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): March 12, 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 March 12, 2020, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2019, 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 March 12, 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: March 12, 2020

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Fourth Quarter and Full Year 2019 Financial and Business Results

Conference call and live webcast scheduled for Thursday, March 12th, 2020 at 8:30 am EDT

CARMIEL, Israel, March 12, 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 fourth quarter and full year ended December 31, 2019, and provided a business update on recent corporate and clinical developments. The Company will discuss the clinical, corporate and financial highlights on a conference call and live webcast, scheduled for Thursday, March 12th, 2020 at 8:30 am EDT.

“2019 was a pivotal year for Protalix, as we successfully expanded on our strong foundation and entered into a new phase of development as a world-class recombinant therapeutic company,” said Dror Bashan, Protalix’s President and Chief Executive Officer. “With this continued forward momentum toward commercialization of our Fabry program, we believe Protalix is positioned for both near- and long-term success,” he continued.

“We are increasingly enthusiastic about our PRX-102 asset now that we have three ongoing, fully-enrolled Phase III clinical trials of PRX-102, and as we anticipate our BLA submission to the U.S. Food and Drug Administration under the Accelerated Approval pathway next quarter,” added Mr. Bashan. “Furthermore, we anticipate the final results of our BRIDGE and BRIGHT trials in the first and second halves of 2020, respectively, which will further support our portfolio of data regarding PRX-102. Protalix is firing on all cylinders right now, and the energy among the entire staff reached a new pinnacle in 2019.”

“We anticipate 2020 to be a banner year for Protalix as we increase our focus on advancing our clinical pipeline, expanding sales in Brazil of Elelyso®, our enzyme replacement therapy for the treatment of Gaucher disease, and leveraging commercial opportunities to expand our global footprint in the treatment of Fabry disease,” he concluded.

Conference Call and Webcast Information

The Company will host a conference call on Thursday, March 12, 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:	13699970
Webcast:	http://public.viavid.com/index.php?id=138400

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

2019 Full-Year and Recent Business Highlights

Clinical Advancements

- The Company and its collaboration partner, Chiesi Farmaceutici S.p.A., or Chiesi, plan the submission of a BLA for PRX-102 via the FDA's Accelerated Approval pathway in the second quarter of 2020, based on data from the completed Phase I/II clinical trial of PRX-102 for the treatment of Fabry disease and the ongoing Phase III BRIDGE clinical trial.
  Results from the Company's Phase I/II clinical trial of PRX-102 were published in an article in the May 2019 edition of the *Journal of Inherited Metabolic Disease*.

- The Company announced positive 12-month interim on-treatment data from the BRIDGE study. 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. The data will be included in the anticipated BLA filing to help to support the application.

- The Company and Chiesi announced the completion of enrollment in the Phase III BALANCE clinical trial. The head-to-head BALANCE 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 initial study.

- Enrollment was completed in the Phase III BRIGHT clinical trial of PRX- 102, via intravenous infusions of 2 mg/kg administered every 4 weeks. Preliminary pharmacokinetic (PK) data showed PRX-102 to be well-tolerated; and infusion of 2 mg/kg PRX-102 administered every 4 weeks resulted in the presence of continuous active enzyme throughout the entire infusion interval. Infusions every 2 weeks is the current standard of care for the treatment of Fabry disease.

Corporate & Financial Developments

- The Company yesterday successfully secured securities purchase agreements to raise proceeds equal to $43.7 million through a private financing with a number of leading Israeli and U.S.- based investors, including Psagot Investment House, More Investment House, Highbridge Capital, UBS O'Connor, Rosalind Capital, and Alrov Properties and Lodging, among others. Rosario Capital and Houlihan Lokey served as financial advisors in the private placement.

- In December 2019, the Company held a special meeting of stockholders to propose the following two critical financial amendments, which stockholders ultimately approved:
  - A reverse stock split (1-for-10); and
  - A reduction in 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.

- In December 2019, the Company enhanced its Board of Directors with addition of two accomplished biopharmaceutical executives, Pol F. Boudes, M.D., and Gwen A. Melincoff.

- In August 2019, the Company's Board of Directors unanimously elected Zeev Bronfeld, an independent director, as Chairman of the Board.

- In July 2019, the Company appointed Eyal Rubin as Senior Vice President and Chief Financial Officer.

- In May 2019, the Company appointed Dror Bashan as President and Chief Executive Officer.

Regulatory Advancements

- In February 2020, Protalix and Chiesi announced the receipt of an agreement letter from the FDA for the Initial Pediatric Study Plan (iPSP) for PRX-102 for the treatment of Fabry disease, outlining an agreed-upon approach to address the needs of pediatric Fabry patients.

Financial Results

For the year ended December 31, 2019, compared to the year ended December 31, 2018

- The Company recorded revenues from selling goods of $15.9 million for the year ended December 31, 2019, an increase of $6.9 million, or 77%, compared to revenues of $9.0 million for the same period of 2018. The increase is primarily due to higher sales of Elelyso® in Brazil as well as an increase in sales of drug substance to Pfizer.

- Research and development expenses, net, were $44.6 million for the year ended December 31, 2019, an increase of $11.3 million, or 34%, compared to $33.3 million for the same period of 2018. The increase resulted primarily from an increase of $9.1 million in clinical trial related costs as well as a decrease of $2.1 million in grants received from the Israeli Innovation Authority.

- Selling, general and administrative expenses were $9.9 million for the year ended December 31, 2019, a decrease of $1.0 million, or 9%, compared to $10.9 million for the same period of 2018. The decrease resulted primarily from costs related to the Company's U.S. Exclusive License and Supply Agreement that the Company entered into in 2018, which were not incurred in 2019.

- Net loss was $18.3 million for the year ended December 31, 2019, or $1.23 per share, basic and diluted, compared to a net loss of $26.5 million, or $1.80 per share, basic and diluted, for the same period of 2018.

- At December 31, 2019, the Company had $17.8 million in cash and cash equivalents.

For the three months ended December 31, 2019, compared to the three months ended December 31, 2018

- The Company recorded revenues from selling goods of $3.8 million during the three-month period ended December 31, 2019, an increase of $2.0 million, or 111%, compared to revenues of $1.8 million for the same period of 2018. The increase is primarily due to higher sales of drug substance to Pfizer Inc. as well as higher sales of Elelyso® in Brazil.

- Research and development expenses, net, were $9.6 million for the three-month period ended each of December 31, 2019 and December 31, 2018.

- Selling, general and administrative expenses were $3.0 million for the three-month period ended December 31, 2019, an increase of $0.8 million, or 36%, compared to $2.2 million for the same period in 2018. The increase is primarily due to costs related to the efforts to evaluate and pursue strategic alternatives, business development advisory fees, and legal fees and costs related to replacement of the Chief Executive Officer.

- Net profit for the three months ended December 31, 2019 was $0.3 million, or $0.02 per share, basic and diluted, compared to a net loss of $5.4 million, or $0.40 per share, basic and diluted, for the three months ended December 31, 2018.

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, potentially clinically superior 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 treatment of Fabry disease in Phase III clinical trials (BALANCE, BRIDGE and BRIGHT studies); 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: the timing of the closing of the PIPE financing, if at all; our inability, or the inability of the investors, to satisfy the conditions to closing for the PIPE financing; 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.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31,	
	2018	**2019**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 37,808	$ 17,792
Accounts receivable – Trade	4,729	4,700
Other assets	1,877	1,832
Inventories	8,569	8,155
Total current assets	$ 52,983	$ 32,479
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,758	$ 1,963
Property and equipment, net	6,390	5,273
Operating lease right of use assets	-	5,677
Total assets	$ 61,131	$ 45,392
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,211	$ 6,495
Other	10,274	11,905
Operating lease liabilities	-	1,139
Contracts liability	9,868	16,335
Promissory note	-	4,301
Total current liabilities	$ 25,353	$ 40,175
LONG TERM LIABILITIES:		
Convertible notes	$ 47,966	$ 50,957
Contracts liability	33,027	16,980
Liability for employee rights upon retirement	2,374	2,565
Operating lease liabilities	-	4,528
Other long term liabilities	5,292	509
Total long term liabilities	$ 88,659	$ 75,539
Total liabilities	$ 114,012	$ 115,714
COMMITMENTS		
CAPITAL DEFICIENCY		
Common Stock, $0.001 par value: Authorized - as of December 31, 2018 and 2019, 25,000,000 shares and 120,000,000 respectively; issued and outstanding, respectively - as of December 31, 2018 and 2019, 14,838,213 shares	15	15
Additional paid-in capital	269,657	270,492
Accumulated deficit	(322,553)	(340,829)
Total capital deficiency	(52,881)	(70,322)
Total liabilities net of capital deficiency	$ 61,131	$ 45,392

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share amounts)

	Year Ended December 31,		
	2017	**2018**	**2019**
REVENUES FROM SELLING GOODS	$ 19,242	$ 8,978	$ 15,866
REVENUES FROM LICENSE AND R&D SERVICES	1,836	25,262	38,827
TOTAL REVENUE	21,078	34,240	54,693
COST OF GOODS SOLD	(15,231)	(9,302)	(10,895)
RESEARCH AND DEVELOPMENT EXPENSES	(32,170)	(35,534)	(44,693)
Less – grants	3,336	2,204	77
RESEARCH AND DEVELOPMENT EXPENSES, NET	(28,834)	(33,330)	(44,616)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(11,530)	(10,916)	(9,899)
OPERATING LOSS	(34,517)	(19,308)	(10,717)
FINANCIAL EXPENSES	(9,725)	(7,685)	(7,966)
FINANCIAL INCOME	188	536	407
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE	(38,061)	-	-
LOSS ON EXTINGUISHMENT OF CONVERTIBLE NOTES	(1,325)	-	-
FINANCIAL EXPENSES – NET	(48,923)	(7,149)	(7,559)
NET LOSS FOR THE YEAR	$ (83,440)	$ (26,457)	$ (18,276)
NET LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	$ (6.37)	$ (1.80)	$ (1.23)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	13,108,596	14,713,518	14,838,213

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