Protalix BioTherapeutics, Inc.
Form 10-Q
May 09, 2013

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 March 31, 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	**20100**
(Address of principal executive offices)	**(Zip Code)**

+972-4-988-9488
(Registrant's telephone number, including area code)

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

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

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

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

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

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

On May 1, 2013, approximately 93,503,268 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," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," 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," "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. 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 and Brazil;
- the risk of significant delays in the commercial introduction of taliglucerase alfa in other markets as planned;
- our ability to enter into supply arrangements with the Brazilian Ministry of Health, or the Brazilian MOH, or other parties and to supply drug product pursuant to such arrangements;
- 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, 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;

- 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, 2012, and are described from time to time in the reports we file with the 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)

	March 31, 2013	December 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,870	$ 52,035
Accounts receivable- Trade	1,698	1,410
Other assets	3,553	3,686
Inventories	5,773	4,039
Total current assets	52,894	61,170
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,343	1,247
PROPERTY AND EQUIPMENT, NET	15,705	16,310
Total assets	$ 69,942	$ 78,727
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,762	$ 5,267
Other	12,055	11,051
Deferred revenues	8,591	9,437
Total current liabilities	24,408	25,755
LONG TERM LIABILITIES:		
Deferred revenues	46,994	48,888
Liability in connection with collaboration operation	2,700	5,425
Liability for employee rights upon retirement	2,123	2,016
Total long term liabilities	51,817	56,329

Total liabilities	76,225	82,084
COMMITMENTS		
CAPITAL DEFICIENCY	(6,283)	(3,357)
Total liabilities net of capital deficiency	$ 69,942	$ 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)

	Three Months Ended	
	March 31, 2013	March 31, 2012
REVENUES	$3,568	$ 3,861
COMPANY'S SHARE IN COLLABORATION AGREEMENT	400	(133)
COST OF REVENUES	(971)	(1,320)
GROSS PROFIT	2,997	2,408
RESEARCH AND DEVELOPMENT EXPENSES (1)	(7,754)	(8,847)
Less – grants and reimbursements	2,431	2,003
RESEARCH AND DEVELOPMENT EXPENSES, NET	(5,323)	(6,844)
GENERAL AND ADMINISTRATIVE EXPENSES (2)	(2,103)	(1,629)
OPERATING LOSS	(4,429)	(6,065)
FINANCIAL INCOME – NET	108	161
NET LOSS FOR THE PERIOD	$(4,321)	$ (5,904)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$0.05	$ 0.07
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	92,184,220	87,821,078
(1) Includes share-based compensation	870	61
(2) Includes share-based compensation	497	68

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

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN CAPITAL DEFICIENCY

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

(Unaudited)

	Common Stock (1)	Common Stock	Additional paid–in capital	Accumulated deficit	Total
	Number of shares	Amount			
Balance at December 31, 2011	85,630,157	$86	$145,814	$(171,977)	$(26,077)
Changes during three-month period ended March 31, 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			129		129
Exercise of options granted to employees and non-employees	17,095	*	7		7
Net Loss for the period				(5,904)	(5,904)
Balance at March 31, 2012	90,822,252	$91	$171,333	$(177,881)	$(6,457)
Balance at December 31, 2012	93,489,809	$93	$180,145	$(183,595)	$(3,357)
Changes during three-month period ended March 31, 2013:					
Share-based compensation related to stock options			347		347
Share-based compensation related to restricted stock award			1,020		1,020
Exercise of options granted to employees	12,421	1	27		28
Net Loss for the period				(4,321)	(4,321)
Balance at March 31, 2013	93,502,230	$94	$181,539	$(187,916)	$(6,283)

* Represents an amount less than $1.

(1) Common Stock, $0.001 par value; Authorized – as of March 31, 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)

	Three Months Ended	
	March 31, 2013	March 31, 2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (4,321)	$ (5,904)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	1,367	129
Depreciation and write down of fixed assets	926	930
Financial income, net (mainly exchange differences)	(78)	(114)
Changes in accrued liability for employee rights upon retirement	60	44
Gain on amounts funded in respect of employee rights upon retirement	(19)	(5)
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non-current portion)	(2,740)	(2,405)
Decrease (increase) in accounts receivable and other assets	(42)	1,270
Decrease (increase) in inventories	(1,734)	16
Decrease in accounts payable and accruals (including long term)	(3,005)	(242)
Net cash used in operating activities	$ (9,586)	$ (6,281)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (642)	$ (810)
Amounts funded in respect of employee rights upon retirement, net	(47)	(42)
Net cash used in investing activities	$ (689)	$ (852)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of shares, net of issuance cost		$ 25,538
Exercise of options		36
Net cash provided by financing activities		$ 25,574
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 110	163
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(10,165)	18,604
BALANCE OF CASH AND CASH **EQUIVALENTS AT BEGINNING OF PERIOD**	52,035	27,001
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 41,870	$ 45,605

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

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands)

(Unaudited)

(Continued) - 2

	Three Months Ended	
	March 31, 2013	March 31, 2012
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 815	$ 829
Issuance cost not yet paid		$ 150
Exercise of options granted to employees	$ 28	$ 2

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

1. Operation

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 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 each of the FDA and the Israeli MOH.

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. 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, 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.

In December 2012, Protalix Ltd. entered into a Clinical Development Agreement with Pfizer under which Protalix Ltd. will continue to manage, administer and sponsor current, ongoing clinical trials relating to taliglucerase alfa. According to the terms of the agreement, Protalix Ltd. was eligible to receive a payment of $8.3 million upon the achievement of certain near-term clinical development goals. The goals were achieved, and the payment made, in December 2012.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

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

The Company is cooperating with Pfizer 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 and Israel. In addition, patients are being treated globally through the Company's clinical 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. 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 Brazil and in other countries.

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

2. Liquidity and Financial Resources

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. In accordance with the terms and conditions of the Pfizer Agreement, the Company received a $25.0 million milestone payment in connection with the FDA's approval of taliglucerase alfa in the United States. 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 also 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 is directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain such approval in the United States and in other countries. The Company cannot reasonably predict the outcome of these activities.

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

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

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

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 Securities and Exchange 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 ("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 7,373,768 and 7,471,571 shares of Common Stock underlying outstanding options and restricted shares of Common Stock for the three months ended March 31, 2012 and 2013, respectively, because the effect would be anti-dilutive.

NOTE 2 - INVENTORIES

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

	March 31, 2013	December 31, 2012
	(U.S. dollars in thousands)	
Raw materials	$ 2,418	$ 2,118
Work in progress	341	192
Finished goods	3,014	1,729
Total inventory	$ 5,773	$ 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 - STOCK TRANSACTIONS

During the three months ended March 31, 2013, the Company issued a total of 12,421 shares of Common Stock in connection with the exercise of a total of 12,421 options by certain employees of the Company. The aggregate proceeds in connection with such exercises totaled approximately $28,000.

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, 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 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 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.

On May 1, 2012, the FDA approved for sale our first commercial product, taliglucerase alfa for injection, which is being marketed under the brand name ELELYSO™, as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved by the Brazilian National Health Surveillance Agency (ANVISA, Agencia Nacional de Vigilancia Sanitaria) 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 is our proprietary, recombinant form of glucocerebrosidase (GCD) that is produced or expressed through ProCellEx. Taliglucerase alfa is the first plant cell-based recombinant therapeutic protein to be approved by each of the FDA and the Israeli MOH, or by the regulatory agencies 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, 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 retained those rights in Israel. 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., our wholly-owned subsidiary.

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 taliglucerase alfa. We are currently sponsoring adult and pediatric extension studies of taliglucerase alfa. New clinical trials for taliglucerase alfa 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, or Genzyme (A Sanofi-Aventis 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. Patients in the extension trials are still being treated with taliglucerase alfa.

Currently, patients are being treated with ELELYSO on a commercial basis in the United States and in 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.

On August 10, 2010, Pfizer entered into a $30 million short-term supply agreement with the Brazilian Ministry of Health, or the Brazilian MOH, pursuant to which Protalix and Pfizer have provided taliglucerase alfa to the Brazilian MOH for the treatment of Gaucher patients. During the remainder of 2010 and the first quarter of 2011, we and Pfizer completed the supply of products deliverable under the short-term supply agreement. During 2011, the Brazilian MOH requested that Pfizer consider the replacement of certain vials that might expire during 2012. During the third quarter of 2012, we and Pfizer resupplied a portion of the returned vials. In addition, we and the Brazilian MOH are in advanced discussions relating to a possible long-term supply agreement that contemplates, among other matters, providing certain components of our manufacturing technology to the Brazilian MOH for implementation by it in Brazil. We are currently unable to assess whether these discussions will result in an agreement and we can make no assurance that we will be able to enter into such an agreement on favorable terms, if at all.

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-105, a plant cell expressed pegylated recombinant acetylcholinesterase product candidate for biodefense and other indications, which was the subject of a completed phase I clinical trial; (3) 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 in a phase I clinical study for which the first patient was treated in April 2013; (4) PRX-106, or pr-antiTNF, a plant cell expressed recombinant fusion protein made from the soluble form of the human

TNF receptor (TNFR) and an antibody portion, which is being developed as a treatment of certain immune diseases such as rheumatoid arthritis, Chrohn's disease, placque psoriasis and other autoimmune disorders, for which we have performed animal studies; and (5) two additional undisclosed therapeutic proteins, both of which are being evaluated in animal studies. We participated in a pre-investigational new drug, or IND, meeting with respect to one of the undisclosed product candidates in the first quarter of 2012 and a pre-IND meeting for the second candidate is planned for 2013. In December 2011, we held a pre-IND meeting with respect to PRX-106 and we expect to submit an IND during 2013.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Israel) which we licensed to Pfizer, we hold the worldwide commercialization rights to all 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 March 31, 2013 compared to the three months ended March 31, 2012

Revenues

We recorded revenues of $3.6 million during the three months ended March 31, 2013, a decrease of $293,000, or 8%, from revenues of $3.9 million for the three months ended March 31, 2012. The revenues represent a pro rata amortization of the $65.0 million upfront and milestone payments of $1.1 million in each quarterly period, $1.0 million for the quarter ended March 31, 2013 in connection with products we sold in Israel and $1.5 million in connection with products we delivered to Pfizer under our license agreement.

Our share in the Collaboration Agreement

We recorded revenue of $400,000 as our share of net income from the collaboration under the Pfizer Agreement during the three months ended March 31, 2013 compared to $133,000 of loss for the three months ended March 31,

2012. Our share in the collaboration agreement recorded during the three months ended March 31, 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 $971,000 and $1.3 million for the three months ended March 31, 2013 and 2012, respectively. Cost of revenues for the three months ended March 31, 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. 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, we capitalize all manufacturing costs associated with taliglucerase alfa.

Research and Development Expenses, Net

Research and development expenses were $7.8 million for the three months ended March 31, 2013, a decrease of $1.1 million, or 12%, from $8.8 million for the three months ended March 31, 2012. The decrease resulted primarily from a decrease of $854,000 in rent and other overhead costs and $1.2 million in materials which have been classified as cost of revenues or capitalized as inventory after the FDA's approval of taliglucerase alfa in May 2012. The decrease was partially offset by an increase of $1.2 million in costs related to salaries expense resulting primarily from share based compensation. The decrease also resulted from increased reimbursement of expenses equal to $1.5 million in accordance with the terms and conditions of the Pfizer Agreement during the three months ended March 31, 2013, compared to the total reimbursement of approximately $434,000 from Pfizer during the three months ended March 31, 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 $2.1 million for the three months ended March 31, 2013, an increase of $474,000, or 29%, from $1.6 million for the three months ended March 31, 2012. The increase resulted primarily from an increase of $605,000 in salaries expense primarily due to share-based compensation.

Financial Expenses and Income

Financial income was $108,000 for the three months ended March 31, 2013, compared to financial income of $161,000 for the three months ended March 31, 2012. Financial income 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 and the lack of significant product sales revenue due to the recent launch of taliglucerase alfa in the United States and Israel, we have not been profitable and have generated operating losses since our inception with the exception of the quarter ended on 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 2012, the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor awarded us a grant of up to approximately $4.3 million for the calendar years 2011 and 2012. 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). 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 at least the next 12 months.

Cash Flows

Net cash used in operations was $9.6 million for the three months ended March 31, 2013. The net loss for the three months ended March 31, 2013 of $4.3 million was further increased by a decrease of $2.7 million in deferred revenues, a decrease of $3.0 million in accounts payable and an increase in inventories, but was partially offset by share based compensation of $1.4 million and $926,000 in depreciation. Net cash used in investing activities for the three months ended March 31, 2013 was $689,000 and consisted primarily of purchases of property and equipment.

Net cash used in operations was $6.3 million for the three months ended March 31, 2012. The net loss for the three months ended March 31, 2012 of $5.9 million was further increased by a decrease of $2.4 million in deferred revenues but was partially offset by a decrease of $1.2 million in accounts receivable. Net cash used in investing activities for the three months ended March 31, 2012 was $852,000 and consisted primarily of purchases of property and equipment. Net cash provided by financing activities for the three months ended March 31, 2012 was $25.6 million, consisting primarily of net proceeds from our February 2012 underwritten public offering.

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 Israel continue to 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 outside of the United States, Israel, Brazil, Mexico and other countries. We expect to continue to incur significant research and development expenses, including expenses related to the clinical trials of PRX-102 and oral glucocerebrosidase and the advancement of other product candidates into clinical trials. We expect that general and administrative expenses will marginally increase as we expand our administrative staff, add infrastructure and incur additional costs related to the continued progression of the commercialization of taliglucerase alfa.

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

Our future capital requirements will depend on many factors, including the progress 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 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, or corporate collaboration and licensing arrangements. 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 three months ended March 31, 2013 or the three months ended March 31, 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 three months ended March 31, 2013 or the three months ended March 31, 2012.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2013 and March 31, 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:

	Three months ended March 31,		Year ended December 31,
	2013	2012	2012
Average rate for period	3.708	3.771	3.856
Rate at period end	3.648	3.715	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 March 31, 2013 that has materially affected, or that is 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, 2012.

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 March 31, 2013.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

On May 9, 2013, our Board of Directors resolved that our 2013 Annual Meeting of Shareholders will be held on or around November 7, 2013, in Tel Aviv, Israel. The final date and location of the meeting will be announced in the proxy statement we will file and distribute in connection with the meeting. Proposals must be received at our principal executive offices on or prior to July 2, 2013 to be considered timely. Proposals should be directed to the attention of the Secretary.

Item 6. Exhibits

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File Number**	**Exhibit**	**Date**	**Filed Herewith**
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	
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: May 9, 2013 By: /s/ David Aviezer
David Aviezer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2013 By: /s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)