Protalix BioTherapeutics, Inc.
Form 10-Q
May 10, 2010

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, 2010

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, 2010, approximately 80,871,322 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 they 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:

- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;
- delays in our preparation and filing of applications for regulatory approval;
- delays in the approval or the potential rejection of any applications we file with the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities;
- any lack of progress of our research and development (including the results of clinical trials we are conducting);
- obtaining on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- our ability to obtain additional financing required to fund our research programs;
- 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 establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationship with Pfizer Inc., Teva Ltd. or with any other collaborator, distributor or partner;
- 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 manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

In addition, 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 by clinical trials of a drug product, the FDA might not accept or approve an NDA filed by a pharmaceutical or biotechnology company for the drug product. These and other risks and uncertainties are detailed in our Annual Report on Form 10-K for the year ended December 31, 2009, Section 1A, under the heading Risk Factors and are described from time to time in the reports we file with the Securities and Exchange Commission. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

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, 2010 (Unaudited)	December 31, 2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 69,364	$ 81,266
Accounts receivable	3,625	2,144
Total current assets	72,989	83,410
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	778	724
PROPERTY AND EQUIPMENT, NET	14,674	14,537
Total assets	$ 88,441	$ 98,671
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals		
Trade	$ 5,429	$ 3,406
Other	9,824	13,561
Deferred revenues	4,563	4,563
Total current liabilities	19,816	21,530
LONG-TERM LIABILITIES:		
Deferred revenues	58,908	60,049
Liability for employee rights upon retirement	1,503	1,209
Total long term liabilities	60,411	61,258
COMMITMENTS		
Total liabilities	80,227	82,788
SHAREHOLDERS EQUITY	8,214	15,883

Total liabilities and shareholders equity	$ 88,441	$ 98,671

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, 2010	**March 31, 2009**
REVENUES	$ 1,141	
RESEARCH AND DEVELOPMENT EXPENSES (1)	8,908	$ 5,086
less grants	(1,266)	(1,292)
	7,642	3,794
GENERAL AND ADMINISTRATIVE EXPENSES (2)	1,619	1,241
OPERATING LOSS	8,120	5,035
FINANCIAL EXPENSES (INCOME) NET	(165)	148
NET LOSS FOR THE PERIOD	$ 7,955	$ 5,183
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED	$ 0.10	$ 0.07
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:		
Basic and diluted	80,850,551	75,947,708
(1) Includes share-based compensation	$ 121	$ 278
(2) Includes share-based compensation	$ 163	$ 184

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
(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, 2008	**75,938,059**	**$ 76**	**$ 119,281**	**$ (75,010)**	**$ 44,347**
Changes during the three month period ended March 31, 2009 (Unaudited):					
Share-based compensation			462		462
Exercise of options granted to employees (includes Net Exercise)	35,068	*	2		2
Net loss for the period				(5,183)	(5,183)
Balance at March 31, 2009 (Unaudited)	**75,973,127**	**$ 76**	**$ 119,745**	**$ (80,193)**	**$ 39,628**
Balance at December 31, 2009	**80,841,237**	**$ 81**	**$ 122,252**	**$ (106,450)**	**$ 15,833**
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**

(1) Common Stock, $0.001 par value; Authorized as of March 31, 2010 and March 31, 2009 - 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, 2010	**March 31, 2009**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,955)	$ (5,183)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities		
Share based compensation	284	462
Depreciation of fixed assets	697	455
Financial income (expenses) net (mainly exchange differences)	(25)	235
Changes in accrued liability for employee rights upon retirement	274	69
Gain on amounts funded in respect of employee rights upon retirement		(7)
Gain on sale of fixed assets		(28)
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non- current portion)	(1,141)	
Increase in accounts receivable	(1,454)	(1,642)
Increase (decrease) in accounts payable and accruals	375	(343)
Net cash used in operating activities	$ (8,945)	$ (5,982)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (2,961)	$ (1,305)
Proceeds from sale of property and equipment		61
Amounts funded in respect of employee rights upon retirement, net	(42)	(20)
Net cash used in investing activities	$ (3,003)	$ (1,264)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of options	$ 2	
Net cash provided by financing activities	$ 2	
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 44	$ (439)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(11,902)	(7,685)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	81,266	42,596
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 69,364	$ 34,911

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, 2010	**March 31, 2009**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 2,398	$ 1,657
Issuance cost not yet paid and accruals other	$ 5	$ 5
Exercise of options granted to employees		$ 2

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 European Medicines Agency, or EMEA, application process in Europe. The Company s lead product development candidate is taliglucerase alfa for the treatment of Gaucher disease (the brand name for which is UPLYSO), which the Company is developing using its ProCellEx protein expression system.

In September 2009, the Company successfully completed its phase III pivotal trial of taliglucerase alfa. In December 2009, the Company filed a New Drug Application (NDA) submission with the U.S. Food and Drug Administration (FDA) for taliglucerase alfa for the treatment of Gaucher disease. 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 patients currently treated under the current standard of care to treatment with taliglucerase alfa. This switchover-study is not a prerequisite for the marketing approval of taliglucerase alfa. In August 2009, the Company received Fast Track Designation for taliglucerase alfa, and in September 2009, the FDA s Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status.

The Company was in the development stage from its inception until November 2009 (see b below).

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.

In addition to taliglucerase alfa, the Company is developing an innovative product pipeline using the Company s ProCellEx protein expression system. The Company s product pipeline currently includes, among other candidates, therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, an acetylcholinesterase enzyme-based therapy for biodefense and intoxication treatments, antiTNF, a plant cell expressed recombinant fusion protein made from the soluble form of the human TNF receptor (TNFR) 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, and additional undisclosed therapeutic proteins, all of which are currently being evaluated in animal studies. In March 2010, the Company initiated a phase I clinical trial of PRX-105, the Company s plant cell expressed pegylated recombinant acetylcholinesterase product candidate for biodefense indications.

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):

Successful completion of the Company s development program 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 sales adequate to support the Company s 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.

2. Subsequent Events

The Company has evaluated events through the date of issuance of the financial statements. See Note 3.

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. Prior to December 2009, the Company was a development stage company as defined under the guidance for Development Stage Enterprises. The Company has determined that, as of November 30, 2009, it is no longer a development stage company.

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, 2009, filed by the Company with the Securities and Exchange Commission. The comparative balance sheet at December 31, 2009 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 restricted Common Stock and the 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 and restricted shares of Common Stock of the Company in the amount of 11,418,079 and 7,264,893 shares of Common Stock for the three months ended March 31, 2009 and 2010, 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. Newly Issued Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board issued an Accounting Standards Update to ASC 605, ASU No. 2009-13, Multiple Deliverable Revenue Arrangements (ASU 2009-13). ASU 2009-13 provides guidance on whether multiple deliverables in a revenue arrangement exist, how the arrangement should be separated, and how the consideration should be allocated. Pursuant to ASU 2009-13, when vendor specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, a best estimate of the selling price is required to separate deliverables and allocate arrangement consideration, using the relative selling price method. In addition, the residual method of allocating arrangement consideration is no longer permitted under ASU 2009-13.

ASU 2009-13 is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the potential impact of ASU 2009-13 on its consolidated financial position, results of operations and cash flows.

NOTE 2 STOCK TRANSACTIONS

a. On February 7, 2010, the Company s Board of Directors approved the grant of options to purchase 160,000 shares of Common Stock to a new executive officer of the Company with an exercise price equal to $6.81 per share. The options vest over a four-year period, with the first 25% to vest on the first anniversary of the date of the grant and the remaining 75% in equal tranches on a quarterly basis for three years thereafter. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $740, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 76.02%; risk-free interest rates of 2.96%; and expected life of 6 years.

b. During the three months ended March 31, 2010, the Company issued a total of 20,007 shares of Common Stock in connection with the exercise of a total of 34,312 options by certain employees of the Company. The Company received aggregate cash proceeds equal to approximately $2 in connection with such exercises, and 20,312 of the options were exercised on a net exercise basis.

c. In February 2010, the Company s Board of Directors approved the grant of options to purchase 1,016,000 shares of Common Stock, in the aggregate, to certain officers and employees of the Company with an exercise price equal to $6.90 per share. The options vest quarterly over three years, commencing after the FDA s approval of taliglucerase alfa, if at all. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $5.7 million, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 75.74%; risk-free interest rates of 3.69%; and expected life of 10 years. The Company will start charging these expenses following the FDA s approval of taliglucerase alfa.

NOTE 3 SUBSEQUENT EVENTS

During April and May 2010, the Company issued a total of 12,893 shares of Common Stock in connection with the exercise of options to purchase 12,893 shares of Common Stock by certain employees of the Company. The aggregate cash proceeds in connection with the exercise of these options are equal to approximately $18.

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, 2009. 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, 2009 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.

Our lead product development candidate is prGCD (taliglucerase alfa) for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. Taliglucerase alfa is our proprietary recombinant form of glucocerebrosidase (GCD), an enzyme naturally found in human cells that is mutated or deficient in patients with Gaucher disease. 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 (SPA) process. The phase III clinical trial was completed in September 2009 and, on October 15, 2009, we announced positive top-line results from the trial. On December 9, 2009, we filed our New Drug Application (NDA) for taliglucerase alfa, and in January 2010 the FDA requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of our NDA. No additional clinical or preclinical information was requested. The request focused primarily on the validation of the manufacturing process in our upgraded manufacturing facility. A validation plan for our manufacturing process of taliglucerase alfa has already been established and reviewed by the FDA. We provided the requested data to the FDA in April 2010.

We expect to submit similar applications with other comparable regulatory agencies in other countries during 2010. In March 2010, the Israeli Ministry of Health completed a successful audit of our manufacturing facilities in Carmiel, Israel. The audit was performed as part of the Ministry of Health s evaluation of our manufacturing process for taliglucerase alfa.

In addition to our recently completed phase III clinical trial, during the third quarter of 2008, we initiated a double-blind, follow-on extension study as part of the trial. We also initiated a home care treatment program for patients enrolled in the extension study and in December 2008, we initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment 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, the only approved enzyme replacement therapy for Gaucher disease. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional. The switch-over study is not a prerequisite for approval of taliglucerase alfa. In December 2009 we filed a proposed pediatric investigation plan to the Pediatric Committee of the European Medicines Agency, or EMEA.

9

Table of Contents

On November 30, 2009, Protalix Ltd. and Pfizer Inc., or 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 our filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. Protalix Ltd. is also eligible to receive potential milestone payments exceeding $50.0 million for the successful achievement of other developmental milestones and to royalties equal to 40% of the net profits earned on Pfizer s sales of taliglucerase alfa, if any. Pfizer and Protalix Ltd. have 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 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. In August 2009, we received Fast Track Designation for taliglucerase alfa and in September 2009, the FDA s Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status. The fast track mechanism was created to facilitate the development and approval of new drugs intended for the treatment of life-threatening conditions for which there are no effective treatments and which demonstrate the potential to address unmet medical needs for the conditions. The fast track process includes scheduling of meetings to seek FDA input into development plans, the option of submitting an NDA serially in sections rather than submitting all components simultaneously, the option to request evaluation of studies using surrogate endpoints, and the potential for a priority review. The fast track designation may be withdrawn by the FDA at any time. The fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that taliglucerase alfa will receive regulatory approval. 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 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.

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, therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, an acetylcholinesterase enzyme-based therapy for biodefense, antiTNF, a plant cell expressed recombinant fusion protein made from the soluble form of the human TNF receptor (TNFR) which is being developed as a treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, calcylosing, spondylitis, psoriatic arthritis and plaque psoriasis, and additional undisclosed therapeutic proteins and intoxication treatments, all of which are currently being evaluated in animal studies. In March 2010, we initiated a phase I clinical trial of PRX-105, our plant cell expressed pegylated recombinant acetylcholinesterase product candidate for biodefense indications.

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 are continuously evaluating potential strategic marketing partnerships.

Our business is conducted by our wholly-owned subsidiary, Protalix Ltd., which we acquired through a reverse merger transaction effective December 31, 2006. Since its inception in December 1993, Protalix Ltd. has generated significant losses in connection with its research and development, including the clinical development of taliglucerase alfa. Since we currently do not generate significant revenue from any of our product candidates, we expect to continue to generate losses over the next several years in connection with research and development activities relating to our

pipeline of product candidates and the commercialization costs associated with the expected launch of taliglucerase alfa in Israel. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful.

Table of Contents

As a result, we believe that our operating losses may be substantial over the next several years. We may need to obtain additional funds to continue the research and clinical development of our other programs.

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 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, 2010 compared to the three months ended March 31, 2009

Revenues

We recorded revenues of $1.1 million during the three months ended March 31, 2010. The revenues represent the pro rata amortization of the $60.0 million upfront payment and $5.0 million milestone payment we received in connection with our license and supply agreement with Pfizer. No revenues were recorded during the three months ended March 31, 2009.

Research and Development Expenses

Research and development expenses were $8.9 million for the three months ended March 31, 2010, an increase of $3.8 million, or 75%, from $5.1 million for the three months ended March 31, 2009. The increase resulted primarily from an increase of $1.4 million in salaries and an increase of $1.2 million in materials expenses, and an increase of $543,000 in costs related to consulting and subcontractors, associated with research and development activities. The increase is the result of the increased number of clinical sites operating and increased number of patients enrolled in our ongoing clinical trials during the first quarter of 2010 when compared to the first quarter of 2009.

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 $1.6 million for the three months ended March 31, 2010, an increase of $378,000, or 30%, from $1.2 million for the three months ended March 31, 2009 primarily due to an increase of $116,000 in salaries expense and an increase of $186,000 in legal and accounting expenses.

Financial Expenses and Income

Financial income was $165,000 for the three months ended March 31, 2010, compared to a financial expense of $148,000 for the three months ended March 31, 2009.

Table of Contents

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 $31.3 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 $14.2 million in connection with the exercise of warrants issued in connection with the sale of such ordinary shares, through December 31, 2009. 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.

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 the foreseeable future.

Cash Flows

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 reflects an increase compared to the same period of 2009 due to an increase in accounts receivable of $1.5 million, mainly 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.

Net cash used in operations was $6.0 million for the three months ended March 31, 2009. The net loss for the three months ended March 31, 2009 of $5.2 million reflects an increase compared to the same period of 2008 due to an increase in accounts receivable of $1.6 million, mainly due to grants to be received from the OCS, but was partially offset by $462,000 of non-cash share-based compensation. Net cash used in investing activities for the three months ended March 31, 2009 was $1.3 million and consisted primarily of purchases of property and equipment.

Future Funding Requirements

Although we have begun to recognize revenues in connection with our licensing and supply agreement with Pfizer for taliglucerase alfa, we expect to continue to generate losses over the next several years in connection with research and development activities relating to our pipeline of product candidates and the commercialization costs associated with the expected launch of taliglucerase alfa in Israel. In addition, we are considering a new manufacturing facility that would meet the FDA requirements for the manufacture of our product candidates, which would increase our capital expenditures significantly.

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

Table of Contents

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, 2010 or the three months ended March 31, 2009.

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, 2010 or the three months ended March 31, 2009.

Recently Issued Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board issued an Accounting Standards Update to ASC 605, ASU No. 2009-13, Multiple Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13 provides guidance on whether multiple deliverables in a revenue arrangement exist, how the arrangement should be separated, and how the consideration should be allocated. Pursuant to ASU 2009-13, when vendor specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, a best estimate of the selling price is required to separate deliverables and allocate arrangement consideration, using the relative selling price method. In addition, the residual method of allocating arrangement consideration is no longer permitted under ASU 2009-13.

ASU 2009-13 is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of ASU 2009-13 on our consolidated financial position, results of operations and cash flows.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2010 and March 31, 2009.

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

Table of Contents

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,
	2010	2009	2009
Average rate for period	3.7344	4.0585	3.933
Rate at period end	3.7130	4.1880	3.775

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.

Table of Contents

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, 2010 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, 2009.

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, 2010.

Use of Proceeds

The effective date of our first registration statement, filed on Form S-3 under the Securities Act of 1933, which was accompanied by a registration statement on Form S-3 filed pursuant to Rule 462(b) under the Securities Act (Nos. 333-144801 and 333-146919), relating to a public offering of our common stock, was September 26, 2007 and the offering date was October 25, 2007. The sole book-running manager of the offering was UBS Investment Bank, and CIBC World Markets (now Oppenheimer & Co., Inc.) served as the co-manager. We sold 10,000,000 shares of common stock in the offering at a price per share of $5.00. Our aggregate net proceeds (after underwriting discounts and expenses) amounted to approximately $46.0 million. The offering closed on October 30, 2007.

The amount of the underwriting discount paid by us was $3.5 million and the expenses of the offering, not including the underwriting discount, were approximately $810,000.

Between October 30, 2007 and March 31, 2010, we used the entire amount of the net proceeds to fund our operating activities, including activities related to the development of our clinical and preclinical product candidates and for working capital, capital expenditures and other general corporate purposes. During the quarter ended March 31, 2010, our research and development expenses comprised approximately 80% of our operating expenses.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

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 10, 2010

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

Date: May 10, 2010

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