Protalix BioTherapeutics, Inc.
Form 10-Q
May 04, 2011

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2011

OR

o **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 þ No o
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 o No o
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 o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

On May 1, 2011, approximately 85,579,610 shares of the Registrant s common stock, $0.001 par value, were outstanding.

FORM 10-Q
TABLE OF CONTENTS

Table of Contents

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, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms anticipate, believe, estimate, expect and intend and words or phrases of similar import, as t relate to us 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 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:

- delays in our response to the Complete Response Letter, or CRL, we received from the U.S. Food and Drug Administration, or FDA, relating to our New Drug Application (NDA) for taliglucerase alfa;
- delays in the FDA s review of any response to the CRL, if any;
- delays in the approval or the potential rejection of any applications we file with the FDA or other regulatory authorities, including the NDA we have filed with the FDA, the marketing application we submitted to the Israeli Ministry of Health, or Israeli MOH, and the Marketing Authorization Application (MAA) we have submitted to each of the European Medicines Agency, or the EMEA, and ANVISA, the National Sanitary Vigilance Agency, an agency of the Brazilian Ministry of Health, or ANVISA, for taliglucerase alfa;
- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;
- delays in our preparation and filing of applications for regulatory approval in the United States, the European Union, Israel, Brazil and elsewhere;
- any lack of progress of our research and development (including the results of our clinical trials);
- our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationships with Pfizer Inc., or Pfizer, Teva Ltd. or with any other collaborator, distributor or partner;
- our ability to obtain on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- risks relating to biogeneric legislation and/or healthcare reform in the United States or elsewhere;
- our ability to obtain additional financing required to fund our research programs and the expansion of our manufacturing capabilities;

the risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all;

our ability to enter into supply arrangements with the Ministry of Health of Brazil or other parties and to supply drug product pursuant to such arrangements;

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

the availability of reimbursement to patients from health care payors for any of our product candidates, if approved;

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; 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

Table of Contents

manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

In February 2011, we received a CRL from the FDA regarding our NDA for taliglucerase alfa for the treatment of Gaucher disease. The main questions raised by the FDA regarding the NDA relate to the clinical and CMC sections. In the clinical section of the CRL, the FDA requested additional data from each of the switchover trial and the long-term extension trial. In the CMC section of the CRL, the FDA requested information regarding testing specifications and assay validation. The FDA did not request additional clinical studies in the CRL. We recently met with FDA and received certain clarifications from the FDA regarding the CRL. We believe we will be able to address all of the FDA requests within the next few months. However, there can be no assurance that the FDA will not make any additional request regarding our NDA. In the past, the FDA has made additional requests to other applicants after the delivery of a CRL. Any additional requests from the FDA relating to the NDA may delay or preclude our response to the CRL. Even if we comply with all of the FDA s requests in the CRL, or otherwise if any, the FDA may ultimately reject the NDA, or fail to approve the NDA in a timely manner, which would have a material adverse effect on our business, financial condition and results of operations. In addition, our resubmission in response to the CRL may result in a longer review time by the FDA and potentially a longer delay in the approval of taliglucerase alfa, if at all, which would have a material adverse effect on our business, financial condition and results of operations. Our efforts to respond to the CRL, and any development with the FDA with respect to our response, may result in changes to our current expectations as reflected in our forward-looking statements.

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 beginning Part II, Item 1A of this Quarterly Report on Form 10-Q, in our Annual Report on Form 10-K for the year ended December 31, 2010, Section 1A, under the heading Risk Factors, and as described from time to time in our future reports to be filed with the SEC.

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.

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2011 (Unaudited)	December 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 50,227	$ 35,900
Accounts receivable:		
Trade	6,423	7,013
Other	4,503	2,231
Inventories	1,101	1,189
Total current assets	62,254	46,333
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,015	942
PROPERTY AND EQUIPMENT, NET	17,654	17,454
Total assets	$ 80,923	$ 64,729
LIABILITIES AND SHAREHOLDERS EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 7,533	$ 6,272
Other	8,034	8,068
Deferred revenues	4,563	4,563
Total current liabilities	20,130	18,903
LONG-TERM LIABILITIES:		
Deferred revenues	54,345	55,486
Liability for employee rights upon retirement	1,743	1,663
Total long term liabilities	56,088	57,149
Total liabilities	76,218	76,052
COMMITMENTS		
SHAREHOLDERS EQUITY (CAPITAL DEFICIENCY)	4,705	(11,323)
Total liabilities and shareholders equity (net of capital deficiency)	$ 80,923	$ 64,729

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

Table of Contents

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

	Three Months Ended	
	March 31, 2011	March 31, 2010
REVENUES	$ 4,128	$ 1,141
COMPANY S SHARE IN COLLABORATION AGREEMENT	1,872	(294)
COST OF REVENUES	(778)	
GROSS PROFIT	5,222	847
RESEARCH AND DEVELOPMENT EXPENSES (1)	(10,563)	(8,978)
less grants and reimbursements	2,292	1,630
	(8,271)	(7,348)
GENERAL AND ADMINISTRATIVE EXPENSES (2)	(1,989)	(1,619)
OPERATING LOSS	(5,038)	(8,120)
FINANCIAL (EXPENSES) INCOME NET	(14)	165
NET LOSS FOR THE PERIOD	$ (5,052)	$ (7,955)
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED	$ 0.06	$ 0.10
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:		
Basic and diluted	81,744,547	80,850,551
(1) Includes share-based compensation	$ 104	$ 121
(2) Includes share-based compensation	$ 138	$ 163

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

Table of Contents

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY (CAPITAL DEFICIENCY)
(U.S. dollars in thousands, except share data)

	Common Stock (1) Number	Common Stock Amount	Additional paid in capital	Accumulated deficit	Total
Balance at December 31, 2009	**80,841,237**	**$ 81**	**$ 122,252**	**$ (106,450)**	**$ 15,883**
Changes during the three month period ended March 31, 2010 (Unaudited):					
Share-based compensation			284		284
Exercise of options granted to employees (includes Net Exercise)	20,007	*	2		2
Net loss for the period				(7,955)	(7,955)
Balance at March 31, 2010 (Unaudited)	**80,861,244**	**$ 81**	**$ 122,538**	**$ (114,405)**	**$ 8,214**
Balance at December 31, 2010	**81,248,472**	**$ 81**	**$ 124,044**	**$ (135,448)**	**$ (11,323)**
Changes during the three month period ended March 31, 2011 (Unaudited):					
Common stock issued for cash (net of issuance costs of $1,410) (see note 3a)	4,000,000	4	20,586		20,590
Share-based compensation			242		242
Exercise of options granted to employees and non- employees	329,475	1	247		248
Net loss for the period				(5,052)	(5,052)
Balance at March 31, 2011 (Unaudited)	**85,577,947**	**$ 86**	**$ 145,119**	**$ (140,500)**	**$ 4,705**

(1) Common Stock, $0.001 par value; Authorized as of March 31, 2011 and March 31, 2010 - 150,000,000 shares.

* Represents an amount less than $1.

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

Table of Contents

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

	Three Months Ended	
	March 31, 2011	March 31, 2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,052)	$ (7,955)
Adjustments required to reconcile net loss to net cash used in operating activities		
Share based compensation	242	284
Depreciation and impairment of fixed assets	878	697
Financial income (expenses) net (mainly exchange differences)	64	(25)
Changes in accrued liability for employee rights upon retirement	33	274
Gain on amounts funded in respect of employee rights upon retirement	(7)	
Changes in operating assets and liabilities:		
Decrease in deferred revenues	(1,141)	(1,141)
Decrease in inventories	88	
Increase in accounts receivable	(1,654)	(1,454)
Increase in accounts payable and accruals	2,561	375
Net cash used in operating activities	$ (3,988)	$ (8,945)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (2,604)	$ (2,961)
Amounts funded in respect of employee rights upon retirement, net	(46)	(42)
Net cash used in investing activities	$ (2,650)	$ (3,003)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of shares, net of issuance cost	$ 20,680	
Exercise of options	256	$ 2
Net cash provided by financing activities	$ 20,936	$ 2
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 29	$ 44
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	14,327	(11,902)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	35,900	81,266
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 50,227	$ 69,364

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

Table of Contents

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

(Continued) 2

	Three Months Ended	
	March 31, 2011	**March 31, 2010**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 1,194	$ 2,398
Issuance cost not yet paid and accruals other	$ 90	
Exercise of options granted to employees	$ 1	

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

5

Table of Contents

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES

a. General

1. Operation

Protalix BioTherapeutics, Inc. and its wholly-owned subsidiary, Protalix Ltd. (the Israeli Subsidiary or Protalix Ltd., and collectively with Protalix BioTherapeutics, Inc., the Company), 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, the Company formed another wholly-owned subsidiary under the laws of the Netherlands in connection with the EMEA application process in Europe. The Company s two subsidiaries are referred to collectively herein as the Subsidiaries. The Company s lead product development candidate is taliglucerase alfa for the treatment of Gaucher disease which the Company is developing using ProCellEx. In addition to taliglucerase alfa, the Company is developing other certain products using ProCellEx.

In September 2009, the Company successfully completed its phase III pivotal trial of taliglucerase alfa. In July 2010, the U.S. Food and Drug Administration (FDA) notified the Company that it had accepted the Company s new drug application (NDA) for taliglucerase alfa for the treatment of Gaucher disease and that it granted to taliglucerase alfa a Prescription Drug User Fee Act (PDUFA) action date of February 25, 2011. On February 25, 2011 the FDA issued a Complete Response Letter (a CRL) indicated that the review is completed and questions remain that preclude the approval of the NDA for taliglucerase alfa in its current form.

In September 2009, the FDA s Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status. In addition to its phase III clinical trial, the Company initiated a clinical study in December 2008 to evaluate the safety and efficacy of switching Gaucher disease patients currently treated under the current standard of care to treatment with taliglucerase alfa. In November 2010 the Company successfully completed the nine month switchover trial in adults.

On November 30, 2009, Protalix Ltd. and Pfizer Inc. (Pfizer) entered into an Exclusive License and Supply Agreement (the Pfizer Agreement) pursuant to which Protalix Ltd. granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa, except in Israel. Under the terms and conditions of the Pfizer Agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel.

On July 13, 2010, the French regulatory authority 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 disease 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.

On August 10, 2010, Pfizer entered into a $30 million short-term supply agreement with the Ministry of Health of Brazil pursuant to which the Company and Pfizer have provided taliglucerase alfa to the Ministry of Health of Brazil for the treatment of Gaucher disease patients. During the first quarter of 2011, the Company and Pfizer supplied the remaining products deliverable under the short-term supply agreement.

Revenue generated from the Ministry of Health of Brazil was recorded by Pfizer and the Company recorded its share of the revenue in accordance with the terms and conditions of the Pfizer Agreement.

Table of Contents

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):

2. Liquidity and Financial Resources

Successful completion of the Company s development programs and its transition to normal operations is dependent upon obtaining necessary regulatory approvals from the FDA prior to selling its products within the United States, and foreign regulatory approvals must be obtained to sell its products internationally. There can be no assurance that the Company will receive regulatory approval of any of its product candidates, and a substantial amount of time may pass before the Company achieves a level of revenues adequate to support its operations, if at all. The Company will also incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during the developmental period. Obtaining marketing approval will be directly dependent on the Company s ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. The Company cannot predict the outcome of these activities.

Based on its current cash and cash equivalents 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 the Company will not need additional funds prior to such time. The Company may need to seek additional financing during the next 12 months if there are unexpected increases in general and administrative expenses, research and development expenses, or other capital needs.

b. General Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial information and Article 10 of Regulation S-X under the Securities Exchange Act of 1934. Accordingly, they do not include all of the information and notes required by GAAP for complete 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, 2010, filed by the Company with the Securities and Exchange Commission. The comparative balance sheet at December 31, 2010 has been derived from the audited financial statements at that date, but does not include all of the information and notes required under GAAP for complete financial statements.

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 $.001 per share (the Common Stock) outstanding for each period.

Shares of Common Stock underlying outstanding options of the Company were not included in the calculation of diluted LPS because the effect would be anti-dilutive.

Diluted LPS does not include options of the Company in the amount of 7,264,893 and 7,643,024 shares of Common Stock for the three months ended March 31, 2010 and 2011, respectively.

Table of Contents

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):

d. Reclassifications

Certain figures in respect of prior quarters have been reclassified to conform to the current year presentation.

NOTE 2 INVENTORIES

Inventory at March 31, 2011 and December 31, 2010 consisted of the following:

	March 31, 2011	December 31, 2010
Raw materials	$ 556	$ 553
Finished goods	545	636
Total inventory	$ 1,101	$ 1,189

NOTE 3 STOCK TRANSACTIONS

a. On March 23, 2011, the Company issued and sold 4,000,000 shares of Common Stock in an underwritten public offering at a price to the public of $5.50 per share. The net proceeds to the Company were approximately $20,590 (net of underwriting commissions and issuance costs of $1,410).

b. During the three months ended March 31, 2011, the Company issued a total of 329,475 shares of Common Stock in connection with the exercise of a total of 329,475 options by certain employees and non-employees of the Company with an aggregate exercise price of $248.

NOTE 4 SUBSEQUENT EVENTS

During April and May 2011, the Company issued a total of 1,663 shares of Common Stock in connection with the exercise of options to purchase 1,663 shares of Common Stock by certain employees of the Company with an aggregate exercise price of $1.

Table of Contents

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 our Annual Report on Form 10-K for the year ended December 31, 2010. 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, 2010 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 or generic versions of recombinant therapeutic proteins based on our plant cell-based expression technology that 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 our ProCellEx protein expression system 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.

Taliglucerase alfa, our proprietary, lead product candidate, is a recombinant form of glucocerebrosidase (GCD) that we are developing for the treatment of Gaucher disease patients using our ProCellEx protein expression system. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. Patients of Gaucher disease suffer from mutations in or deficiencies of GCD, which is an enzyme that is naturally found in human cells. In July 2007, we reached an agreement with the U.S. Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of taliglucerase alfa through the FDA s special protocol assessment process (SPA). We completed the phase III clinical trial of taliglucerase alfa for the treatment of Gaucher disease in September 2009 and, on October 15, 2009, we announced positive top-line results from the trial. We originally filed a New Drug Application (NDA) for taliglucerase alfa on December 9, 2009, and in January 2010 the FDA requested additional data regarding the chemistry, manufacturing and controls (CMC) section of the NDA. We provided the requested data to the FDA in April 2010, and in July 2010 we received notification from the FDA that it had accepted the filing of our NDA and assigned a Prescription Drug User Fee Act (PDUFA) date of February 25, 2011 to taliglucerase alfa for the treatment of Gaucher disease. In addition to the NDA, in November 2010 we submitted a marketing application to the Israeli Ministry of Health, or the Israeli MOH, and a Marketing Authorization Application (MAA) to each of the European Medicines Agency, or the EMEA, and ANVISA, the National Sanitary Vigilance Agency, an agency of the Brazilian Ministry of Health, or the ANVISA, for taliglucerase alfa for the treatment of Gaucher disease.

On February 25, 2011, we announced that the FDA issued a Complete Response Letter, or a CRL, regarding our NDA for taliglucerase alfa for the treatment of Gaucher disease. A CRL is issued by the FDA s Center for Drug Evaluation and Research when the review of a file is completed and questions remain that preclude the approval of the NDA in its current form. The main questions raised by the FDA regarding the NDA relate to the clinical and CMC sections. In the clinical section of the CRL, the FDA requested additional data from the ongoing switchover trial and the long-term extension trial. At the time the NDA was submitted, full data from these trials was not available. In the CMC section of the CRL, the FDA requested information regarding testing specifications and assay validation. The FDA did not request additional clinical studies in the CRL. The marketing application submitted to the Israeli MOH and the MAAs submitted to each of the EMEA and ANVISA include certain data now being requested by the FDA in the CRL as those applications were submitted approximately a year after we filed our NDA and after we had collected additional data from our ongoing trials. We are working with Pfizer Inc., or Pfizer, our commercialization partner, to respond to the CRL. We have already begun preparing our response to the CRL, with Pfizer s cooperation. We recently

met with the FDA and received certain clarifications regarding the CRL.

Table of Contents

We believe we will be able to address all of the FDA requests in the next few months, and submit our response to the CRL. However there can be no assurance that the FDA will not make additional requests regarding our NDA. In February 2010, the Israeli MOH completed a successful good manufacturing practices (GMP) audit of our manufacturing facilities in Carmiel, Israel. The audit was performed as part of the Israeli MOH s evaluation of our manufacturing process for taliglucerase alfa. On February 20, 2011, we received a letter from the FDA notifying us that the FDA had completed its review of the Establishment Inspection Report in connection with the FDA s inspection of our facility in Carmiel, Israel, and that the FDA had classified our facility as acceptable.

In addition to our recently completed phase III clinical trial, we initiated a double-blind, follow-on extension study as part of the trial during the second quarter of 2008. We also initiated a home care treatment program for patients enrolled in the extension study and, in December 2008, we initiated a nine-month, worldwide, multi-center, open-label, switch-over clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with taliglucerase alfa. Patients in these trials are still being treated with taliglucerase alfa. The current standard of care for Gaucher patients is enzyme replacement therapy with Cerezyme, which is produced by Genzyme Corporation and, until the recent approval of VPRIV by Shire plc in February 2010, was the only approved enzyme replacement therapy for Gaucher disease. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are infused into patients in whom the enzyme is lacking or dysfunctional. Taliglucerase alfa has an amino acid, glycan and three-dimensional structure that is very similar to Cerezyme, which is a mammalian cell expressed version of the same protein. We believe taliglucerase alfa may prove more cost-effective than the currently marketed alternatives due to the cost benefits of expression through our ProCellEx protein expression system. Although the FDA did not originally require the switch-over study in the SPA as a prerequisite for approval of taliglucerase alfa, the FDA has now requested data from the switchover trial in the CRL. In November 2010, we announced positive preliminary data from the first 15 patients that completed the switchover clinical study of taliglucerase alfa. Only pediatric patient enrollment remains open for this study. In December 2009, we filed a proposed pediatric investigation plan to the Pediatric Committee of the EMEA which was approved during the first quarter of 2010 and have since initiated the study and completed enrollment of all the naive patients required according to the study protocol.

On November 30, 2009, Protalix Ltd., our wholly-owned subsidiary, and Pfizer entered into an exclusive license and supply agreement pursuant to which Pfizer was granted an exclusive, worldwide license to develop and commercialize taliglucerase alfa. Under the terms and conditions of the Pfizer agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel. In connection with the execution of the Pfizer agreement, Pfizer made an upfront payment to Protalix Ltd. of $60.0 million in connection with the execution of the agreement and subsequently paid Protalix Ltd. an additional $5.0 million upon its filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. Protalix Ltd. is also eligible to receive potential milestone payments totaling $50.0 million for the successful achievement of other regulatory milestones. Pfizer and Protalix Ltd. will also share future revenues and expenses for the development and commercialization of taliglucerase alfa on a 60% and 40% basis, respectively, and have also agreed to a specific allocation of the responsibilities for the continued development efforts for taliglucerase alfa.

In July 2009, following a request by the FDA, we submitted a treatment protocol to the FDA in order to address an expected shortage of the current enzyme replacement therapy approved for Gaucher disease. The treatment protocol was approved by the FDA in August 2009, and we are continuing to treat patients in the United States under this protocol. In September 2009, the FDA s Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status. In January 2010, the Committee for Orphan Medicinal Products (COMP) of the EMEA, after reviewing all relevant clinical data, recommended that the European Commission grant Orphan Drug designation to taliglucerase alfa for the treatment of Gaucher disease. The Orphan Drug designation in the United States for taliglucerase alfa for the treatment of Gaucher disease provides special status to taliglucerase alfa provided that it meets certain criteria. As a result of the Orphan Drug designation, we are qualified for the tax credit and marketing incentives of the Orphan Drug Act of 1983. A marketing application for a prescription drug product that has been designated as a drug for a rare disease or condition is not subject to a prescription drug user fee unless the application includes an indication for other than a rare disease or condition.

On July 13, 2010, we 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

Table of Contents

make non-approved drugs available to patients in France when a genuine public health need exists. This ATU allows patients with Gaucher disease 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. Recently, the French Ministry of Health announced again that there is a shortage of enzyme replacement therapy for Gaucher disease, and we are currently providing taliglucerase alfa to patients under the ATU. In addition to the United States, France and Brazil, taliglucerase alfa is also currently being provided to Gaucher disease patients under special access agreements or Named Patient provisions in the rest of the world.

On August 10, 2010, Pfizer entered into a $30 million short-term supply agreement with the Ministry of Health of Brazil pursuant to which Protalix and Pfizer have provided taliglucerase alfa to the Ministry of Health of Brazil for the treatment of patients with Gaucher disease. During the first quarter of 2011, we and Pfizer supplied the remaining products deliverable under the short-term supply agreement. Revenue generated from the Ministry of Health of Brazil was recorded by Pfizer, and we recorded our share of the revenue in accordance with the terms and conditions of the Pfizer agreement. In addition, we and the Ministry of Health of Brazil are in discussions relating to a possible long-term supply agreement that contemplates, among other matters, providing certain components of our manufacturing technology to the Ministry of Health of Brazil 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 any event, we do not expect to enter into a long-term supply agreement with the Ministry of Health of Brazil until we receive marketing approval of taliglucerase alfa from the FDA or ANVISA, 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, (2) PRX-105, a plant cell expressed pegylated recombinant acetylcholinesterase product candidate for biodefense and other indications, (3) 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, juvenile idiopathic arthritis, ankylosing, spondylitis, psoriatic arthritis and plaque psoriasis, (4) an orally administrated glucocerebrosidase enzyme for treating Gaucher patients utilizing the oral delivery of the recombinant enzyme produced within carrot cells and (5) additional undisclosed therapeutic proteins, all of which are currently being evaluated in animal studies. In March 2010, we initiated a preliminary phase I clinical trial of PRX-105 which we completed in June 2010. We are currently preparing for further efficacy trials of this product candidate in larger animals. In our preclinical studies we utilized an analogue to nerve gas. However, we anticipate that we will use live nerve gas rather than an analogue in the proposed additional efficacy trials in animals. In December 2010, we held a pre-investigational new drug, or IND, meeting with the FDA with respect to PRX-102. We expect to submit an IND to the FDA within the next 12 months in connection with an anticipated phase I/II study of PRX-102 and to initiate the trial once the IND is approved, if at all.

Except for the license we have granted to Pfizer, we hold the worldwide commercialization rights to our proprietary development candidates and we intend to establish an internal, commercial infrastructure and targeted sales force to market taliglucerase alfa in Israel and our other products, if approved, in North America, the European Union and in other significant markets, including Israel. In addition, we plan to continue evaluating potential strategic marketing partnerships.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing at the end of this Quarterly Report. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and

judgments, including those described in greater detail below. We base our estimates on historical

Table of Contents

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, 2011 compared to the three months ended March 31, 2010

Revenues

We recorded revenues of $4.1 million during the three months ended March 31, 2011, an increase of $3.0 million, or 262% from revenues of $1.1 million for the three months ended March 31, 2010. The revenues represent a pro rata amortization of the $65.0 million upfront and milestone payments of $1.1 million in each quarterly period and $3.0 million for the quarter ended March 31, 2011 in connection with products delivered to Pfizer under our license agreement. The increase resulted from the fact that no products were shipped during the three months ended March 31, 2010.

Our share in the Collaboration Agreement

We recorded $1.9 million of income as our share in the collaboration under the Pfizer Agreement during the three months ended March 31, 2011 compared to a loss of $294,000 for the three months ended March 31, 2010. Our share in the collaboration for the three months ended March 31, 2011 resulted primarily from our 40% share of the approximately remaining $7.8 million of revenues generated from Pfizer s sale of taliglucerase alfa to the Ministry of Health of Brazil under the short term supply agreement between Pfizer and the Ministry of Health of Brazil during Pfizer s 2011 first fiscal quarter net of the associated operating costs. No products were sold during the three months ended March 31, 2010 and our share of loss of $294,000 represents our 40% share of certain clinical expenses incurred with respect to taliglucerase alfa. Under the terms and conditions of the Pfizer Agreement, we record income or loss equal to 40% of the profit or loss realized from sales of taliglucerase alfa, and related expenses incurred based on reports we receive from Pfizer summarizing the results of the collaborative activities under the agreement for the applicable 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.

Research and Development Expenses

Research and development expenses were $10.6 million for the three months ended March 31, 2011, an increase of $1.6 million, or 18%, from $9.0 million for the three months ended March 31, 2010. The increase resulted primarily from an increase of $1.4 million in costs related to consulting and subcontractors associated with research and development activities. The increase resulted primarily from the increased number of clinical sites operating and increased number of patients enrolled in our ongoing clinical trials during the first quarter of 2011 compared to the first quarter of 2010. Such increase was partially offset by grants received from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, the OCS, of approximately $936,000 and reimbursement for certain expenses in accordance with the terms and conditions of the Pfizer Agreement of $1.4 million during the three months ended March 31, 2011 compared to the grants of $1.3 million from the OCS, and the reimbursement from Pfizer of $364,000 in connection with certain expenses incurred during the three months ended March 31, 2010.

We expect research and development expenses to continue to be our primary expense until we receive regulatory approval of taliglucerase alfa from the FDA, if at all, and potentially thereafter.

General and Administrative Expenses

General and administrative expenses were $2.0 million for the three months ended March 31, 2011, an increase of $370,000, or 23%, from $1.6 million for the three months ended March 31, 2010. The increase resulted primarily from an increase of $147,000 in salaries expense and an increase of $188,000 in legal and accounting expenses.

Table of Contents

Financial Expenses and Income

Financial expense was $14,000 for the three months ended March 31, 2011, compared to financial income of $165,000 for the three months ended March 31, 2010. The decrease resulted primarily from the devaluation of the U.S. dollar against the New Israeli Shekel, or NIS.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since our inception. To date, we have funded our operations primarily with proceeds equal to $51.9 million from the private sale of our shares of common stock and from sales 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 ordinary shares, through December 31, 2010. In addition, on October 25, 2007, we generated gross proceeds of $50.0 million in connection with an underwritten public offering of our common stock and on March 23, 2011, we generated gross proceeds of $22.0 million in connection with an underwritten public offering of our common stock.

Furthermore, on November 30, 2009, we entered into an exclusive license and supply agreement with Pfizer, pursuant to which Pfizer made an upfront payment to Protalix Ltd. of $60.0 million in connection with the execution of the agreement and subsequently paid Protalix Ltd. an additional $5.0 million upon our achievement of a certain milestone, as provided in the agreement. Protalix Ltd. is also eligible to receive potential milestone payments of up to $50.0 million for the successful achievement of other regulatory-related milestones. Protalix Ltd. is entitled to payments equal to 40% of the net profits earned by Pfizer on its sales of taliglucerase alfa, if any. 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.

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 $4.0 million for the three months ended March 31, 2011. The net loss for the three months ended March 31, 2011 of $5.1 million was partially offset by an increase in accounts payable of $2.6 million and other net working capital changes. Net cash used in investing activities for the three months ended March 31, 2011 was $2.7 million and consisted primarily of purchases of property and equipment. Net cash provided by financing activities was $20.9 million, consisting mainly of net proceeds of $20.7 million from our public underwritten offering and $256,000 from the exercise of options.

Net cash used in operations was $8.9 million for the three months ended March 31, 2010. The net loss for the three months ended March 31, 2010 of $8.0 million was further increased due to an increase in accounts receivable of $1.5 million, primarily due to grants to be received from the OCS, and a decrease of $1.1 million in deferred revenues. Net cash used in investing activities for the three months ended March 31, 2010 was $3.0 million and consisted primarily of purchases of property and equipment.

Future Funding Requirements

We expect that our operating losses may continue to be substantial over the next several years. However, we anticipate that we will generate revenues to offset any such losses upon the successful launch of taliglucerase alfa, if at all. We expect to incur significant research and development expenses, including expenses related to the hiring of personnel and the advancement of the product candidates in our pipeline into clinical trials. We expect that general and administrative expenses will increase as we expand our finance and administrative staff, add infrastructure and incur additional costs related to our preparation for the commercial phase for our lead product candidate, taliglucerase alfa. In addition, we are working on the expansion of our manufacturing facility so that it will be capable of producing approximately half of the anticipated market for taliglucerase alfa, if approved. The expansion will increase our capital expenditures significantly, and is estimated to cost approximately $25.0 million in total.

Table of Contents

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 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. The 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, 2011 or the three months ended March 31, 2010.

Currency fluctuations could affect us by increased or decreased costs mainly for goods and services acquired outside of Israel. We do not believe currency fluctuations have had a material effect on our results of operations during the three months ended March 31, 2011 or the three months ended March 31, 2010.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2011 and March 31, 2010.

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 are currently in the development stage with 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.

Table of Contents

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,
	2011	2010	2010
Average rate for period	3.6012	3.7344	3.733
Rate at period end	3.4810	3.7130	3.549

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.

15

Table of Contents

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, 2011 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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, 2010.

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, 2011.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and reserved)

Item 5. Other Information

None.

Table of Contents

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-Q	001-33357	3.6	August 8, 2008	
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

Table of Contents

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 4, 2011

By: /s/ David Aviezer
David Aviezer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 4, 2011

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