

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): August 9, 2017

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

Delaware
(State or other jurisdiction
of incorporation)

001-33357
(Commission File Number)

65-0643773
(IRS Employer
Identification No.)

2 Snunit Street
Science Park, POB 455
Carmiel, Israel
(Address of principal executive offices)

20100
(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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication 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.

Item 2.02. Results of Operations and Financial Condition

On August 9, 2017, Protalix BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2017. 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 August 9, 2017.

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: August 9, 2017

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and Chief Executive Officer

Protalix BioTherapeutics Reports 2017 Second Quarter Results and Provides Corporate Update

Cystic Fibrosis Foundation Approves Letter of Application Enabling Protalix to Apply for Grant Funding

Debt Refinancing and Financing Significantly Improves Financial Position

CARMIEL, Israel, August 9, 2017 -- GlobeNewswire /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 six months ended June 30, 2017 and provided a corporate update.

“Substantial progress was made across all three of our clinical assets in the second quarter, including active enrollment in all Fabry trials, nearing the end of enrollment for our PRX-106 trial and progress with our interactions with the CF Foundation,” said Moshe Manor, Protalix’s President and Chief Executive Officer. “Recently, we executed a \$10 million debt financing to counter balance a similar amount of cash paid out to settle conversions of our 7.50% convertible notes. In addition, we refinanced \$9 million principal amount of our 4.50% convertible notes due September 2018 into \$8.55 million of new 4.50% convertible notes due February 2022. These transactions solidify our cash position into 2019.”

2017 First Half and Recent Clinical and Corporate Highlights

General Corporate Highlight

- The U.S. Food and Drug Administration (FDA) approved the Company’s current manufacturing facility to operate as a multi-product facility to support the potential manufacturing of both pegunigalsidase alfa and taliglucerase alfa on a commercial scale.
- Manufacturing for drug substance for all phase III clinical trials of pegunigalsidase alfa are complete, and manufacturing capacity is readily available for commercial needs.

Pegunigalsidase alfa (PRX-102) for Fabry Disease

- Both the Company’s Balance and Bridge studies are currently enrolling patients with the Bright study to initiate its first site this month.
- To date, all of the patients in the Balance study that switched to pegunigalsidase alfa from Fabrazyme[®] have demonstrated excellent tolerability and no infusion reaction has been observed. A number of patients in the study have been moved to home care therapy following successful initial infusion periods in the infusion center.

Alidornase alfa (PRX-110) for Cystic Fibrosis

- The Cystic Fibrosis Foundation approved the Company’s letter of intent application. With that approval, the Company has been invited to apply for a grant to support the clinical development of alidornase alfa.
- An oral presentation titled, “Phase II clinical trial results with alidornase alfa for the treatment of CF,” made by Professor Eitan Kerem, Head of the Division of Pediatrics, Children’s Hospital, Hadassah Medical Center, and principal investigator of the phase 2a clinical trial of alidornase alfa at the 40th European Cystic Fibrosis Society Conference.

Oral anti-TNF (OPRX-106) for Ulcerative Colitis

- Enrollment is nearing completion in global clinical trial sites. Full results are expected around year-end.
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Alfatiglicerase for Gaucher Disease

- Shipment of approximately \$3.6 million of alfatiglicerase was completed in June with an additional shipment of \$1.3 million completed in July and \$2.2 million scheduled to be shipped later this quarter.
- According to the purchase order received by the Company, additional shipments are scheduled to be made during fourth quarter.

Financial Results for Six Months ended June 30, 2017

- The Company reported a net loss of \$20.6 million, or \$0.16 per share, basic and diluted, excluding a one-time, non-cash net charges of \$38.1 million in connection with the remeasurement of a derivative which was reversed in its entirety into the Company's income statement and shareholder equity section in the second quarter, compared to a net loss of \$19.5 million, or \$0.20 per share, basic and diluted, for the same period of 2016.
- The Company recorded total revenues of \$9.2 million, compared to \$2.4 million during the same period of 2016. The increase is attributed primarily to increased sales of drug product to Brazil and drug substance to Pfizer Inc.
- Research and development expenses, net were \$13.5 million, compared to \$13.8 million for the same period in 2016. Selling, general and administrative expenses were \$5.4 million, compared to \$4.2 million incurred during the same period of 2016. The increase is primarily attributed to increased activities in Brazil.
- On June 30, 2017, the Company had \$34.5 million of cash and cash equivalents. With the addition of the \$10 million from the recent financing, cash is currently projected to fund operations into 2019.
- During the period, investors converted approximately \$10.8 million of face value of the Company's 7.5% convertible notes, of which \$7.7 million face value were settled for \$11 million in cash (including accrued interest and make whole). This conversion was the primary driver of the recent \$10 million notes offering announced July 25, 2017.
- Approximately principal amount \$3.6 million of the 4.50% convertible notes due February 2022 have been converted into approximately 4.2 million shares of common stock since the issuance of the notes.
- As of today, the Company's outstanding convertible notes include 4.50% convertible notes due September 2018 with an aggregate principal amount of \$5.9 million, senior secured 7.50% convertible notes due November 2021 with an aggregate principal amount of \$61.9 million and 4.50% convertible notes due February 2022 an aggregate principal amount of \$5.0 million.

Conference Call and Webcast Information

The Company will host a conference call on Wednesday, August 9, 2017, 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 64212629.

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.

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. Factors that might cause material differences include, among others: 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 our ability to enter into transactions regarding the matters discussed herein; 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; 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; 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 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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Source: Protalix BioTherapeutics, Inc.

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

	June 30, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 34,533	\$ 63,281
Accounts receivable – Trade	3,005	693
Other assets	4,081	2,321
Inventories	7,059	5,245
Assets of discontinued operation	213	327
Total current assets	\$ 48,891	\$ 71,867
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,951	1,677
PROPERTY AND EQUIPMENT, NET	8,158	8,703
Total assets	\$ 59,000	\$ 82,247
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 7,852	\$ 4,007
Other	9,339	7,496
Convertible notes		53,872
Deferred revenues	1,925	837
Total current liabilities	\$ 19,116	\$ 66,212
LONG TERM LIABILITIES:		
Convertible notes	53,580	19,343
Liability for employee rights upon retirement	2,671	2,348
Promissory note	4,301	4,301
Total long term liabilities	\$ 60,552	\$ 25,992
Total liabilities	\$ 79,668	\$ 92,204
COMMITMENTS		
CAPITAL DEFICIENCY		
Total liabilities net of capital deficiency	\$ (20,668)	\$ (9,957)

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

	Six Months Ended		Three Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
REVENUES	\$ 9,247	\$ 2,448	\$ 6,358	\$ 1,769
COST OF REVENUES	(7,611)	(2,198)	(5,523)	(1,675)
GROSS PROFIT	1,636	250	835	94
RESEARCH AND DEVELOPMENT EXPENSES (1)	(15,271)	(17,347)	(9,304)	(10,013)
Less – grants	1,816	3,503	478	2,194
RESEARCH AND DEVELOPMENT EXPENSES, NET	(13,455)	(13,844)	(8,826)	(7,819)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(5,351)	(4,201)	(2,814)	(2,206)
OPERATING LOSS	(17,170)	(17,795)	(10,805)	(9,931)
FINANCIAL EXPENSES	(5,132)	(1,805)	(3,045)	(901)
FINANCIAL INCOME	1,665	338	40	96
(LOSS) INCOME FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE	(38,061)		14,260	
FINANCIAL (EXPENSES) INCOME, NET	(41,528)	(1,467)	11,255	(805)
(LOSS) INCOME FROM CONTINUING OPERATIONS	(58,698)	(19,262)	450	(10,736)
LOSS FROM DISCONTINUED OPERATIONS	-	(189)	-	(117)
NET (LOSS) INCOME FOR THE PERIOD	<u>\$ (58,698)</u>	<u>\$ (19,451)</u>	<u>\$ 450</u>	<u>\$ (10,853)</u>
NET (LOSS) EARNINGS PER SHARE OF COMMON STOCK:				
BASIC				
(Loss) earnings from continuing operations	(0.47)	(0.20)	0.00	(0.11)
Earnings from discontinued operations	-	0.00	-	0.00
Net (loss) earnings per share of common stock	<u>\$ (0.47)</u>	<u>\$ (0.20)</u>	<u>\$ 0.00</u>	<u>\$ (0.11)</u>
DILUTED				
Loss from continuing operations	(0.47)	(0.20)	(0.06)	(0.11)
Earnings from discontinued operations	-	0.00	-	0.00
Net loss per share of common stock	<u>\$ (0.47)</u>	<u>\$ (0.20)</u>	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING (LOSS) INCOME PER SHARE				
BASIC	126,000,782	99,737,348	127,523,706	99,758,511
DILUTED	126,000,782	99,737,348	192,598,389	99,758,511
(1) Includes share-based compensation	\$ 120	\$ 366	\$ 55	\$ 128
(2) Includes share-based compensation	\$ 96	\$ 236	\$ 43	\$ 99