouraged by the initial pharmacokinetic (PK) data from our BRIGHT study, which were presented at the 15th Annual WORLD*Symposium*™ 2019 in February 2019, that demonstrate the potential for PRX-102 to be infused once-monthly, compared to the current treatment regimen of every two weeks."

First Quarter 2019 and Recent Clinical and Corporate Highlights

- The Company's BRIGHT phase III clinical trial of pegunigalsidase alfa, or PRX-102, for the treatment of Fabry disease is currently one patient away from completion of enrollment.
- The Company's BALANCE phase III clinical trial of pegunigalsidase alfa for the treatment of Fabry disease is currently eleven patients away from completion of enrollment.
- The Company presented results from the BRIGHT Study at the 15th Annual WORLD Symposium showing that infusion of pegunigalsidase alfa every 4 weeks results in the presence of continuous active enzyme throughout the entire infusion interval.
- The Company is scheduled to present three posters during the 6th Update on Fabry Disease international conference being held in Prague, Czech Republic, on May 26-28, 2019.
- To date, more than 40 patients are being treated in the Company's various extension studies after opting to continue treatment with pegunigalsidase alfa after they completed an initial study.
- The Company plans to meet with the U.S. Food and Drug Administration (FDA) for a follow up meeting during the second quarter of 2019 in connection with the potential accelerated approval filing path for pegunigalsidase alfa.

First Quarter 2019 Financial Results

- The Company recorded total revenues of $10.4 million during the three months ended March 31, 2019, compared to $6.7 million for the same period of 2018. The increase is primary attributable to the recognition of $6.9 million of license revenues in the three months ended on March 31, 2019 compared to the recognition of $2.2 million in the same period of 2018.
- Research and development expenses for the three months ended March 31, 2019, were $11.7 million, compared to $7.3 million for the same period in 2018. Selling, general and administrative expenses for the three months ended March 31, 2019 were $2.2 million, compared to $2.5 million incurred during the same period in 2018.
- Net loss for the three months ended March 31, 2019 was $7.3 million compared to $7.2 million for the three months ended March 31, 2018.
- On March 31, 2019, the Company had $30.4 million of cash and cash equivalents, compared to $37.8 million at March 31, 2018, which is currently projected to fund operations into mid-2020. As of March 31, 2019, the Company had outstanding $57.9 million of its 7.50% convertible promissory notes due November 2021.

Conference Call and Webcast Information

The Company will host a conference call on Monday, May 6, 2019, at 8:30 am ET 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: United States: +1-844-358-6760; International: +1-478-219-0004. Conference ID number 6169584.

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's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (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; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; 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: 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; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of superiority, 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 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 our commercialization efforts for 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; risks related to the amount of our future revenues, operations 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 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

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Protalix BioTherapeutics, Inc.

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

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 30,363	$ 37,808
Accounts receivable – Trade	8,565	4,729
Other assets	1,706	1,877
Inventories	6,707	8,569
Total current assets	$ 47,341	$ 52,983
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	$ 1,801	$ 1,758
PROPERTY AND EQUIPMENT, NET	6,058	6,390
OPERATING LEASE RIGHT OF USE ASSETS	5,844	-
Total assets	$ 61,044	$ 61,131
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,870	$ 5,211
Other	10,480	10,274
Operating lease liabilities	1,257	
Contracts liability	9,429	9,868
Total current liabilities	$ 27,036	$ 25,353
LONG TERM LIABILITIES:		
Convertible notes	$ 48,670	$ 47,966
Contracts liability	32,979	33,027
Liability for employee rights upon retirement	2,426	2,374
Operating lease liabilities	4,498	
Other long term liabilities	5,290	5,292
Total long term liabilities	$ 93,863	$ 88,659
Total liabilities	$ 120,899	$ 114,012
COMMITMENTS		
CAPITAL DEFICIENCY	(59,855)	(52,881)
Total liabilities net of capital deficiency	$ 61,044	$ 61,131

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

	Three Months Ended	
	March 31, 2019	**March 31, 2018**
REVENUES FROM SELLING GOODS	$ 3,530	$ 4,553
REVENUES FROM LICENSE AND R&D SERVICES	6,909	2,161
COST OF GOODS SOLD	(2,045)	(2,924)
RESEARCH AND DEVELOPMENT EXPENSES (1)	(11,701)	(7,286)
Less – grants	3	843
RESEARCH AND DEVELOPMENT EXPENSES, NET	(11,698)	(6,443)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(2,230)	(2,498)
OPERATING LOSS	(5,534)	(5,151)
FINANCIAL EXPENSES	(1,920)	(2,220)
FINANCIAL INCOME	190	132
FINANCIAL EXPENSES, NET	(1,730)	(2,088)
LOSS FOR THE PERIOD	$ (7,264)	$ (7,239)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.05)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	148,382,299	145,305,982
(1) Includes share-based compensation	$ 178	$ 42
(2) Includes share-based compensation	$ 112	$ 20