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, 2013

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**	
(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 ☒ 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 ☒ 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	☒
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 ☒

On November 1, 2013, approximately 93,561,765 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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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." refer 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, or the Securities Act, 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," "predict," "project," "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. 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 and other countries;
- the risk of significant delays in the commercial introduction of taliglucerase alfa in other markets as planned;
- the risk that we will not be able to develop a successful sales and marketing organization for any of our product candidates in a timely manner, if at all;
- 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;
- 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 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., or Pfizer, Fundação Oswaldo Cruz or any other collaborator, distributor or partner;
- 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 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, our product candidates may be subject to potential marketing and commercialization restrictions;
- the impact of the development of competing therapies and/or technologies;
- 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;

- 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;

- 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, the European Union and 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 this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2012, and are described from time to time in the reports we file with the Securities and Exchange Commission, or the Commission. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements. In addition, any or all of our 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. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2013	December 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 91,397	$ 52,035
Accounts receivable - Trade	2,053	1,410
Other assets	4,173	3,686
Inventories	7,577	4,039
Total current assets	105,200	61,170
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,467	1,247
PROPERTY AND EQUIPMENT, NET	14,340	16,310
DEFERRED CHARGES	149	—
Total assets	$ 121,156	$ 78,727
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,313	$ 5,267
Other	12,400	11,051
Deferred revenues	9,513	9,437
Total current liabilities	25,226	25,755
LONG TERM LIABILITIES:		
Deferred revenues	43,419	48,888
Convertible notes	66,944	—
Liability in connection with collaboration operation	—	5,425
Liability for employee rights upon retirement	2,273	2,016
Total long term liabilities	112,636	56,329
Total liabilities	137,862	82,084
COMMITMENTS		
CAPITAL DEFICIENCY	(16,706)	(3,357)
Total liabilities net of capital deficiency	$ 121,156	$ 78,727

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 data)
(Unaudited)

	Nine Months Ended		Three Months Ended	
	September 30, 2013	**September 30, 2012**	**September 30, 2013**	**September 30, 2012**
REVENUES	$ 8,116	$ 33,698	$ 2,284	$ 3,724
COMPANY'S SHARE IN COLLABORATION AGREEMENT	2,275	678	1,075	1,666
COST OF REVENUES (1)	(3,876)	(6,966)	(1,587)	(2,367)
GROSS PROFIT	6,515	27,410	1,772	3,023
RESEARCH AND DEVELOPMENT EXPENSES (2)	(23,467)	(27,717)	(7,723)	(8,326)
Less – grant s and reimbursements	6,049	5,655	2,086	1,963
RESEARCH AND DEVELOPMENT EXPENSES, NET	(17,418)	(22,062)	(5,637)	(6,363)
GENERAL AND ADMINISTRATIVE EXPENSES (3)	(6,065)	(7,353)	(1,780)	(2,220)
OPERATING LOSS	(16,968)	(2,005)	(5,645)	(5,560)
FINANCIAL INCOME (EXPENSES) – NET	63	264	(102)	81
NET LOSS FOR THE PERIOD	$ (16,905)	$ (1,741)	$ (5,747)	$ (5,479)
LOSS PER SHARE OF COMMON STOCK:				
BASIC AND DILUTED	$ 0.18	$ 0.02	$ 0.06	$ 0.06
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:				
BASIC AND DILUTED	92,307,170	90,491,421	92,433,502	91,929,445
(1) Includes share-based compensation	—	220	—	220
(2) Includes share-based compensation	2,198	3,690	609	1,247
(3) Includes share-based compensation	1,255	2,155	345	840

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

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDER'S EQUITY (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, 2011	**85,630,157**	**$ 86**	**$ 145,814**	**$ (171,977)**	**$ (26,077)**
Changes during the nine-month period ended September 30, 2012:					
Common stock issued for cash (net of issuance costs of $1,780)	5,175,000	5	25,383		25,388
Share-based compensation related to stock options			4,217		4,217
Share-based compensation related to restricted stock award	1,500,000	1	1,847		1,848
Exercise of options granted to employees	1,156,184	1	1,136		1,137
Net loss for the period				(1,741)	(1,741)
Balance at September 30, 2012	**93,461,341**	**$ 93**	**$ 178,397**	**$ (173,718)**	**$ 4,772**
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)**

(1) Common Stock, $0.001 par value; Authorized – as of September 30, 2013 and 2012 - 150,000,000 shares.

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)

	Nine Months Ended	
	September 30, 2013	**September 30, 2012**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,905)	$ (1,741)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	3,453	6,065
Depreciation and write down of fixed assets	2,689	2,772
Financial expenses (income), net (mainly exchange differences)	(140)	14
Changes in accrued liability for employee rights upon retirement	145	218
Gain on amounts funded in respect of employee rights upon retirement	(26)	(24)
Amortization of debt issuance costs and debt discount	15	
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non-current portion)	(5,393)	(4,981)
Increase in accounts receivable and other assets	(798)	(2,099)
Increase in inventories	(3,538)	(1,779)
Increase (decrease) in accounts payable and accruals (including long term)	(5,413)	369
Net cash used in operating activities	$ (25,911)	$ (1,186)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (1,668)	$ (1,817)
Amounts funded in respect of employee rights upon retirement, net	(121)	(93)
Investment in restricted deposit	(42)	—
Net cash used in investing activities	$ (1,831)	$ (1,910)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of convertible notes	$ 66,930	$
Issuance of shares, net of issuance cost	—	25,328
Exercise of options	30	1,096
Net cash provided by financing activities	$ 66,960	$ 26,424
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 144	$ (113)
NET INCREASE IN CASH AND CASH EQUIVALENTS	39,362	23,215
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	52,035	27,001
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 91,397	$ 50,216

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)
(Unaudited)

(Continued) - 2

	Nine Months Ended	
	September 30, 2013	**September 30, 2012**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 187	$ 821
Issuance cost related to convertible note offering not yet paid	$ 150	
Exercise of options granted to employees	$ 73	$ 72

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

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. Taliglucerase alfa is the first plant cell-based recombinant therapeutic protein approved by the FDA or any other major regulatory authority.

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.

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, subject to the effectiveness of the Brazil Agreement (as defined below), in Brazil. 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 an additional $25.0 million milestone payment in connection with the FDA's approval of taliglucerase alfa in the United States, which was considered to be a substantive milestone for purposes of revenue recognition, and, accordingly, was recorded as revenue during the period in which the milestone was achieved. 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, subject to the effectiveness of the Brazil Agreement, in Brazil, where the Company retained or will retain 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.

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 becomes effective upon its approval by the Brazilian National Institute of Industrial Property, which is expected to occur very shortly.

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 UPLYSO in Mexico, Chile and Uruguay. 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 and Israel. In addition, patients are being treated globally through the Company’s clinical trials and related studies, compassionate use programs and other programs. On July 13, 2010, the Company announced that the French regulatory authority had granted an Autorisation Temporaire d’Utilisation (ATU), or Temporary Authorization for Use, for taliglucerase alfa for the treatment of Gaucher disease.

An ATU is the 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. This ATU allows Gaucher patients in France to receive treatment with taliglucerase alfa before marketing authorization for the product is granted in the European Union. Payment for taliglucerase alfa has been secured through government allocations to hospitals. 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.

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

In addition to the approval of taliglucerase alfa for marketing in the United States, Israel, Brazil, Mexico 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, 2012, filed by the Company with the Commission. The comparative balance sheet at December 31, 2012 has been derived from the audited financial statements at that date.

c. Net loss per share

Basic and diluted loss per share are calculated by dividing the net loss by the weighted average number of shares of the Company's common stock, par value $0.001 (the "Common Stock"), outstanding for each period.

Diluted loss per share does not include options, restricted shares and shares issuable upon conversion of the convertible notes issued in September 2013 (see Note 3) in the amount of 7,169,035 and 7,879,601 shares of Common Stock for the nine months ended September 30, 2012 and 2013, respectively, and 7,508,240 and 8,817,090 shares of Common Stock for the three months ended September 30, 2012 and 2013, respectively, because the effect would be anti-dilutive.

d. Convertible notes

The convertible notes are accounted for using the guidance provided set forth in FASB Accounting Standards Codification (ASC) 815 requiring that the Company determine whether the embedded conversion option must be separated and accounted for separately. The Company accounts for the convertible notes as a liability, on an aggregated basis, in their entirely.

NOTE 2 - INVENTORIES

Inventory at September 30, 2013 and December 31, 2012 consisted of the following:

	September 30, 2013	December 31, 2012
	(U.S. dollars in thousands)	
Raw materials	$ 2,574	$ 2,118
Work in progress	140	192
Finished goods	4,863	1,729
Total inventory	$ 7,577	$ 4,039

Prior to the FDA's approval of taliglucerase alfa, manufacturing costs related to taliglucerase alfa were not capitalized; rather, such costs were expensed as research and development expenses. Effective as of the FDA approval of taliglucerase alfa on May 1, 2012, the Company capitalizes all manufacturing costs associated with taliglucerase alfa.

NOTE 3 – CONVERTIBLE NOTE

On September 18, 2013, the Company completed a private placement of $69.0 million in aggregate principal amount of 4.50% convertible notes due 2018 (the "Notes"), including $9.0 million aggregate principal amount of Notes related to the initial purchaser's over-allotment option, which was exercised in full. In connection with the completion of the offering, the Company entered into an indenture (the "Indenture") with The Bank of New York Mellon Trust Company, N.A., as trustee, governing the Notes. The Notes accrue interest at a rate of 4.50% per year, payable semiannually in arrears on March 15 and September 15 of each year, beginning on March 15, 2014. The Notes mature on September 15, 2018.

The net proceeds from the offering, including net proceeds from the exercise in full by the initial purchaser of its option to purchase an additional $9.0 million in aggregate principal amount of the Notes, were $66.8 million, after deducting the initial purchaser's discount and commission and the estimated offering expenses payable by the Company.

Holders may convert their Notes at any time prior to the close of business on the business day immediately preceding September 15, 2018. The initial conversion rate for the Notes is 173.6593 shares of the Common Stock for each $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $5.76 per share of the Common Stock. Upon conversion, the Company will deliver a number of shares of Common Stock, per $1,000 principal amount of Notes, equal to the conversion rate. The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest.

Prior to September 19, 2016, the Company may not redeem the Notes, and no sinking fund is provided for the Notes. On or after September 19, 2016, the Company may redeem for cash all or part of the Notes (except for the notes that the Company is then required to repurchase in connection with a fundamental change, as defined below) if the last reported sale price of the Common Stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on the trading day immediately preceding the date on which the Company provides the notice of redemption. The redemption price will equal the sum of (i) 100% of the principal amount of the Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date, plus (iii) the sum of the present values of each of the remaining scheduled payments of interest that would have been made on the Notes being redeemed had such Notes remained outstanding from the redemption date to the maturity date.

NOTE 3 – CONVERTIBLE NOTE (continued)

The following table sets forth total interest expense recognized related to the Notes (in thousands):

	Nine Months Ended		Three Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Contractual interest expense	$ 104	—	$ 104	—
Amortization of debt issuance costs	$ 15	—	$ 15	—
Total	$ 119	—	$ 119	—

NOTE 4 - STOCK TRANSACTIONS

During the nine months ended September 30, 2013, the Company issued a total of approximately 64,768 shares of Common Stock in connection with the exercise of a total of approximately 64,768 options by certain employees of the Company. The aggregate proceeds in connection with such exercises totaled approximately $103,000.

NOTE 5 – 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, 2013 is $71,760,000. The fair value was estimated based on quoted market prices.

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 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, 2012. 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 this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2012 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 or 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.

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, and by the applicable regulatory authorities in Uruguay, Mexico and Chile. Taliglucerase alfa will be marketed under the name UPLYSO™ in Brazil and certain other countries. 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, subject to the effectiveness of the Brazil Agreement, as described below, 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. Since 2013, taliglucerase alfa has been marketed in Israel by Protalix Ltd.

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 MOH, for taliglucerase alfa. 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 becomes effective upon its approval by the Brazilian National Institute of Industrial Property, which is expected to occur very shortly.

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 December 2012, we entered into a Clinical Development Agreement with Pfizer under which we will continue to manage, administer and sponsor current, ongoing clinical trials relating to ELELYSO. We are currently sponsoring extension studies of ELELYSO in adult and pediatric patients. New clinical trials for ELELYSO will be conducted and sponsored by Pfizer. Under the terms of the agreement, we were eligible to receive a payment of $8.3 million upon the achievement of certain near-term clinical development goals. The goals were achieved prior to the end of fiscal year 2012 and the $8.3 million payment has been paid in full. This agreement helps to maintain the continuity of the ongoing clinical trials for Gaucher patients and physicians and reinforces the companies' mutual commitment to the Gaucher community.

We performed a number of studies on taliglucerase alfa to supplement the pivotal phase III clinical trial, which we completed in September 2009. We initiated a double-blind, follow-on extension study in 2008 which consisted of eligible patients who had completed nine months of treatment in the pivotal phase III clinical trial. The patients were offered the opportunity to continue to receive taliglucerase alfa at the same dose they received in the pivotal trial for an additional 15 months in a blinded manner. We also conducted a nine-month, worldwide, multi-center, open-label, switch-over clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated with Cerezyme®, which is produced by Genzyme Corporation (a Sanofi company), with taliglucerase alfa, which was successfully completed in 2011. We also conducted a 12-month clinical trial of naïve and switchover pediatric patients, which was successfully completed in 2012. Based on the data from this study, an application for a supplement to the NDA for Elelyso, allowing a pediatric use indication to be added to the product label, has recently been submitted by Pfizer to the FDA.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 and Israel. Globally, patients are being treated through our extension trials and related studies, compassionate use programs, special access agreements, named patient provisions and other programs designed to ensure that treatments are available to Gaucher patients in light of recent shortages of approved treatments. 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 to the United States and France, taliglucerase alfa is currently being provided to Gaucher patients under special access agreements or named patient provisions in Brazil and in other 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 for which the first patient was treated in December 2012.

(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, the subject of a phase I clinical study. We recently announced initial positive results from the trial. We also announced that since some of the patients participating in the trial who suffer from thrombocytopenia and had low platelet counts demonstrated a meaningful improvement in platelet count, the trial has been extended to enroll and evaluate additional patients with low platelet counts.

(3) PRX-106, an antiTNF, a plant cell expressed recombinant fusion protein combined of the soluble form of the human TNF receptor (TNFR) and an antibody portion, which is being developed for the treatment of certain immune and inflammatory diseases, such as rheumatoid arthritis, Chrohn's disease, colitis, psoriasis and other autoimmune and inflammatory disorders, for which we have performed several animal studies. We are now conducting additional preclinical studies focused on our proprietary orally administered delivery treatment with the PRX-106 protein using plant cells, for several attractive indications.

(4) PRX-107, a proprietary plant cell recombinant human Alpha1-antitrypsin, or AAT, under development for the treatment of emphysema due to hereditary AAT deficiency, to be administered by inhalation. We believe this will be the first recombinant form of the AAT protein drug. We plan to hold a pre-Investigational New Drug, or IND, meeting with the FDA during the first half of 2014 to discuss next steps for this compound.

(5) PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1 under development for the treatment of cystic fibrosis, to be administered by inhalation. We held a pre-IND meeting with the FDA in 2012, and plan to file an IND with the FDA following the completion of toxicology studies, which is expected to occur in early 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 our proprietary development candidates. We have built an internal marketing team designed to serve the Israeli 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, 2012.

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. 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, 2013 compared to the three months ended September 30, 2012

Revenues

We recorded revenues of $2.3 million during the three months ended September 30, 2013, compared to revenues of $3.7 million for the three months ended September 30, 2012. The revenues represent a pro rata amortization equal to $1.1 million resulting from the $65.0 million upfront and milestone payments we received from Pfizer in 2009, revenues generated from our sales of taliglucerase alfa in Israel and the cost of products we delivered to Pfizer under the Pfizer Agreement. We recorded revenues of $1.4 million for the three months ended September 30, 2013 from products we sold in Israel.

Our share in the Collaboration Agreement

We recorded revenue of $1.1 million as our share of net income from the collaboration under the Pfizer Agreement during the three months ended September 30, 2013, compared to revenue of $1.7 million for the three months ended September 30, 2012. Our share in the collaboration agreement recorded during the three months ended September 30, 2013 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. During the three months ended September 30, 2012, the majority of the revenues generated by Pfizer were from sales in Brazil. Under the terms and conditions of the Pfizer Agreement, financial information of Pfizer's subsidiaries that operate outside the United States is included based on the fiscal year ending November 30, while financial information for the U.S. entity is included based on the fiscal year ending December 31.

Cost of Revenues

Cost of revenues was $1.6 million and $2.4 million for the three months ended September 30, 2013 and 2012, respectively. Cost of revenues for the three months ended September 30, 2013 consists primarily 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 we sold in Israel. Prior to the FDA's approval of taliglucerase alfa, manufacturing costs related to taliglucerase alfa were classified as research and development expenses. Effective as of the FDA approval of taliglucerase alfa, we capitalize all manufacturing costs associated with taliglucerase alfa and expense such costs as cost of revenues, as applicable.

Research and Development Expenses, Net

Research and development expenses were $5.6 million for the three months ended September 30, 2013, a decrease of $726,000, or 11%, from $6.4 million for the three months ended September 30, 2012. The decrease resulted primarily from a decrease of $1.1 million in certain clinical trials expenses resulting from the winding down of certain clinical trials for taliglucerase alfa.

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

General and Administrative Expenses

General and administrative expenses were $1.8 million for the three months ended September 30, 2013, a decrease of $440,000, or 20%, from $2.2 million for the three months ended September 30, 2012. The decrease resulted primarily from a decrease of $506,000 in salaries expenses primarily due to share-based compensation.

Financial Expenses and Income

Financial expense was $102,000 for the three months ended September 30, 2013 mainly due to the interest expense accrued in connection with the convertible note and the devaluation of the US dollar against the NIS during the period, compared to financial income of $81,000 for the three months ended September 30, 2012, mainly due to interest earned on short term deposits during the period.

Nine months ended September 30, 2013 compared to the nine months ended September 30, 2012

Revenues

We recorded revenues of $8.1 million during the nine months ended September 30, 2013, compared to revenues of $33.7 million for the nine months ended September 30, 2012. The revenues represent primarily a pro rata amortization equal to $1.1 million in each quarterly period resulting from the $65.0 million upfront and milestone payments we received from Pfizer in 2009, revenues generated from our sales of taliglucerase alfa in Israel and the cost of products we deliver to Pfizer under the Pfizer Agreement. The revenues for the nine months ended September 30, 2012 included a $25.0 million payment we received from Pfizer under the Pfizer Agreement in connection with the FDA's approval of taliglucerase alfa on May 1, 2012. The revenues for the nine months ended September 30, 2013 include $3.6 million from products we sold in Israel.

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, 2013, compared to revenue of $678,000 for the nine months ended September 30, 2012. Our share in the collaboration agreement recorded during the nine months ended September 30, 2013 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, financial information of Pfizer’s subsidiaries that operate outside the United States is included based on the fiscal year ending November 30, while financial information for the U.S. entity is included based on the fiscal year ending December 31.

Cost of Revenues

Cost of revenues was $3.9 million for the nine months ended September 30, 2013, a decrease of $3.1 million, or 44%, compared to $7.0 million for the nine months ended September 30, 2012. Cost of revenues for the nine months ended September 30, 2013 consists primarily 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 we sold in Israel and products we delivered to Pfizer for which revenues were recognized during the period. Cost of revenues for the nine months ended September 30, 2012 included an aggregate of $2.1 million in royalties to the OCS and to a certain academic institution in connection with gross sales of taliglucerase alfa during the period. Prior to the FDA's approval of taliglucerase alfa, manufacturing costs related to taliglucerase alfa were classified as research and development expenses. Effective as of the FDA approval of taliglucerase alfa, we capitalize all manufacturing costs associated with taliglucerase alfa and expense such costs as cost of revenues, as applicable.

Research and Development Expenses, Net

Research and development expenses were $17.4 million for the nine months ended September 30, 2013, a decrease of $4.6 million, or 21%, from $22.1 million for the nine months ended September 30, 2012. The decrease resulted primarily from a decrease of approximately $2.2 million in certain clinical trials expenses resulting from the winding down of certain clinical trials for taliglucerase alfa, a decrease of $1.0 million in salaries expenses primarily due to share-based compensation and a decrease of $725,000 in materials which we have been classified as cost of revenues or capitalized as inventory after FDA’s approval of taliglucerase alfa in May 2012.

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

General and Administrative Expenses

General and administrative expenses were $6.1 million for the nine months ended September 30, 2013, a decrease of $1.3 million, or 18%, from $7.4 million for the nine months ended September 30, 2012. The decrease resulted primarily from a decrease of $1.3 million in salaries expenses primarily due to share-based compensation.

Financial Expenses and Income

Financial income was $63,000 for the nine months ended September 30, 2013, compared to financial income of $264,000 for the nine months ended September 30, 2012. Financial income resulted primarily from interest earned on short term deposits, net of interest expense on the convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures 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.

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 2013, the OCS awarded us a grant of up to approximately $3.6 million for the calendar year 2013. The award was granted to promote the advancement of our drug development programs.

In addition to the foregoing, 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, subject to the effectiveness of the Brazil Agreement, 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 goals 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 $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 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.

Net cash used in operations was $1.2 million for the nine months ended September 30, 2012. The net loss for the nine months ended September 30, 2012 of $1.7 million decreased primarily due to $6.1 million in share-based compensation and $2.8 million in depreciation, which was partially offset by a decrease of $5.0 million in deferred revenues and increase of $2.1 million in accounts receivable and increase of $1.8 million in inventory. Net cash used in investing activities for the nine months ended September 30, 2012 was $1.9 million and consisted primarily of purchases of property and equipment. Net cash provided by financing activities was $26.4 million, consisting primarily of net proceeds from our February 2012 underwritten public offering of common stock.

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 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.

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 months ended September 30, 2013 or the nine months ended September 30, 2012.

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 months ended September 30, 2013 or the nine months ended September 30, 2012.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2013 and September 30, 2012.

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 dollar. We currently have no significant source of revenues; therefore we consider the currency of the primary economic environment to be the currency in which we expend cash. Approximately 50% of our expenses and capital expenditures are incurred in 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.

Approximately 35% 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,
	2013	2012	2012
Average rate for period	3.639	3.861	3.856
Rate at period end	3.537	3.912	3.733

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, 2013 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

We describe certain risk factors below. In addition to the risks, uncertainties and other factors set forth below and elsewhere in this Quarterly Report on Form 10-Q, see, the "Risk Factors" section contained in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to pay interest on, or to make any scheduled payment of the principal of, the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. If we raise additional debt, it would increase our interest expense, leverage and operating and financial costs. In addition, the terms of the indenture governing the Notes and the agreements governing future indebtedness may restrict us from adopting any of these alternatives. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. The failure to generate sufficient cash flow or to effect any of these alternatives could significantly adversely affect the value of the Notes and our ability to pay amounts due under the Notes.

Our significant level of indebtedness could adversely affect our business, financial condition and results of operations and prevent us from fulfilling our obligations under the Notes and our other indebtedness.

The outstanding Notes represent a significant amount of indebtedness and substantial debt service requirements. We may also incur additional indebtedness to meet future financing needs. Our substantial indebtedness could have material adverse effects on our business, financial condition and results of operations. For example, it could:

- make it more difficult for us to satisfy our financial obligations, including with respect to the Notes;
- result in an event of default if we fail to comply with the financial and other restrictive covenants contained in agreements governing any future indebtedness, which event of default could result in all of our debt becoming immediately due and payable;
- increase our vulnerability to general adverse economic, industry and competitive conditions;
- reduce the availability of our cash flow to fund working capital, capital expenditures, acquisitions and other general corporate purposes because we will be required to dedicate a substantial portion of our cash flow from operations to the payment of principal and interest on our indebtedness;
- limit our flexibility in planning for, or reacting to, and increasing our vulnerability to changes in our business, the industry in which we operate and the general economy;
- prevent us from raising funds necessary to purchase Notes surrendered to us by holders upon a fundamental change (as described in the indenture governing the Notes), which failure would result in an event of default with respect to the Notes;
- place us at a competitive disadvantage compared to our competitors that have less indebtedness or are less highly leveraged and that, therefore, may be able to take advantage of opportunities that our debt levels or leverage prevent us from exploiting; and

- limit our ability to obtain additional financing.

Each of these factors may have a material and adverse effect on our business, financial condition and results of operations and our ability to meet our payment obligations under the Notes and our other indebtedness. Our ability to make payments with respect to the Notes and to satisfy any other debt obligations will depend on our future operating performance and our ability to generate significant cash flow in the future, which will be affected by prevailing economic conditions and financial, business, competitive, legislative and regulatory factors as well as other factors affecting our company and industry, many of which are beyond our control.

Any conversion of the Notes will dilute the ownership interest of our existing stockholders, including holders who had previously converted their notes.

The conversion of some or all of the Notes will dilute the ownership interests of our existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could depress the price of our common stock.

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, 2013.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

Not applicable.

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	
4.1	Indenture, dated as of September 18, 2013, between Protalix BioTherapeutics, Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee.	8-K		4.1	September 18, 2013	
4.2	Form of 4.50% Convertible Note due 2018	8-K	001-33357	4.2	September 18, 2013	
10.1	Purchase Agreement, dated September 12, 2013 between Protalix BioTherapeutics, Inc. and Citigroup Capital Markets Inc.	8-K	001-33357	10.1	September 18, 2013	
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 7, 2013 By: /s/ David Aviezer
David Aviezer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2013 By: /s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, David Aviezer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalix BioTherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2013

/s/ David Aviezer

David Aviezer, Ph.D.
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Yossi Maimon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalix BioTherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2013

/s/ Yossi Maimon

Yossi Maimon
Chief Financial Officer, Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2013 as filed with the Securities and Exchange Commission (the "Report"), I, David Aviezer, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: November 7, 2013

/s/ David Aviezer

David Aviezer, Ph.D.
President and Chief Executive Officer

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2013 as filed with the Securities and Exchange Commission (the "Report"), I, Yossi Maimon, Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: November 7, 2013

/s/ Yossi Maimon

Yossi Maimon
Vice President and Chief Financial Officer