Protalix BioTherapeutics Reports Second Quarter 2021 Financial Results and Financial and Business Update

August 16, 2021

CARMIEL, Israel, Aug. 16, 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 second quarter ended June 30, 2021 and provided a financial and business update.

"We continue to work closely with the FDA to address the issues raised in the Complete Response Letter received in April for PRX-102 for the proposed treatment of adult patients with Fabry disease," said Dror Bashan, Protalix's President and Chief Executive Officer. "We look forward to the meeting with the FDA, which has been scheduled for September 9, 2021. In addition, we strengthened our balance sheet by entering into definitive agreements with a majority of our institutional note holders relating to exchanges by such note holders of a total of $54.65 million principal amount of our outstanding 7.50% Senior Secured Convertible Notes due 2021 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 accrued and unpaid interest through the closing date. We plan to close the exchanges as soon as practicable. This transaction will allow us the use of our cash resources to continue to realize the PRX-102 potential and advance our early-stage pipeline. We are grateful for the continued support from our team members and external partners and look forward to a productive finish to 2021."

2021 Second Quarter and Recent Business Update

Regulatory Updates

- On April 28, 2021, the Company, together with its development and commercialization partner, Chiesi Farmaceutici S.p.A., or Chiesi, announced the receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Biologics License Application (BLA) seeking accelerated approval of pegunigalsidase alfa, or PRX-102, for the proposed treatment of adult patients with Fabry disease. The CRL did not report any concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package.
- On August 2, 2021, the Company announced that a Type A meeting request was submitted to the FDA to discuss the CRL dated April 27, 2021 regarding the BLA for PRX-102 for the proposed treatment of adult patients with Fabry disease. The FDA has scheduled the Type A meeting for September 9, 2021.

Clinical Advancements

- On June 2, 2021, the Company, together with Chiesi, announced initial top-line results from an interim analysis of the phase III BALANCE clinical trial, a study designed to evaluate the safety and efficacy of 1 mg/kg of PRX-102 dosed every two weeks compared to agalsidase beta (Fabrazyme®).
- Based on the interim analysis of the 12-month data generated from the BALANCE study, and in combination with previously reported positive data from the phase III BRIGHT and BRIDGE clinical trials of PRX-102, Protalix and Chiesi intend to submit a Marketing Authorization Application (MAA) to the European Medicines Agency for the review of PRX-102 for the proposed treatment of Fabry disease, subject to a positive meeting with the EMA rapporteur.

Corporate & Financial Developments

- On August 12, 2021, the Company entered into definitive agreements relating to exchanges of an aggregate of $54.65 million principal amount of the Company's outstanding 7.50% Senior Secured Convertible Notes due 2021 for an aggregate of $28.75 million principal amount of newly issued 7.50% Senior Secured Convertible Notes due 2024 (the "Exchange Notes"), $25.90 million in cash and accrued and unpaid interest through the closing date. The exchanges are expected to close as soon as practicable, subject to satisfaction of certain closing conditions. At closing, we will have reduced our debt by $28.75 million and effectively extended the maturity for substantially all of the remaining debt from 2021 until 2024. The support and willingness of our note holders to extend the maturity underscores their confidence in our core technology and expanding pipeline.
- On May 13, 2021, the Company and Chiesi entered into a binding term sheet pursuant to which they amended the two exclusive license and supply agreements for PRX-102 in order to provide the Company with near-term capital. Chiesi agreed to make a $10.0 million payment to the Company before the end of the second quarter in exchange for a $25.0 million reduction in a longer-term regulatory milestone payment in the Ex-U.S. Exclusive License and Supply Agreement. All other regulatory and commercial milestone payments remain unchanged. The Company and Chiesi also agreed to negotiate certain manufacturing related matters. The $10.0 million payment was received in June 2021.
- On July 2, 2021, the Company entered into an ATM Sales Agreement with H.C. Wainwright & Co., LLC (the agent) whereby the Company may sell, from time-to-time, shares of its common stock through the agent up to an aggregate offering price of $20.0 million. Upon execution of the sales agreement, the Company terminated the ATM Equity Offering Sales Agreement it had previously entered into with BofA Securities, Inc.

Second Quarter 2021 Financial Highlights

- The Company recorded revenues from selling goods of $3.2 million during the three months ended June 30, 2021, a decrease of $0.4 million, or 11%, compared to revenues of $3.6 million for the same period of 2020.
- Revenues from license and R&D services for the three months ended June 30, 2021 were $3.2 million, a decrease of $4.1 million, or 56%, compared to $7.3 million for the same period of 2020. 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. The decrease resulted primarily from an updated costs estimation throughout the trials until completion in the amount of $4.1 million and from revenues recognized in connection with the progress of the Company's clinical trials that have been completed during 2020.
- Cost of goods sold for the three months ended June 30, 2021 was $4.7 million, an increase of $2.9 million, or 161%, compared to $1.8 million for the same period in 2020. The increase in cost of goods sold was primarily the result of certain one-time manufacturing costs incurred while preparing for the then anticipated FDA approval of the PRX-102 BLA.
- Research and development expenses for the three months ended June 30, 2021 were $7.7 million, a decrease of $1.5 million, or 16%, compared to $9.2 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 more advanced stages of preclinical and clinical trials for certain of its product candidates.
- Selling, general and administrative expenses for the three months ended June 30, 2021 were $3.2 million, an increase of $1.0 million, or 45%, compared to $2.2 million for the same period in 2020. The increase resulted primarily from an increase in corporate costs related to insurance and funding.
- Financial expenses, net were $2.1 million for the three months ended June 30, 2021 and $1.9 million for the three months ended June 30, 2020. The increase resulted primarily from an increase in the amortization of debt issuance costs and debt discount.
- Cash, cash equivalents and short-term bank deposits were approximately $76.9 million at June 30, 2021.
- Net loss for the three months ended June 30, 2021 was approximately $11.2 million, or $0.25 per share, basic and diluted, compared to a net loss of $4.2 million, or $0.13 per share, basic and diluted, for the same period in 2020.

Conference Call and Webcast Information

The Company will host a conference call today, August 16, 2021 at 8:30 am Eastern Daylight Time, to review the clinical, corporate, and financial highlights, 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, August 16, 2021, 8:30 a.m. Eastern Daylight Time (EDT)

Domestic: 877-423-9813
International: 201-689-8573
Conference ID: 13721687

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/3y2rx6za

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 a 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 a–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, and with SarcoMed USA, Inc. for the worldwide development and commercialization of PRX–110 for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery.

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 relating to our ability to complete our proposed exchange transaction in a timely manner or at all; risks related to the timing and progress of the preparation of an updated BLA addressing the CRL; 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 the use of 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 we file 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; and inability to monitor patients adequately during or after treatment; 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, including the Exchange 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 novel coronavirus disease, or COVID-19, outbreak, which may adversely impact our business, preclinical studies and clinical trials; 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
Chuck Padala, Managing Director
LifeSci Advisors
646-627-8390
chuck@lifesciadvisors.com

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

	June 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,882	$ 18,265
Short-term bank deposits	43,058	20,280
Accounts receivable – Trade	2,330	2,000
Other assets	3,013	2,096
Inventories	13,640	13,082
Total current assets	$ 95,923	$ 55,723
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	1,884	$ 1,799
Property and equipment, net	4,991	4,845
Operating lease right of use assets	5,406	5,567
Total assets	$ 108,204	$ 67,934
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,128	$ 7,221
Other	14,420	13,926
Operating lease liabilities	1,235	1,420
Contracts liability	18,109	5,394
Convertible notes	56,355	54,427

Promissory note		4,086
Total current liabilities	$ 96,247	$ 86,474
LONG TERM LIABILITIES:		
Contracts liability	1,269	1,716
Liability for employee rights upon retirement	2,302	2,263
Operating lease liabilities	4,507	4,467
Other long term liabilities	38	51
Total long term liabilities	$ 8,116	$ 8,497
Total liabilities	$ 104,363	$ 94,971
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	3,841	(27,037)
Total liabilities and stockholders' equity (net of capital deficiency)	$ 108,204	$ 67,934

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, 2021	June 30, 2020	June 30, 2021	June 30, 2020
REVENUES FROM SELLING GOODS	$ 7,754	$ 8,679	$ 3,243	$ 3,648
REVENUES FROM LICENSE AND R&D SERVICES	9,993	23,934	3,184	7,319
TOTAL REVENUE	17,747	32,613	6,427	10,967
COST OF GOODS SOLD (1)	(9,498)	(5,253)	(4,733)	(1,827)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(14,811)	(19,526)	(7,689)	(9,186)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(6,309)	(5,381)	(3,171)	(2,194)
OPERATING INCOME (LOSS)	(12,871)	2,453	(9,166)	(2,240)
FINANCIAL EXPENSES	(4,240)	(5,177)	(2,203)	(1,948)
FINANCIAL INCOME	344	241	128	38
FINANCIAL EXPENSES – NET	(3,896)	(4,936)	(2,075)	(1,910)
OTHER INCOME	51			
NET LOSS FOR THE PERIOD	$ (16,716)	$ (2,483)	$ (11,241)	$ (4,150)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.39)	$ (0.12)	$ (0.25)	$ (0.13)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	42,744,426	19,923,935	45,436,907	32,442,636
(1) Includes share-based compensation	$ 152	$	$ 43	$
(2) Includes share-based compensation	$ 370	$ 73	160	(5)
(3) Includes share-based compensation	$ 872	$ 625	$ 375	$ 272

View original content:https://www.prnewswire.com/news-releases/protalix-biotherapeutics-reports-second-quarter-2021-financial-results-and-financial-and-business-update-301355662.html

SOURCE Protalix BioTherapeutics, Inc.