Protalix BioTherapeutics, Inc.
Form 10-Q
November 10, 2014

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, 2014

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 **(State or other jurisdiction** **of incorporation or organization)**	**65-0643773** **(I.R.S. Employer** **Identification No.)**
2 Snunit Street **Science Park** **POB 455** **Carmiel, Israel** **(Address of principal executive offices)**	**20100** **(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, 2014, approximately 93,672,564 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 related to the commercialization efforts for taliglucerase alfa in the United States, Israel, Brazil, Canada, Australia and other countries;
- risks related to the supply of drug product pursuant to our supply arrangement with Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, or the Brazilian MOH;
- risks relating to the compliance by Fiocruz 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;
- the risk of significant delays in the commercial introduction of taliglucerase alfa in the United States, Brazil, Israel, Canada, Australia and other markets as planned;

- risks related to the acceptance and use of taliglucerase alfa or any of our product candidates, if approved, by physicians, patients and third-party payors;

- the risk that we will not be able to develop a successful sales and marketing organization for taliglucerase alfa in Israel 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;

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- delays in the approval or the potential rejection of any application filed with or submitted to the regulatory authorities reviewing taliglucerase alfa outside of the United States, Israel, Brazil, Canada, Australia and other countries in which taliglucerase alfa is already approved;

- our ability to establish and maintain strategic license, collaboration and distribution arrangements, and to manage our relationships with Pfizer Inc., Fiocruz and any other collaborator, distributor or partner;

- 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, the expansion of our manufacturing capabilities and the ongoing costs in the case of delays in regulatory approvals for taliglucerase alfa outside of the United States, Israel, Brazil, Canada, Australia and other countries in which taliglucerase alfa is already approved;

- 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 biosimilar legislation and/or healthcare reform 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 the FDA, 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, 2013, 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, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 60,317	$ 86,398
Accounts receivable - Trade	1,992	2,091
Other assets	2,069	1,457
Inventories	6,830	7,957
Total current assets	71,208	97,903
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,621	1,578
PROPERTY AND EQUIPMENT, NET	11,846	13,711
DEFERRED CHARGES	120	141
Total assets	$ 84,795	$ 113,333
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,578	$ 5,254
Other	14,186	12,073
Deferred revenues	6,620	9,369
Total current liabilities	24,384	26,696
LONG TERM LIABILITIES:		
Convertible notes	67,359	67,048
Deferred revenues	38,373	41,796
Liability in connection with collaboration operation	—	2,371
Liability for employee rights upon retirement	2,373	2,368
Total long term liabilities	108,105	113,583
Total liabilities	132,489	140,279

COMMITMENTS		
CAPITAL DEFICIENCY	(47,694)	(26,946)
Total liabilities net of capital deficiency	$ 84,795	$ 113,333

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

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

	Nine Months Ended		Three Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
REVENUES	$11,517	$8,116	$2,396	$2,284
COMPANY'S SHARE IN COLLABORATION AGREEMENT	2,259	2,275	1,311	1,075
COST OF REVENUES	(7,476)	(3,876)	(1,798)	(1,587)
GROSS PROFIT	6,300	6,515	1,909	1,772
RESEARCH AND DEVELOPMENT EXPENSES (1)	(23,280)	(23,467)	(8,052)	(7,723)
Less – grants and reimbursements	6,146	6,049	1,947	2,086
RESEARCH AND DEVELOPMENT EXPENSES, NET	(17,134)	(17,418)	(6,105)	(5,637)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(7,289)	(6,065)	(2,012)	(1,780)
OPERATING LOSS	(18,123)	(16,968)	(6,208)	(5,645)
FINANCIAL EXPENSES	(3,490)	(153)	(1,851)	(131)
FINANCIAL INCOME	139	216	49	29
FINANCIAL INCOME (EXPENSES) – NET	(3,351)	63	(1,802)	(102)
NET LOSS FOR THE PERIOD	$(21,474)	$(16,905)	$(8,010)	$(5,747)
NET LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED:	$(0.23)	$(0.18)	$(0.09)	$(0.06)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED:	92,828,851	92,307,170	92,971,572	92,433,502
(1) Includes share-based compensation	764	2,198	173	609
(2) Includes share-based compensation	(81)	1,255	(67)	345

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

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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, 2012	93,489,809	$ 93	$ 180,145	$ (183,595)	$ (3,357)
Changes during the nine-month period ended September 30, 2013:					
Share-based compensation related to stock options			895		895
Share-based compensation related to restricted stock award, net of forfeitures of 1,667 shares	(1,667)		2,558		2,558
Exercise of options granted to employees	64,768	1	102		103
Net loss for the period				(16,905)	(16,905)
Balance at September 30, 2013	93,552,910	$ 94	$ 183,700	$ (200,500)	$ (16,706)
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)

* Represents amount less than $1

(1) Common Stock, $0.001 par value; Authorized – as of September 30, 2014 and 2013 - 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, 2014	September 30, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(21,474)	$ (16,905)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	683	3,453
Depreciation and write down of fixed assets	2,418	2,689
Financial expenses (income), net (mainly exchange differences)	869	(140)
Changes in accrued liability for employee rights upon retirement	149	145
Gain on amounts funded in respect of employee rights upon retirement	(25)	(26)
Amortization of debt issuance costs and debt discount	332	15
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non-current portion)	(6,172)	(5,393)
Increase in accounts receivable and other assets	(578)	(798)
Decrease (increase) in inventories	1,127	(3,538)
Decrease in accounts payable and accruals (including long term)	(1,736)	(5,413)
Net cash used in operating activities	$(24,407)	$ (25,911)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$(617)	$ (1,668)
Investment in restricted deposit	(93)	(42)
Amounts funded in respect of employee rights upon retirement, net	(122)	(121)
Net cash used in investing activities	$(832)	$ (1,831)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of convertible notes	—	$ 66,930
Exercise of options	$43	$ 30
Net cash provided by financing activities	$43	$ 66,960
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$(885)	$ 144
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(26,081)	39,362
BALANCE OF CASH AND CASH **EQUIVALENTS AT BEGINNING OF PERIOD**	86,398	52,035
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$60,317	$ 91,397

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)

(Continued) - 2

	Nine Months Ended	
	September 30, 2014	September 30, 2013
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 122	$ 187
Issuance cost related to convertible note offering not yet paid		$ 150
Exercise of options granted to employees		$ 73

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

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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"). 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 taliglucerase alfa for injection, the Company's first approved drug product, as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Taliglucerase alfa is a proprietary, recombinant form of glucocerebrosidase (GCD) that the Company developed using ProCellEx. Taliglucerase alfa was also approved by the Israeli Ministry of Health (the "Israeli MOH") in September 2012, by the Brazilian Ministry of Health (the "Brazilian MOH") in March 2013 and by the applicable regulatory authorities of certain other countries, including Chile, Canada and Australia. Taliglucerase alfa is the first plant cell-based recombinant therapeutic protein approved by the FDA or any other major regulatory authority.

In August 2014, the FDA approved taliglucerase alfa for injection for pediatric patients. Prior to this approval, taliglucerase alfa was approved for pediatric indications in Australia and Canada but in no other jurisdiction.

Taliglucerase alfa is being marketed in the United States under the brand name ELELYSO™ by Pfizer Inc. ("Pfizer"), the Company's commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd. and Pfizer (the "Pfizer Agreement"). The Company, through Protalix Ltd., markets ELELYSO in Israel, and in Brazil under the brand name UPLYSO™.

Protalix Ltd. granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement, but retained those rights in Israel and, since 2014, in Brazil (see below). The Company has agreed to a specific allocation between Protalix Ltd. and Pfizer regarding the responsibilities for the continued development efforts for taliglucerase alfa. To date, the Company has received an upfront payment of $60.0 million in connection with the execution of the Pfizer Agreement and shortly thereafter an additional $5.0 million clinical development-related milestone payment. The Company received during 2012 an additional $25.0 million milestone payment in connection with the FDA’s approval of taliglucerase alfa in the United States. The agreement provides that the Company share with Pfizer the net profits or loss related to the development and commercialization of taliglucerase alfa on a 40% and 60% basis, respectively, except with respect to the profits or losses related to commercialization efforts in Israel and Brazil, where the Company retained exclusive marketing rights. In calculating the net profits or losses under the agreement, there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

On June 18, 2013, Protalix Ltd. entered into a Supply and Technology Transfer Agreement (the "Brazil Agreement") with Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian MOH, for taliglucerase alfa. The brand name for taliglucerase alfa in Brazil is UPLYSO. The first term of the technology transfer is seven years and the agreement may be extended for an additional five-year term, as needed, to complete the technology transfer. The technology transfer is designed to be effected 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. Under the agreement, Fiocruz has committed to purchase at least approximately $40 million worth of taliglucerase alfa during the first two years of the agreement. In subsequent years, Fiocruz is required to purchase at least approximately $40 million worth of taliglucerase alfa per year. Additionally, Protalix Ltd. is not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately $280 million worth of taliglucerase alfa. The Brazil Agreement became effective during the first quarter of 2014.

During the nine months ended September 30, 2014, the Company recorded revenues of approximately $3.5 million from the sale of products to Fiocruz.

In September 2014, CONITEC, the National Commission for Incorporation of Technologies in Brazil's Unified Healthcare System, announced that it had decided to give a positive funding recommendation for taliglucerase alfa in the treatment of adult patients with types 1 and 3 Gaucher disease, and established that taliglucerase alfa will be the first choice for treatment for new adult Gaucher patients in Brazil. The Company anticipates that CONITEC's resolution will be implemented around the end of 2014.

To facilitate the arrangement with Fiocruz, Pfizer amended its exclusive license and supply agreement with Protalix Ltd. The amendment provides for the transfer of the commercialization and other rights to taliglucerase alfa in Brazil back to Protalix Ltd. As consideration for the transfer of the commercialization and supply rights, Protalix Ltd. agreed to pay Pfizer a maximum amount of approximately $12.5 million from its net profits (as defined in the license and supply agreement) per year. Pfizer has also agreed to perform certain transitional services in Brazil on Protalix Ltd.'s behalf in connection with the supply of taliglucerase alfa to Fiocruz.

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

In addition to the approvals from the FDA, the Israeli MOH and the Brazilian MOH, marketing approval has been granted to ELELYSO in Canada, Australia, Mexico, Chile, Uruguay and Albania. In addition, the Company is cooperating with Pfizer in its efforts to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. Currently, marketing authorization applications have been filed in a number of countries.

Currently, patients are being treated with taliglucerase alfa on a commercial basis in the United States, Brazil, Chile and Israel. In addition, taliglucerase alfa is currently being provided to Gaucher patients under special access agreements or named patient provisions in other countries.

In addition to taliglucerase alfa, the Company is working on the development of certain other products using ProCellEx.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

In addition to the approval of taliglucerase alfa for marketing in the United States, Israel, Brazil and other countries, successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining the foreign regulatory approvals required to sell its products internationally. A substantial amount of time may pass before the Company achieves a level of revenues adequate to support its operations, if at all, and the Company expects to incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during their respective developmental periods.

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.

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, 2013, filed by the Company with the Securities and Exchange Commission. The comparative balance sheet at December 31, 2013 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 7,879,601 and 18,781,572 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, 2013 and 2014, respectively, and 8,817,090 and 18,661,182 shares of Common Stock for the three months ended September 30, 2013 and 2014, respectively, because the effect would be anti-dilutive.

NOTE 2 - INVENTORIES

Inventory at September 30, 2014 and December 31, 2013 consisted of the following:

	September 30, 2014	December 31, 2013
	(U.S. dollars in thousands)	
Raw materials	$ 1,660	$ 2,342
Work in progress	0	92
Finished goods	5,170	5,523
Total inventory	$ 6,830	$ 7,957

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PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 2 - INVENTORIES (continued)**:**

During the nine months ended September 30, 2014, 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, 2014 is approximately $59.4 million based on a level 2 measurement.

NOTE 4 – STOCK TRANSACTIONS

a. During the nine months ended September 30, 2014, the Company issued a total of 113,800 shares of Common Stock in connection with the exercise of a total of 116,801 options by certain employees of the Company. The aggregate proceeds in connection with such exercises totaled approximately $43,000.

b. On July 24, 2014, the Company's Board of Directors approved, subject to certain terms and conditions, the grant of a 10-year option to purchase 150,000 shares of Common Stock to its newly elected chairman of the Board of Directors with an exercise price of $3.37 per share. The options vest over a three-year period; the first 50,000 shares vest on the first anniversary of the grant date and the remaining shares vest in eight equal quarterly increments over the subsequent two year period. Vesting of the options will be accelerated in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Company's 2006 Stock Incentive Plan. The Company estimated the fair value of the option on the date of board approval using the Black-Scholes option-pricing model to be approximately $293,000.

c. On September 28, 2014, the Company's Board of Directors approved, subject to certain terms and conditions, the grant of a 10-year option to purchase 900,000 shares of Common Stock to its newly appointed President and Chief Executive Officer with an exercise price of $2.37 per share. The options vest over a four-year period in 16 equal quarterly increments. Vesting of the options will be accelerated in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Company's 2006 Stock Incentive Plan. The Company estimated the fair value of the option on the date of board approval using the Black-Scholes option-pricing model to be approximately $1,236,490.

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, 2013. 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, 2013 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, biobetter and biosimilar versions of recombinant therapeutic proteins, based on our plant cell-based expression technology, that primarily target large, established pharmaceutical markets and that 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. We believe ProCellEx will enable us to develop proprietary recombinant proteins that are therapeutically equivalent or superior to existing recombinant proteins currently marketed for the same indications. Because we are primarily targeting biologically equivalent versions of highly active, well-tolerated and commercially successful therapeutic proteins, we believe our development process is associated with relatively less risk compared to other biopharmaceutical development processes for completely novel therapeutic proteins. We are now also applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins, with the first two product candidates being glucocerebrosidase and antiTNF fusion protein, and we are performing research focused on the expression, and subsequently the oral delivery, of antibodies in plant cells.

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, which is being marketed in the United States and Israel under the brand name ELELYSO, as 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 by the Brazilian National Health Surveillance Agency (Agencia Nacional de Vigilancia Sanitaria, or ANVISA) in March 2013, by the Israeli Ministry of Health, or the Israeli MOH, in September 2012, by the Australian Therapeutic Goods Administration (TGA) in May 2014, by Health Canada in May 2014 and by the applicable regulatory authorities in Uruguay, Mexico and Chile. Taliglucerase alfa is being marketed under the name UPLYSO in Brazil and certain other Latin American countries.

In August 2014, the FDA approved ELELYSO for injection for pediatric patients. Prior to this approval, ELEYSO was approved for pediatric indications in Australia and Canada but in no other jurisdictions. In September 2014, CONITEC, the National Commission for Incorporation of Technologies in Brazil's Unified Healthcare System, announced that it had decided to give a positive funding recommendation for UPLYSO in the treatment of adult patients with types 1 and 3 Gaucher disease, and established that UPLYSO will be the first choice for treatment for new adult Gaucher patients in Brazil. We anticipate that CONITEC's resolution will be implemented around the end of 2014.

Taliglucerase alfa is our proprietary, recombinant form of glucocerebrosidase, or GCD, that is produced or expressed through ProCellEx. Taliglucerase alfa is the first plant cell-based recombinant therapeutic protein to be approved by the FDA or by the regulatory authorities with jurisdiction over any substantial market. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. Gaucher patients suffer from mutations in or deficiencies of GCD, an enzyme that is naturally found in human cells.

Since May 2012, taliglucerase alfa has been marketed 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. We granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement, but we retained those rights in Israel and in Brazil. We have agreed to a specific allocation between Protalix Ltd. and Pfizer of the responsibilities for the continued development efforts for taliglucerase alfa outside of Israel. Protalix Ltd. has been marketing taliglucerase alfa in Israel since 2013 and in Brazil since January 2014.

On June 18, 2013, we entered into a Supply and Technology Transfer Agreement, or the Brazil Agreement, with Fiocruz, 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 initial term of the technology transfer is seven years. Under the agreement, Fiocruz has committed to purchase at least approximately $40 million worth of taliglucerase alfa during the first two years of the term. In subsequent years, Fiocruz is required to purchase at least approximately $40 million worth of taliglucerase alfa per year. Additionally, 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.

The Brazil Agreement may be extended for an additional five-year term, as needed, to complete the technology transfer. All of the terms of the arrangement, including the minimum annual purchases, will apply during the additional term. Upon completion of the technology transfer, and subject to Fiocruz receiving approval from ANVISA to manufacture taliglucerase alfa in its facility in Brazil, the agreement will enter into the final term and will remain in effect until our last patent in Brazil expires. During such period, Fiocruz will be the sole provider of this important treatment option for Gaucher patients in Brazil and shall pay us a single-digit royalty on net sales.

To facilitate the arrangement with Fiocruz, we and Pfizer agreed to an amendment of our exclusive license and supply agreement, which amendment provides for the transfer of the commercialization and other rights to taliglucerase alfa in Brazil back to us. As consideration for the transfer of the commercialization and supply rights, we agreed to pay Pfizer a maximum amount of approximately $12.5 million from its net profits (as defined in the license and supply agreement) per year. Pfizer has also agreed to perform certain transitional services in Brazil on our behalf in connection with the supply of taliglucerase alfa to Fiocruz.

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

We are cooperating with Pfizer to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. In addition to those countries in which taliglucerase alfa has been approved, marketing authorization applications have been filed in other countries.

In addition to naive and switch studies in adults which were successfully completed, we conducted a 12-month clinical trial of naïve and switchover pediatric patients, which was successfully completed in 2012. The application for our approved pediatric indication was based on the data from this study. Patients in the extension trials are still being treated with taliglucerase alfa.

Currently, patients are being treated with taliglucerase alfa on a commercial basis in the United States, Brazil, Israel and Chile. In France, Gaucher patients are being treated with taliglucerase alfa through an Autorisation Temporaire d'Utilisation (ATU), or Temporary Authorization for Use, a regulatory mechanism used by the French Health Products and Safety Agency to make non-approved drugs available to patients in France when a genuine public health need exists. In addition taliglucerase alfa is currently being provided to Gaucher patients under special access agreements or named patient provisions in certain countries. Hundreds of patients, in the aggregate, have been treated with taliglucerase alfa.

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, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, currently in a phase I/II clinical trial. We expect to complete patient recruitment and report interim results around year end, and to report final results during 2015.

(2) 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, currently the subject of a phase IIa clinical trial treating 10 Gaucher patients for 28 days. Enrollment of required patients for this trial has been completed and we expect to report results by the end of 2014.

(3) PRX-106, our oral antiTNF product candidate which is being developed as an orally-administered treatment for immune mediated disorders using plant cells as a natural capsule for the expressed protein. We are currently conducting preclinical studies on oral antiTNF for several attractive indications, and we expect to initiate a phase I clinical trial of oral anti TNF for the oral treatment of autoimmune diseases around year end.

(4) PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1 under development for the treatment of cystic fibrosis, to be administered by inhalation. We have already held a pre-IND meeting with the FDA regarding this product candidate, and plan to file an IND with the FDA following the completion of toxicology studies around year end, 2014.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Brazil and Israel), which we licensed to Pfizer, we hold the worldwide commercialization rights to all of our proprietary development candidates. We have built an internal marketing team designed to serve the Israeli and Brazilian market for taliglucerase alfa and we intend to establish internal commercialization and marketing teams for our other product candidates in North America, the European Union and in other significant markets, including Israel, subject to required marketing approvals, as the need arises. 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, 2013.

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, 2014 compared to the three months ended September 30, 2013

Revenues

We recorded revenues of $2.4 million during the three months ended September 30, 2014, an increase of approximately $112,000, or 5%, compared to revenues of $2.3 million for the three months ended September 30, 2013. Revenues for the three months ended September 30, 2014 included $1.3 million of sales of ELEYSO in Israel. 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 $1.3 million as our share of net income from the collaboration under the Pfizer Agreement during the three months ended September 30, 2014, compared to revenues of $1.1 million for the three months ended September 30, 2013. Our share in the collaboration agreement recorded during the three months ended September 30, 2014 represents our 40% share of the net income generated during the period, which was primarily the result of revenues generated by Pfizer in the United States which exceeded the expenses during such period. Under the terms and conditions of the Pfizer Agreement, 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 $1.8 million for the three months ended September 30, 2014, an increase of approximately $211,000, or 13%, compared to $1.6 million for the three months ended September 30, 2013. Cost of revenues for the three months ended September 30, 2014 and September 30, 2013 consists mainly 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 we sold in Israel for which revenues were recognized during the period.

Research and Development Expenses, Net

Research and development expenses were $6.1 million for the three months ended September 30, 2014, an increase of $468,000, or 8%, from $5.6 million for the three months ended September 30, 2013. The increase resulted primarily from an increase of $1.2 million in expenses related to subcontractors and consultants in connection with preclinical and clinical activities, which was partially offset by a decrease of $399,000 in costs related to materials and a decrease in $181,000 in salaries expenses.

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 $2.0 million for the three months ended September 30, 2014, an increase of $232,000, or 13%, from $1.8 million for the three months ended September 30, 2013. The increase resulted primarily from marketing expenses of approximately $539,000 which was partially offset by a decrease of approximately $385,000 in salaries expense.

Financial Expenses and Income

Financial expenses, net, was $1.8 million for the three months ended September 30, 2014, compared to financial expense of $102,000 for the three months ended September 30, 2013. Financial expenses resulted primarily from interest expense of 888,000 for the 4.5% convertible note and as a result of the devaluation of the New Israeli Shekel against the U.S. dollar during the period in the amount of $913,000, which was partially offset by financial income which resulted primarily from interest earned on short term deposits.

Nine months ended September 30, 2014 compared to the nine months ended September 30, 2013

Revenues

We recorded revenues of $11.5 million during the nine months ended September 30, 2014, an increase of $3.4 million, or 42%, compared to revenues of $8.1 million for the nine months ended September 30, 2013. Revenues for the nine months ended September 30, 2014 include $3.8 million of products sold in Israel, $3.5 million in Brazil and $1.4 million in connection with products we delivered at cost to Pfizer under the Pfizer Agreement. 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 $2.3 million as our share of net income from the collaboration under the Pfizer Agreement during the nine months ended September 30, 2014 and September 30, 2013. Our share in the collaboration agreement recorded during the nine months ended September 30, 2014 represents our 40% share of the net income generated during the period, which was primarily the result of revenues generated by Pfizer in the United States which exceeded the expenses during such period. Under the terms and conditions of the Pfizer Agreement, 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 $7.5 million for the nine months ended September 30, 2014, an increase of $3.6 million, or 93%, compared to cost of revenues of $3.8 million for the nine months ended September 30, 2013. Cost of revenues for the nine months ended September 30, 2014 consists of the costs of the $1.0 million of products we delivered at cost to Pfizer under the Pfizer Agreement, write-down of inventory of $1.6 million, and 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 we sold in Israel and Brazil for which revenues were recognized during the period.

Research and Development Expenses, Net

Research and development expenses were $17.1 million for the nine months ended September 30, 2014 and $17.4 million for the nine months ended September 30, 2013.

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 $7.3 million for the nine months ended September 30, 2014, an increase of $1.2 million, or 20%, from $6.1 million for the nine months ended September 30, 2013. The increase resulted primarily from sales and marketing expenses of approximately $1.8 million, primarily in connection with sales in Brazil, which was partially offset by a decrease of $491,000 in salaries expense.

Financial Expenses and Income

Financial expenses were $3.4 million for the nine months ended September 30, 2014, compared to financial income of $63,000 for the nine months ended September 30, 2013. Financial expenses resulted primarily from interest expense of $2.7 million for the 4.5% convertible note and from the devaluation of the New Israeli Shekel against the U.S. dollar in the amount of $800,000, which was partially offset by financial income which resulted primarily from interest earned on short term deposits.

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 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. Protalix Ltd. is also entitled to payments equal to 40% of the net profits earned by Pfizer on its global sales of taliglucerase alfa (except in Israel and Brazil). In calculating net profits there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold. 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.

We believe that the funds currently available to us as are sufficient to satisfy our capital needs for the foreseeable future.

Cash Flows

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.

Net cash used in operations was $25.9 million for the nine months ended September 30, 2013. The net loss for the nine months ended September 30, 2013 of $16.9 million was further increased by a decrease of $5.4 million in deferred revenues, a decrease of $5.4 million in accounts payable and accruals and an increase of $3.5 million in inventories, but was partially offset by share based compensation of $3.5 million and $2.7 million in depreciation. Net cash used in investing activities for the nine months ended September 30, 2013 was $1.8 million and consisted primarily of purchases of property and equipment. Net cash provided by financing activities was $67.0 million, consisting primarily of net proceeds from our offering of 2018 4.5% convertible notes.

Future Funding Requirements

We expect to continue to incur significant expenditures in the near future. However, we anticipate that we will generate revenues to offset such losses as Pfizer's commercialization efforts for taliglucerase alfa in the United States and as our commercialization efforts for taliglucerase alfa in Brazil and Israel progress, and as taliglucerase alfa is launched by Pfizer in other countries in which taliglucerase alfa was recently approved. We also anticipate that we will generate additional revenues after additional anticipated marketing approvals of taliglucerase alfa are granted in new countries. We expect to continue to incur significant research and development expenses, including expenses related primarily to the clinical trials of PRX-102 and oral glucocerebrosidase and the advancement of PRX-106 and 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 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.

Our future capital requirements will depend on many factors, including the progress of Pfizer’s commercialization efforts for taliglucerase alfa in the United States and other countries, the progress of our commercialization efforts for taliglucerase alfa in Brazil and Israel and, if anticipated marketing approvals of taliglucerase alfa are granted in other jurisdictions, the progress of Pfizer’s global commercialization efforts for taliglucerase alfa, 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, 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 public or private equity offerings, debt financings, corporate collaboration, licensing arrangements or through other means. 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, 2014 or the nine and three months ended September 30, 2013.

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, 2014 or the nine and three months ended September 30, 2013.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2014 and September 30, 2013.

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,
	2014	2013	2013
Average rate for period	3.491	3.639	3.611
Rate at period end	3.695	3.537	3.471

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, 2014 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, 2013.

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, 2014.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

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	Amended and Restated Bylaws of the Company	10-K	001-33357	3.6	February 28, 2013	
10.1	Employment Agreement with Moshe Manor dated September 28, 2014	8-K	001-33357	10.1	September 29, 2014	

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 10, 2014	By:	/s/ Moshe Manor Moshe Manor President and Chief Executive Officer (Principal Executive Officer)
Date: November 10, 2014	By:	/s/ Yossi Maimon Yossi Maimon Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)