Protalix BioTherapeutics, Inc.
Form 10-Q
November 09, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2015

OR

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

001-33357

(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Florida	**65-0643773**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2 Snunit Street

Science Park

POB 455

Carmiel, Israel	**20100**
(Address of principal executive offices)	**(Zip Code)**

+972-4-988-9488

(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "large accelerated filer" and "accelerated filer" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer ¨	Accelerated filer x

Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

On November 1, 2015, approximately 99,800,397 shares of the Registrant's common stock, $0.001 par value, were outstanding.

FORM 10-Q

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Except where the context otherwise requires, the terms, "we," "us," "our" or "the Company," refer to the business of Protalix BioTherapeutics, Inc. and its consolidated subsidiaries, and "Protalix" or "Protalix Ltd." refers to the business of Protalix Ltd., our wholly-owned subsidiary and sole operating unit.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth under the captions "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations", and other statements included elsewhere in this Quarterly Report on Form 10-Q, which are not historical, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predi "should," "will," "would" and words or phrases of similar import, as they relate to our company or our subsidiaries or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the following:

- risks relating to the compliance by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, with its purchase obligations under our supply and technology transfer agreement which may result in the termination of such agreement which may have a material adverse effect on our company;

- risks related to the commercialization efforts for taliglucerase alfa in Brazil;

- risks related to our supply of drug product to Pfizer Inc., or Pfizer, pursuant to our amended and restated exclusive license and supply agreement with Pfizer;

- risks related to our supply of drug product to Fiocruz pursuant to our supply arrangement with Fiocruz;

- the risk that we will not be able to develop a successful sales and marketing organization for taliglucerase alfa in Brazil, or for any other product candidate, in a timely manner, if at all;

- failure or delay in the commencement or completion of our preclinical studies and clinical trials which may be caused by several factors, including: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; or lack of sufficient funding to finance our clinical trials;

- the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy, that our product candidates will not have the desired effects or include undesirable side effects or other unexpected characteristics;

- our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services;

- risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our 2018 convertible notes, or any other indebtedness;

- risks relating to our ability to finance our research programs;

- delays in our preparation and filing of applications for regulatory approval of our other product candidates in the United States, the European Union and elsewhere;

- our expectations with respect to the potential commercial value of our product and product candidates;

- the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, will be subject to potential marketing and commercialization restrictions;

- the impact of development of competing therapies and/or technologies by other companies;

- any lack of progress of our research and development activities and our clinical activities with respect to any product candidate;

- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;

- potential product liability risks, and risks of securing adequate levels of product liability and clinical trial insurance coverage;

- the possibility of infringing a third party's patents or other intellectual property rights;

- the uncertainty of obtaining patents covering our products and processes and in 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.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the U.S. Food and Drug Administration or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

These forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These and other risks and uncertainties are detailed under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014, and are described from time to time in the reports we file with the U.S. Securities and Exchange Commission, or the Commission.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 34,248	$ 54,767
Accounts receivable - Trade	4,573	1,884
Other assets	2,716	2,202
Inventories	6,339	6,667
Total current assets	47,876	65,520
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,569	1,555
PROPERTY AND EQUIPMENT, NET	9,957	11,282
DEFERRED CHARGES	90	113
Total assets	$ 59,492	$ 78,470
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,057	$ 3,951
Other	11,946	15,496
Deferred revenues	6,850	6,763
Total current liabilities	22,853	26,210
LONG TERM LIABILITIES:		
Convertible notes	67,774	67,464
Deferred revenues	35,127	37,232
Liability in connection with collaboration operation		912

Liability for employee rights upon retirement	2,249	2,253
Total long term liabilities	105,150	107,861
Total liabilities	128,003	134,071
COMMITMENTS		
CAPITAL DEFICIENCY	(68,511)	(55,601)
Total liabilities net of capital deficiency	$59,492	$78,470

The accompanying notes are an integral part of the condensed consolidated financial statements.

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

	Nine Months Ended		Three Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
REVENUES	$12,475	$11,517	$4,301	$2,396
COMPANY'S SHARE IN COLLABORATION AGREEMENT	3,084	2,259	1,545	1,311
COST OF REVENUES	(6,785)	(7,476)	(2,346)	(1,798)
GROSS PROFIT	8,774	6,300	3,500	1,909
RESEARCH AND DEVELOPMENT EXPENSES (1)	(18,493)	(23,280)	(5,260)	(8,052)
Less – grants and reimbursements	3,856	6,146	1,207	1,947
RESEARCH AND DEVELOPMENT EXPENSES, NET	(14,637)	(17,134)	(4,053)	(6,105)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(6,259)	(7,289)	(2,254)	(2,012)
OPERATING LOSS	(12,122)	(18,123)	(2,807)	(6,208)
FINANCIAL EXPENSES	(2,805)	(3,490)	(1,030)	(1,851)
FINANCIAL INCOME	64	139	117	49
FINANCIAL EXPENSES – NET	(2,741)	(3,351)	(1,013)	(1,802)
NET LOSS FOR THE PERIOD	$(14,863)	$(21,474)	$(3,820)	$(8,010)
NET LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED:	$(0.16)	$(0.23)	$(0.04)	$(0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED:	93,599,414	92,828,851	93,943,772	92,971,572
(1) Includes share-based compensation	667	764	258	173
(2) Includes share-based compensation	752	(81)	188	(67)

The accompanying notes are an integral part of the condensed consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN CAPITAL DEFICIENCY

(U.S. dollars in thousands, except share data)

(Unaudited)

	Common Stock (1)	Common Stock	Additional paid–in capital	Accumulated deficit	Total
	Number of shares	Amount			
Balance at December 31, 2013	93,551,098	$94	$184,345	$(211,385)	$(26,946)
Changes during the nine-month period ended September 30, 2014:					
Share-based compensation related to stock options			161		161
Share-based compensation related to restricted stock award, net of forfeitures of 1,834 shares	(1,834)		522		522
Exercise of options granted to employees (includes net exercise)	113,800	*	43		43
Net loss for the period				(21,474)	(21,474)
Balance at September 30, 2014	93,663,064	$94	$185,071	$(232,859)	$(47,694)
Balance at December 31, 2014	93,603,819	$94	$185,633	$(241,328)	$(55,601)
Changes during the nine-month period ended September 30, 2015:					
Share-based compensation related to stock options			947		947
Share-based compensation related to restricted stock award, net of forfeitures of 2,501 shares	(2,501)		472		472
Exercise of options	550,000	*	534		534
Net loss for the period				(14,863)	(14,863)
Balance at September 30, 2015	94,151,318	94	187,586	(256,191)	(68,511)

*Represents amount less than thousand

(1)Common Stock, $0.001 par value; Authorized – as of September 30, 2015 and 2014 - 150,000,000 shares.

The accompanying notes are an integral part of the condensed consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands)

(Unaudited)

	Nine Months Ended	
	September 30, 2015	September 30, 2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(14,863)	$(21,474)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	1,419	683
Depreciation	1,811	2,418
Financial expenses, net (mainly exchange differences)	102	869
Changes in accrued liability for employee rights upon retirement	16	149
Loss (Gain) on amounts funded in respect of employee rights upon retirement	28	(25)
Amortization of debt issuance costs and debt discount	333	332
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non-current portion)	(2,018)	(6,172)
Increase in accounts receivable and other assets	(3,187)	(578)
Decrease in inventories	328	1,127
Decrease in accounts payable and accruals (including long term)	(4,396)	(1,736)
Net cash used in operating activities	$(20,427)	$(24,407)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$(460)	$(617)
Investment in restricted deposit		(93)
Amounts funded in respect of employee rights upon retirement, net	(56)	(122)
Net cash used in investing activities	$(516)	$(832)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of options	$534	$43
Net cash provided by financing activities	$534	$43
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$(110)	$(885)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(20,519)	(26,081)
BALANCE OF CASH AND CASH **EQUIVALENTS AT BEGINNING OF PERIOD**	54,767	86,398

BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$34,248	$60,317

The accompanying notes are an integral part of the condensed consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands)

(Unaudited)

(Continued) - 2

	Nine Months Ended September 30, 2015	September 30, 2014
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$146	$ 122
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$3,105	$ 3,079

The accompanying notes are an integral part of the condensed consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the "Company"), and its wholly-owned subsidiary, Protalix Ltd., are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx® protein expression system ("ProCellEx"). Using the ProCellEx system, the Company is developing a pipeline of proprietary recombinant therapeutic proteins. The Company's initial commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease. The Company's strategy is to develop proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications. To date, the Company has successfully developed a treatment for Gaucher disease that has been approved for marketing in the United States, Brazil, Israel and other markets, and the Company has number of product candidates in varying stages of the clinical development process. In September 2009, Protalix Ltd. formed another wholly-owned subsidiary under the laws of the Netherlands, Protalix B.V., in connection with the European Medicines Agency ("EMA") application process in the European Union. The Company's two subsidiaries are referred to collectively herein as the "Subsidiaries."

On May 1, 2012, the U.S. Food and Drug Administration ("FDA") approved for sale the Company's first commercial product, taliglucerase alfa for injection, an enzyme replacement therapy ("ERT") for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved for marketing by the regulatory authorities of other countries. Taliglucerase alfa is being marketed under the name Uplyso™ in Brazil and certain other Latin American countries and Elelyso™ in the rest of the territories.

Since its approval by the FDA, taliglucerase alfa has been marketed mainly in the United States by Pfizer Inc. ("Pfizer"), the Company's commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd., the Company's wholly-owned subsidiary, and Pfizer, which is referred to herein as the Pfizer Agreement. In October 2015, the Company entered into an Amended and Restated Exclusive License and Supply Agreement (the "Amended Pfizer Agreement") which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, the Company sold to Pfizer its share in the collaboration created under the initial Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, the Company agreed to transfer its rights to Elelyso in Israel to Pfizer while gaining full rights to Elelyso in Brazil. Under the initial Pfizer Agreement, Pfizer and the Company shared revenues and expenses for the development and

commercialization of Elelyso on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Pfizer Agreement, Pfizer is responsible for 100% of expenses, and entitled to all of the revenues, globally for Elelyso, excluding Brazil, where the Company is responsible for all expenses and retains all revenues. The Amended Pfizer Agreement eliminates Pfizer's entitlement to annual payments of up to $12.5 million in relation to commercialization of Elelyso in Brazil. For further details please see Note 5.

On June 18, 2013, the Company entered into a Supply and Technology Transfer Agreement (the "Brazil Agreement") with Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health for taliglucerase alfa. The agreement became effective in January 2014. The technology transfer is designed to be completed in four stages and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high-quality, and cost-effective supply of taliglucerase alfa. The Company is not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately $280 million worth of taliglucerase alfa.

Fiocruz's purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, the Company is, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. Approximately 10% of adult Gaucher patients in Brazil are currently treated with Uplyso. The Company is discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, the Company will determine what it believes to be the course of action that is in the best interest of the Company.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

The Company will pay a fee equal to 5% of the net proceeds generated in Brazil to an agent for services provided in assisting the Company complete the Brazil Agreement pursuant to an agreement between the agent and the Company. The agreement will remain in effect with respect to the Brazil Agreement until the termination thereof.

In addition to taliglucerase alfa, the Company is developing an innovative product pipeline using its ProCellEx protein expression system. The Company's product pipeline currently includes, among other candidates:

(1) PRX-102, or alpha-GAL-A, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans.

(2) PRX-106, the Company's oral antiTNF product candidate which is being developed as an orally-delivered anti inflammatory treatment using plant cells as a natural capsule for the expressed protein.

(3) PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase, under development for the treatment of cystic fibrosis, to be administered by inhalation.

(4) PRX-112, an orally administered glucocerebrosidase enzyme for the treatment of Gaucher patients utilizing oral delivery of the recombinant GCD enzyme produced and encapsulated within carrot cells.

Obtaining marketing approval with respect to any product candidate in any country is directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain such approvals. The Company cannot reasonably predict the outcome of these activities.

Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least 12 months, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing.

b. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for annual financial statements. In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2014, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission"). The comparative balance sheet at December 31, 2014 has been derived from the audited financial statements at that date.

c. Net loss per share

Basic and diluted loss per share ("LPS") are computed by dividing net loss by the weighted average number of shares of the Company's common stock, par value $0.001 per share (the "Common Stock") outstanding for each period. Diluted LPS does not include 18,781,572 and 19,797,190 shares of Common Stock underlying outstanding options and restricted shares of Common Stock and shares issuable upon conversion of the convertible notes (issued in September 2013) for the nine months ended September 30, 2014 and 2015, respectively, and 18,661,182 and 19,820,485 shares of Common Stock for the three months ended September 30, 2014 and 2015, respectively, because the effect would be anti-dilutive.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 2 - INVENTORIES

Inventory at September 30, 2015 and December 31, 2014 consisted of the following:

	September 30, 2015	December 31, 2014
	(*U.S. dollars in thousands)*	
Raw materials	$1,502	$ 1,616
Work in progress		132
Finished goods	4,837	4,919
Total inventory	$6,339	$ 6,667

During the nine months ended September 30, 2015, the Company recorded approximately $1.6 million for write-down of inventory under cost of revenues.

NOTE 3 – FAIR VALUE MEASUREMENT

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received from the sale of an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date.
The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.
The fair value of the financial instruments included in the working capital of the Company is usually identical or close to their carrying value.

The fair value of the convertible notes as of September 30, 2015 is approximately $45.5 million based on a level 2 measurement.

NOTE 4 – STOCK TRANSACTIONS

On March 23, 2015, the Company's compensation committee approved the grant of a 10-year option to purchase 1,909,000 shares of Common Stock to its officers and other employees with an exercise price equal to $1.72 per share under the Company's 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The options vest over a four-year period; the first 25% shares vest on the first anniversary of the grant date and the remaining shares vest in 12 equal quarterly increments over the subsequent three-year period. Vesting of the options granted to certain executive officers are subject to acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $1.9 million based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 61.7%; risk-free interest rates of 1.6%; and expected life of six years.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 5 – SUBSEQUENT EVENTS

On October 12, 2015, the Company entered into the Amended Pfizer Agreement which amends and restates, in its entirety, the Pfizer Agreement. See Note 1. Pursuant to the Amended Pfizer Agreement, the Company sold its share in the collaboration with Pfizer on the commercialization of Elelyso to Pfizer in exchange for a cash payment equal to $36.0 million. As part of the sale, the Company agreed to transfer its rights to Elelyso in Israel to Pfizer in exchange for full rights to Elelyso in Brazil. Under the Amended Pfizer Agreement, the Company will continue to manufacture drug substance for Pfizer, subject to certain terms and conditions. In addition, the Company issued to Pfizer a promissory note for approximately $4.2 million, representing the Company's share of accumulated losses as of the date of the Amended Pfizer Agreement. The note is to be paid in October 2020, subject to certain terms and conditions. Under the Pfizer Agreement, Pfizer and the Company shared in revenues and expenses for the development and commercialization of Elelyso on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Pfizer Agreement, Pfizer is responsible for 100% of expenses, and entitled to all of the revenues, globally for Elelyso, excluding Brazil, where the Company is responsible for all expenses and retains all revenues. The Amended Pfizer Agreement eliminates Pfizer's entitlement to annual payments of up to $12.5 million in relation to commercialization of Elelyso in Brazil.

On October 12, 2015, the Company also entered into a Stock Purchase Agreement with Pfizer, pursuant to which the Company issued 5,649,079 shares of the Company's common stock for an aggregate purchase price equal to $10.0 million subject to certain other terms set forth in the Stock Purchase Agreement. As part of the Stock Purchase Agreement, Pfizer has agreed to a 180-day lock-up with respect to the purchased shares and the Company's directors and executive officers have entered into 90-day lock up agreements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the consolidated financial statements and the related notes included elsewhere in this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2014. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2014 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx® protein expression system, or ProCellEx. Using our ProCellEx system, we are developing a pipeline of proprietary, clinically superior versions of recombinant therapeutic proteins that primarily target large, established pharmaceutical markets and that in most cases rely upon known biological mechanisms of action. Our initial commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease. With our experience, and having successfully developed Elelyso™, our first drug product, we believe ProCellEx will enable us to develop additional proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications. We are now also applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins.

On May 1, 2012, the U.S. Food and Drug Administration, or the FDA, approved for sale our first commercial product, taliglucerase alfa for injection, an enzyme replacement therapy, or ERT, for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved for marketing by the regulatory authorities of other countries. Taliglucerase alfa is being marketed under the name Uplyso™ in Brazil and certain other Latin American countries, and as Elelyso in the rest of the territories.

Since its approval by the FDA, taliglucerase alfa has been marketed mainly in the United States by Pfizer Inc., or Pfizer, our commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd., our wholly-owned subsidiary, and Pfizer, which we refer to as the Pfizer Agreement. In October 2015, we entered into an Amended and Restated Exclusive License and Supply Agreement, or the Amended Pfizer Agreement, which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, we sold to Pfizer our share in the collaboration created under the initial Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, we agreed to

transfer our rights to Elelyso in Israel to Pfizer, while gaining full rights to Elelyso in Brazil. Under the Amended Pfizer Agreement, we will continue to manufacture drug substance for Pfizer, subject to certain terms and conditions. In addition, we issued to Pfizer a promissory note for approximately $4.2 million, representing our share of accumulated losses as of the date of the Amended Pfizer Agreement. The note is to be paid in October 2020, subject to certain terms and conditions. Under the initial Pfizer Agreement, Pfizer shared revenues and expenses for the development and commercialization of Elelyso with us on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Pfizer Agreement, Pfizer is responsible for 100% of expenses, and entitled to all of the revenues, globally for Elelyso, excluding Brazil, where we are responsible for all expenses and retains all revenues. The Amended Pfizer Agreement eliminates Pfizer's entitlement to annual payments of up to $12.5 million in relation to commercialization of Elelyso in Brazil.

For the first 10-year period after the execution of the Amended Pfizer Agreement, we have agreed to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods subject to certain terms and conditions. The Amended Pfizer Agreement also includes provisions regarding cooperation for regulatory matters, supply of the drug substance to Pfizer, including provisions addressing failure to supply, and patent enforcement, and contains customary provisions regarding termination, indemnification and insurance requirements.

On October 12, 2015, we also entered into a Stock Purchase Agreement with Pfizer, pursuant to which we issued 5,649,079 shares of our common stock for an aggregate purchase price equal to $10.0 million subject to certain other terms set forth in the Stock Purchase Agreement. As part of the Stock Purchase Agreement, Pfizer has agreed to a 180-day lock-up with respect to the purchased shares of common stock and our directors and executive officers have entered into 90-day lock up agreements.

On June 18, 2013, we entered into a Supply and Technology Transfer Agreement, or the Brazil Agreement, with Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health for taliglucerase alfa. The agreement became effective in January 2014. The technology transfer is designed to be completed in four stages and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high-quality, and cost-effective supply of taliglucerase alfa. We are not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately $280 million worth of taliglucerase alfa.

Fiocruz's purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, we are, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. Approximately 10% of adult Gaucher patients in Brazil are currently treated with Uplyso. We are discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, we will determine what we believe to be the course of action that is in the best interest of our company.

We will pay a fee equal to 5% of the net proceeds generated in Brazil to an agent for services provided in assisting us complete the Brazil Agreement pursuant to an agreement between us and the agent. The agreement will remain in effect with respect to the Brazil Agreement until the termination thereof.

In addition to taliglucerase alfa, we are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates:

(1) PRX-102, or alpha-GAL-A, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, currently in an ongoing phase I/II clinical trial. We expect to report final efficacy and safety results for the 0.2mg, 1 mg and 2mg/kg dose groups of the trial during the fourth quarter of 2015.

(2) PRX-106, our oral antiTNF product candidate which is being developed as an orally-delivered anti inflammatory treatment using plant cells as a natural capsule for the expressed protein. We concluded the phase I clinical trial, which demonstrated that the drug was safe and well tolerated, showing biological activity in the gut and inducement of regulatory T cells. We expect to initiate a proof of concept efficacy study by early 2016.

(3) PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase, under development for the treatment of cystic fibrosis, to be administered by inhalation. We expect to initiate a phase I clinical trial in healthy volunteers during the fourth quarter followed by proof of concept efficacy study in patients during the first half of

2016.

(4) PRX-112, an orally administered glucocerebrosidase enzyme for the treatment of Gaucher patients utilizing oral delivery of the recombinant GCD enzyme produced and encapsulated within carrot cells. PRX-112 has been the subject of successful proof of concept clinical trials, and we intend to focus our efforts on a new formulation of the treatment during 2015 before proceeding to more advanced clinical trials.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Brazil), which we licensed to Pfizer, we hold the worldwide commercialization rights to all of our proprietary development candidates. In addition, we continuously evaluate potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutes.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing in this Quarterly Report. There have not been any changes to our significant accounting policies since the Annual Report on Form 10-K for the year ended December 31, 2014.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

Three months ended September 30, 2015 compared to the three months ended September 30, 2014

Revenues

We recorded revenues of $4.3 million during the three months ended September 30, 2015, an increase of $1.9 million, or 80%, from revenues of $2.4 million for the three months ended September 30, 2014. The increase resulted primarily from the $1.3 million of products sold in Brazil during the three months ended September 30, 2015. Revenues also represent a pro rata amortization of the $65.0 million upfront and milestone payments of $1.1 million in each quarterly period.

Our share in the Collaboration Agreement

We recorded revenue of $1.5 million as our share of net income from the collaboration under the Pfizer Agreement during the three months ended September 30, 2015, an increase of $234,000 from revenues of $1.3 million for the three months ended September 30, 2014. Our share in the collaboration agreement recorded during the three months ended September 30, 2015 represents our 40% share of the net income generated during the period. Under the terms and conditions of the Pfizer Agreement prior to its amendment, we record income or loss equal to 40% of the profit or loss realized from sales of taliglucerase alfa and related expenses incurred based on reports we receive from Pfizer summarizing the results of the collaborative activities under the Pfizer Agreement for the applicable period.

Cost of Revenues

Cost of revenues was $2.3 million for the three months ended September 30, 2015, an increase of $548,000, or 30%, from cost of revenues of $1.8 million for the three months ended September 30, 2014. The increase resulted primarily from an increase in the amount of products sold to Pfizer at cost during the three months ended September 30, 2015. Cost of revenues is generally composed of certain fixed costs relating to our manufacturing facility, including rent, depreciation, salary and maintenance expenses, and to a much lesser extent, the direct cost of products sold.

Research and Development Expenses, Net

Research and development expenses were $4.1 million for the three months ended September 30, 2015, a decrease of $2.0 million, or 34%, from $6.1 million for the three months ended September 30, 2014. The decrease resulted primarily from a decrease of $1.3 million in expenses related to subcontractors and consultants in connection with preclinical and clinical activities and $859,000 in costs related to salaries expense, partially due to the devaluation of the New Israeli Shekel against the U.S. dollar during the three months ended on September 30, 2015. The decrease was partially offset by a decrease in reimbursement of expenses of $522,000 in accordance with the terms and conditions of the Pfizer Agreement during the three months ended September 30, 2015 compared to the three months ended September 30, 2014.

We expect research and development expenses for our various development programs to continue to be our primary expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.3 million for the three months ended September 30, 2015, an increase of $242,000, from $2.0 million for the three months ended September 30, 2014.

Financial Expenses and Income

Financial expenses, net were $1.0 million for the three months ended September 30, 2015 compared to financial expenses, net, of $1.8 million for the three months ended September 30, 2014. Financial expenses is composed primarily from interest expense of $776,000 for each three-month period for the 4.5% convertible notes described below.

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Revenues

We recorded revenues of $12.5 million during the nine months ended September 30, 2015, an increase of $1.0 million, or 8%, from revenues of $11.5 million for the nine months ended September 30, 2014. The increase resulted primarily from an increase of $841,000 of products sold in Brazil. Revenues also represent a pro rata amortization of the $65.0 million upfront and milestone payments of $1.1 million in each quarterly period.

Our share in the Collaboration Agreement

We recorded revenue of $3.1 million as our share of net income from the collaboration under the Pfizer Agreement during the nine months ended September 30, 2015, an increase of $825,000, or 37%, from revenues of $2.3 million for the nine months ended September 30, 2014. Our share in the collaboration agreement recorded during the nine months ended September 30, 2015 represents our 40% share of the net income generated during the period. Under the terms and conditions of the Pfizer Agreement prior to its amendment, we record income or loss equal to 40% of the profit or loss realized from sales of taliglucerase alfa and related expenses incurred based on reports we receive from Pfizer summarizing the results of the collaborative activities under the Pfizer Agreement for the applicable period.

Cost of Revenues

Cost of revenues was $6.8 million for the nine months ended September 30, 2015, a decrease of $691,000, or 9%, from cost of revenues of $7.5 million for the nine months ended September 30, 2014. Cost of revenues is generally composed of certain fixed costs relating to our manufacturing facility, including rent, depreciation, salary and maintenance expenses, and to a much lesser extent, the direct cost of products sold.

Research and Development Expenses, Net

Research and development expenses were $14.6 million for the nine months ended September 30, 2015, a decrease of $2.5 million, or 15%, from $17.1 million for the nine months ended September 30, 2014. The decrease resulted primarily from a decrease of $2.8 million in costs related to salaries expense, mainly due to bonuses that were paid in the nine months ended September 30, 2014 and the devaluation of the New Israeli Shekel against the U.S. dollar during the period and a decrease of $1.1 million in expenses related to subcontractors and consultants in connection with preclinical and clinical activities. The decrease was partially offset by a decrease in reimbursement of expenses of $2.0 million in accordance with the terms and conditions of the Pfizer Agreement during the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014.

We expect research and development expenses for our various development programs to continue to be our primary expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $6.3 million for the nine months ended September 30, 2015, a decrease of $1.0 million, or 14%, from $7.3 million for the nine months ended September 30, 2014. The decrease resulted primarily from a decrease of $788,000 in sales and marketing expenses.

Financial Expenses and Income

Financial expenses net were $2.7 million for the nine months ended September 30, 2015 compared to financial expenses of $3.4 million for the nine months ended September 30, 2014. Financial expenses is composed primarily from interest expense of $2.3 million for each nine month period for the 4.5% convertible notes described below.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures which supersedes our product sales revenue, we have not been profitable and have generated operating losses since our inception with the exception of the quarter ended June 30, 2012 due to the $25.0 million milestone payment we received from Pfizer in connection with FDA approval of taliglucerase alfa in that period. To date, we have funded our operations primarily with proceeds equal to $31.3 million from the sale of shares of convertible preferred and ordinary shares of Protalix Ltd., and an additional $14.1 million in connection with the exercise of warrants issued in connection with the sale of such shares, through December 31, 2008. In addition, on October 25, 2007, we generated gross proceeds of $50 million in connection with an underwritten public offering of our common stock and on each of March 23, 2011 and February 22, 2012, we generated gross proceeds of $22.0 million and $27.2 million, respectively, in connection with underwritten public offerings of our common stock. In October 2015, we generated gross proceeds of $10 million from a private sale of our common stock.

In addition to the foregoing, on September 18, 2013, we completed a private placement of $69.0 million in aggregate principal amount of 4.50% convertible notes due 2018, or the Notes, including $9.0 million aggregate principal amount of Notes related to the offering’s initial purchaser’s over-allotment option, which was exercised in full.

In November 2009, Pfizer paid Protalix Ltd. $60.0 million as an upfront payment in connection with the execution of the Pfizer Agreement and subsequently paid to Protalix Ltd. an additional $5.0 million upon Protalix Ltd.'s meeting a certain milestone. Protalix Ltd. also received a milestone payment of $25.0 in connection with the FDA's approval of taliglucerase alfa in May 2012. Pfizer has also paid Protalix Ltd. $8.3 million in connection with the successful achievement of certain milestones under the Clinical Development Agreement between Pfizer and Protalix Ltd. In October 2015, we entered into the Amended Pfizer Agreement, which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, we sold to Pfizer our share in the collaboration created under the initial Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36 million. Under the terms of the Amended Pfizer Agreement, we are no longer entitled to any share from the net income from Pfizer's sales of Elelyso.

We believe that our existing cash and cash equivalents will be sufficient for the foreseeable future. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Cash Flows

Net cash used in operations was $20.4 million for the nine months ended September 30, 2015. The net loss for the nine months ended September 30, 2015 of $14.8 million was further increased by a decrease of $2.0 million in deferred revenues, by an increase of $3.2 million in accounts receivable and other assets and by a decrease of $4.4 million in accounts payable, but was partially offset by depreciation expense of $1.8 million and $1.4 million of share based compensation. Net cash used in investing activities for the nine months ended September 30, 2015 was $516,000 and consisted primarily of purchases of property and equipment. Net cash provided from financing activities was $534,000 primarily from the exercise of stock options.

Net cash used in operations was $24.4 million for the nine months ended September 30, 2014. The net loss for the nine months ended September 30, 2014 of $21.5 million was further increased by a decrease of $6.2 million in deferred revenues, and a decrease of $1.7 million in accounts payable and accruals, but was partially offset by depreciation expense of $2.4 million and a decrease of $1.1 million in inventories. Net cash used in investing activities for the nine months ended September 30, 2014 was $832,000 and consisted primarily of purchases of property and equipment.

Future Funding Requirements

We expect to continue to incur significant expenditures in the near future. We expect to continue to incur significant research and development expenses, including expenses related primarily to the clinical trials of PRX-102 and the advancement of our other product candidates into clinical trials.

We believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least 12 months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, our progress in commercializing taliglucerase alfa in Brazil, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

We may need to finance our future cash needs through corporate collaboration, licensing or similar arrangements, public or private equity offerings or debt financings. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. Any sale of additional equity or debt securities will likely result in dilution to our shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or

eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Effects of Inflation and Currency Fluctuations

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine and three months ended September 30, 2015 or the nine and three months ended September 30, 2014.

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services. We do not believe currency fluctuations have had a material effect on our results of operations during the nine and three months ended September 30, 2015 or the nine and three months ended September 30, 2014.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2015 and September 30, 2014.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Currency Exchange Risk

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar. We consider the currency of the primary economic environment to be the currency in which we generate revenues and expend cash. Most of our revenues are denominated in U.S. dollars, approximately 50% of our expenses and capital expenditures are incurred in U.S. dollars, and a significant source of our financing has been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

A portion of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our income before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Nine months ended September 30,		Year ended December 31,
	2015	2014	2014
Average rate for period	3.890	3.491	3.578
Rate at period end	3.923	3.695	3.889

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS.

These measures, however, may not adequately protect us from material adverse effects due to the impact of inflation in Israel.

Interest Rate Risk

Our exposure to market risk is confined to our cash and cash equivalents. We consider all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents. The primary objective of our investment activities is to preserve principal while maximizing the interest income we receive from our investments, without increasing risk. We invest any cash balances primarily in bank deposits and investment grade interest-bearing instruments. We are exposed to market risks resulting from changes in interest rates. We do not use derivative financial instruments to limit exposure to interest rate risk. Our interest gains may decline in the future as a result of changes in the financial markets.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the Commission, and that material information relating to our company and our consolidated subsidiary is made known to management, including the Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in internal controls

There were no changes to our internal controls over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended September 30, 2015 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities during the three months ended September 30, 2015.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

Our 2015 Annual Meeting of Shareholders was held on November 8, 2015. Holders of 56.57% of the Company's outstanding shares of common stock entitled to vote as of the record date for the meeting participated in person or by proxy.

The matters voted upon at the meeting are set forth below including the number of votes cast for, number of votes cast against or withheld, as applicable, the number of abstentions, the number of broker non-votes and other applicable votes with respect to each such matter.

(1) Election of Directors

	For	**Withheld**	**Broker Non-Votes**
Shlomo Yanai	32,873,863	10,166,072	10,139,104
Moshe Manor	37,547,409	5,560,682	10,139,104
Zeev Bronfeld	20,150,869	22,889,066	10,139,104
Amos Bar Shalev	35,991,301	7,048,634	10,139,104
Yodfat Harel Buchris	35,992,870	7,047,065	10,139,104
Roger D. Kornberg, Ph.D.	14,124,189	28,983,902	10,139,104
Aharon Schwartz, Ph.D.	29,995,219	13,044,716	10,139,104

(2) Approval, on a non-binding, advisory basis, the compensation of the Company’s named executive officers

For	**Against**	**Abstain**	**Broker Non-Votes**
31,889,394	9,875,043	1,343,654	10,139,104

(3) Ratification of the appointment of Kesselman & Kesselman

For	**Against**	**Abstain**	**Broker Non-Votes**
52,062,567	1,040,538	144,090	--

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Date	
3.1	Amended and Restated Articles of Incorporation of the Company	S-4	333-48677	3.4	March 26, 1998	
3.2	Article of Amendment to Articles of Incorporation dated June 9, 2006	8-A	001-33357	3.2	March 9, 2007	
3.3	Article of Amendment to Articles of Incorporation dated December 13, 2006	8-A	001-33357	3.3	March 9, 2007	
3.4	Article of Amendment to Articles of Incorporation dated December 26, 2006	8-A	001-33357	3.4	March 9, 2007	
3.5	Article of Amendment to Articles of Incorporation dated February 26, 2007	8-A	001-33357	3.5	March 9, 2007	
3.6	Article of Amendment to Articles of Incorporation dated December 17, 2014	10-K	001-33357	3.6	March 12, 2015	
3.7	Amended and Restated Bylaws of the Company	10-K	001-33357	3.7	March 12, 2015	
10.1	Amended and Restated Exclusive License and Supply Agreement dated as of October 12, 2015 between Protalix Ltd. and Pfizer Inc.					X
18						

31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer	X
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer	X
101.INS	XBRL INSTANCE FILE	X
101.SCH	XBRL SHEMA FILE	X
101.CAL	XBRL CALCULATION FILE	X
101.DEF	XBRL DEFINITION FILE	X
101.LAB	XBRL LABEL FILE	X
101.PRE	XBRL PRESENTATION FILE	X

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November 9, 2015 By: /s/ Moshe Manor
Moshe Manor

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 9, 2015 By: /s/ Yossi Maimon
Yossi Maimon

Chief Financial Officer, Treasurer and Secretary

(Principal Financial and Accounting Officer)