

Protalix BioTherapeutics, Inc.
Form 10-Q
November 07, 2011

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

001-33357
(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Florida
(State or other jurisdiction
of incorporation or organization)

65-0643773
(I.R.S. Employer
Identification No.)

2 Snunit Street
Science Park
POB 455
Carmiel, Israel
(Address of principal executive offices)

20100
(Zip Code)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

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required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

On November 1, 2011, approximately 85,623,627 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

FORM 10-Q
TABLE OF CONTENTS

	Page
PART I – FINANCIAL INFORMATION	
	ii
Item 1.	1
Cautionary Statement Regarding Forward-Looking Statements	1
Financial Statements	2
Condensed Consolidated Balance Sheets – As of September 30, 2011 (Unaudited) and December 31, 2010	3
Condensed Consolidated Statements of Operations (Unaudited) – For the Nine Months and the Three Months Ended September 30, 2011 and 2010	4
Condensed Consolidated Statement of Changes in Shareholders' Equity (Capital Deficiency) (Unaudited) – For the Nine Months Ended September 30, 2011 and 2010	6
Condensed Consolidated Statements of Cash Flows (Unaudited) – For the Nine Months Ended September 30, 2011 and 2010	7
Notes to Condensed Consolidated Financial Statements	9
Item 2.	15
Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3.	17
Quantitative and Qualitative Disclosures About Market Risk	17
Item 4.	21
Controls and Procedures	22
PART II – OTHER INFORMATION	
Item 1.	23
Legal Proceedings	23
Item 1A.	21
Risk Factors	21
Item 2.	22
Unregistered Sales of Equity Securities and Use of Proceeds	22
Item 3.	22
Defaults Upon Senior Securities	22
Item 4.	22
(Removed and Reserved)	22
Item 5.	22
Other Information	22
Item 6.	23
Exhibits	23
Signatures	23

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. 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 the FDA’s review of 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 approval or the potential rejection of any applications we file with the FDA or other regulatory authorities, including, with respect to our lead product candidate, taliglucerase alfa, the NDA we filed with the FDA and comparable filings and submissions made with the Israeli Ministry of Health, or Israeli MOH, and the European Medicines Agency, or the EMA, the National Sanitary Vigilance Agency, an agency of the Brazilian Ministry of Health, or ANVISA and the Australian Ministry of Health.
- risks relating to our ability to finance our ongoing costs in the case of delays in regulatory approvals 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, Australia 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 including risks relating to potential restrictions on the sale of some of our product candidates due to the orphan drug status that may be issued to competing products;
 - 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 for taliglucerase alfa in Israel or for any other product candidate 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 manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

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,” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, Part II, Item 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.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 34,564	\$ 35,900
Accounts receivable:		
Trade	2,276	7,013
Other	3,015	2,231
Inventories	427	1,189
Total current assets	40,282	46,333
LONG-TERM RECEIVABLES:		
Funds in respect of employee rights upon retirement	1,028	942
Deferred costs	1,009	
Total long term receivables	2,037	942
PROPERTY AND EQUIPMENT, NET	18,510	17,454
Total assets	\$ 60,829	\$ 64,729
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 4,955	\$ 6,272
Other	7,726	8,068
Deferred revenues	5,633	4,563
Total current liabilities	18,314	18,903
LONG-TERM LIABILITIES:		
Deferred revenues	53,425	55,486
Long term payable	4,738	
Liability for employee rights upon retirement	1,705	1,663
Total long term liabilities	59,868	57,149
Total liabilities	78,182	76,052
COMMITMENTS		
CAPITAL DEFICIENCY	(17,353)	(11,323)
Total liabilities net of capital deficiency	\$ 60,829	\$ 64,729

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

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Nine Months Ended		Three Months Ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
REVENUES	\$6,024	\$ 5,466	\$1,132	\$ 3,184
COMPANY'S SHARE IN COLLABORATION AGREEMENT	(3,745)	(1,887)	(235)	(1,065)
COST OF REVENUES	(1,130)		(220)	
GROSS PROFIT	1,149	3,579	677	2,119
RESEARCH AND DEVELOPMENT EXPENSES (1)	(28,671)	(25,647)	(9,340)	(6,322)
less – grants and reimbursements	5,163	5,255	1,422	2,776
RESEARCH AND DEVELOPMENT EXPENSES, NET	(23,508)	(20,392)	(7,918)	(3,546)
GENERAL AND ADMINISTRATIVE EXPENSES (2)	(5,314)	(4,305)	(1,526)	(1,421)
OPERATING LOSS	(27,673)	(21,118)	(8,767)	(2,848)
FINANCIAL INCOME (EXPENSES)– NET	57	648	(108)	374
NET LOSS FOR THE PERIOD	\$(27,616)	\$ (20,470)	\$(8,875)	\$ (2,474)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED:	\$0.33	\$ 0.25	\$0.10	\$ 0.03
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:				
Basic and diluted	84,351,420	80,879,843	85,585,777	80,914,930

- (1) Research and development expenses include share-based compensation of \$348 and \$431 for the nine-month periods ended September 30, 2011 and September 30, 2010, respectively, and \$92 and \$213 for the three-month periods ended September 30, 2011 and September 30, 2010, respectively.
- (2) General and administrative expenses include share-based compensation of \$382 and \$456 for the nine-month periods ended September 30, 2011 and September 30, 2010, respectively, and \$117 and \$142 for the three-month periods ended September 30, 2011 and September 30, 2010, respectively.

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

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	Additional paid-in capital Amount	Accumulated deficit	Total
Balance at December 31, 2009	80,841,237	\$81	\$122,252	\$ (106,450)	\$15,883
Changes during the nine month period ended September 30, 2010 (Unaudited):					
Share-based compensation			\$887		\$887
Exercise of options granted to employees (includes Net Exercise)	172,300	*	159		159
Net loss for the period				(20,470)	(20,470)
Balance at September 30, 2010 (Unaudited)	81,013,537	\$81	\$123,298	\$ (126,920)	\$(3,541)
Balance at December 31, 2010	81,248,472	\$81	\$124,044	\$ (135,448)	\$(11,323)
Changes during the nine month period ended September 30, 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			\$730		\$730
Exercise of options granted to employees and non-employees	350,045	1	265		266
Net loss for the period				(27,616)	(27,616)
Balance at September 30, 2011 (Unaudited)	85,598,517	\$86	\$145,625	\$ (163,064)	\$(17,353)

(1)Common Stock, \$0.001 par value; Authorized – as of September 30, 2011, December 31, 2010 and September 30, 2010 - 150,000,000 shares.

* Represents an amount less than \$1.

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

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

	Nine Months Ended	
	September 30, 2011	September 30, 2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(27,616)	\$ (20,470)
Adjustments required to reconcile net loss to net cash used in operating activities		
Share based compensation	730	887
Depreciation and impairment of fixed assets	2,698	2,244
Financial expenses, net (mainly exchange differences)	156	(331)
Changes in accrued liability for employee rights upon retirement	115	330
Gain on amounts funded in respect of employee rights upon retirement	(12)	(16)
Loss on sale of fixed assets	2	11
Changes in operating assets and liabilities:		
Decrease in deferred revenues	(991)	(3,422)
Decrease (increase) in inventories	762	(6,702)
Decrease (increase) in accounts receivable	2,810	(5,097)
Increase in accounts payable and accruals	4,388	2,133
Net cash used in operating activities	\$(16,958)	\$ (30,433)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	\$(5,001)	\$ (6,816)
Proceeds from sale of property and equipment	2	
Amounts funded in respect of employee rights upon retirement, net	(122)	(101)
Net cash used in investing activities	\$(5,121)	\$ (6,917)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of shares, net of issuance cost	\$20,650	
Exercise of options	\$263	\$ 159
Net cash provided by financing activities	\$20,913	\$ 159
EFFECT OF EXCHANGE RATE CHANGES ON CASH	\$(170)	\$ 326
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,336)	(36,865)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	35,900	81,266
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$34,564	\$ 44,401

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

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

(Continued) - 2

	Nine Months Ended September 30,September 30, 20112010	
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	\$1,477	\$ 1,268
Issuance cost not yet paid and accruals – other	\$60	\$ 5
Exercise of options granted to employees	\$12	

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

1. Operation

Protalix BioTherapeutics, Inc. and its wholly-owned subsidiaries, Protalix Ltd. and Protalix B.V. (collectively, the “Company”), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company’s proprietary ProCellExtm protein expression system (“ProCellEx”). In September 2009, the Company formed Protalix B.V. under the laws of the Netherlands in connection with the EMEA application process in Europe. The Company’s 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 product candidates 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 for review 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”) indicating that the review is completed and questions remain that preclude the approval of the NDA for taliglucerase alfa in its current form. In August 2011, the Company submitted its reply to the CRL. Later in August 2011, the FDA notified the Company that it had accepted for review the resubmission of the taliglucerase alfa NDA, had deemed the resubmission a class 2, or 6-month, response and established February 1, 2012 as the new PDUFA date.

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. The 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.

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (Continued):

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 remainder of 2010 and the first quarter of 2011, the Company and Pfizer completed the supply of products deliverable under the short-term supply agreement. During the second quarter of 2011 Pfizer recorded an allowance for sales return in connection with such agreement because the Ministry of Health of Brazil requested that Pfizer consider the replacement of certain vials that might expire during 2012. Revenue, net of allowance for sales return, generated from the Ministry of Health of Brazil was recorded by Pfizer and the Company recorded its share, in accordance with the terms and conditions of the Pfizer Agreement.

2. Liquidity and Financial Resources

Successful completion of the Company's development programs and its transition to 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. Each FDA and the European Medicine Agency ("EMA") approval triggers a \$25 million milestone payment from Pfizer, pursuant to the Pfizer Agreement. 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 also expects to incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during the developmental period.

The ability of the Company to continue as a going concern is dependent on either gaining regulatory approval or through raising additional capital. There can be no assurance that the Company will be able to raise the necessary funds if and when needed to finance its ongoing costs. These factors raise substantial doubt about the ability of the Company to continue as a going concern.

The accompanying unaudited condensed consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

b. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for annual financial statements. In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 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. There have not been any changes to the Company's significant accounting policies since the Annual Report on Form 10-K for the year ended December 31, 2010.

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (Continued):

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.

Diluted LPS does not include options to purchase 7,729,307 and 7,498,026 shares of Common Stock for the nine months ended September 30, 2010 and 2011, respectively, and 7,954,811 and 7,428,201 shares of Common Stock for the three months ended September 30, 2010 and 2011, respectively, because the effect would be anti-dilutive.

d. Reclassifications

Certain comparative figures have been reclassified to conform to the current period presentation.

NOTE 2 - INVENTORIES

a. Inventory as of September 30, 2011 and December 31, 2010 consisted of the following:

	September 30, 2011	December 31, 2010
Raw materials	\$ 427	\$ 553
Finished goods		636
	\$ 427	\$ 1,189

b. During the nine months ended September 30, 2011, the Company recorded a \$363 write-down of inventory under cost of revenues.

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 nine months ended September 30, 2011, the Company issued a total of 350,045 shares of Common Stock in connection with the exercise of options to purchase 350,045 shares of Common Stock by certain employees and non-employees of the Company. The Company received aggregate cash proceeds equal to approximately \$266 in connection with such exercises.

NOTE 4 - SUBSEQUENT EVENTS

During October 2011, the Company issued a total of 25,110 shares of Common Stock in connection with the exercise of options to purchase 25,110 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 \$27.

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 and in our Quarterly Report for the quarter ended June 30, 2011 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 ProCellExTM 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 taliglucerase alfa for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. On December 9, 2009, we filed a New Drug Application (NDA) for taliglucerase alfa with the FDA and on February 25, 2011, the FDA issued a Complete Response Letter, or a CRL, indicating that the FDA's review was complete and questions remain that preclude the approval of the NDA for taliglucerase alfa in its then current form. The main questions raised by the FDA regarding the NDA relate to the clinical and chemistry, manufacturing and controls (CMC) sections. In the clinical section of the CRL, the FDA requested additional data from our ongoing switchover trial and our 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. We met with the FDA in May 2011 to clarify the FDA's requests, and in August 2011 we submitted our reply to the CRL. In August 2011, the FDA notified us that it had accepted for review the resubmission of the taliglucerase alfa NDA, had deemed the resubmission a class 2, or 6-month, response and established February 1, 2012 as the new Prescription Drug User Fee Act (PDUFA) date.

In addition to the taliglucerase alfa NDA, in November 2010 we submitted a marketing application with respect to taliglucerase alfa to the Israeli Ministry of Health, or the Israeli MOH. We have also submitted a Marketing Authorization Application (MAA) to each of the European Medicines Agency, or the EMEA, the National Sanitary Vigilance Agency, an agency of the Brazilian Ministry of Health, or ANVISA, and with the Australian Ministry of Health.

In February 2010, the Israeli MOH completed a successful good manufacturing practices, or 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 June 2011, ANVISA completed a successful GMP audit of the facility and determined that the facility is acceptable.

In addition to the completed phase III clinical trial we completed in September 2009, 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. 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, and in July 2011 we announced final top line results from all 26 adult patients participating in the trial. 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 naïve pediatric patients required according to the study protocol.

On November 30, 2009, Protalix Ltd., our wholly-owned subsidiary, and Pfizer Inc., or Pfizer, entered into an exclusive license and supply agreement, which we refer to as the Pfizer agreement or the Collaboration 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 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. 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. During the second quarter of 2011, the Ministry of Health of Brazil requested that Pfizer consider the replacement of certain vials that might expire during 2012. As a result, Pfizer recorded an allowance for sales return. If and when such vials are replaced, revenues will be recorded upon the supply of such replaced vials, and if it is determined that there is no longer a need for the replacement of vials, the allowance will be reversed and the revenues will be recognized accordingly. 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 are currently conducting preclinical trials in small and large animals and we expect to submit an IND to the FDA before the end of the current year 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. We are also conducting pre clinical trials of our orally-administrated glucocerebrosidase enzyme for the treatment of Gaucher disease in small and large animals.

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 in this Quarterly Report. We believe that these accounting policies are critical for one to fully understand and evaluate our financial condition and results of operations. There have not been any changes to the Company's significant accounting policies since the Annual Report on Form 10-K for the year ended December 31, 2010.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

Three months ended September 30, 2011 compared to the three months ended September 30, 2010

Revenues

We recorded revenues of \$1.1 million during the three months ended September 30, 2011, a decrease of \$2.1 million, or 66%, from \$3.2 million during the three months ended September 30, 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 and products delivered to Pfizer under such agreement.

Our share in the Collaboration Agreement

We recorded \$235,000 of loss as our share of the collaboration under the Pfizer agreement during the three months ended September 30, 2011 compared to \$1.1 million during the three months ended September 30, 2010. Under the terms and conditions of the Pfizer agreement, we record income or loss equal to 40% of the profit or loss realized from sales of taliglucerase alfa and related expenses incurred based on reports we receive from Pfizer summarizing the results of the collaborative activities under the Pfizer agreement for the applicable period. 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 \$9.3 million for the three months ended September 30, 2011, an increase of \$3.0 million or 48%, from \$6.3 million for the three months ended September 30, 2010. The increase resulted primarily from an increase of \$3.8 million in materials and consumables mostly in connection with the capitalization of certain cost into inventory incurred during the three months ended on September 30, 2010 in connection with the deliverables for the short term supply agreement with Brazil. In the absence of a definitive supply agreement or regulatory marketing approval the Company does not capitalize costs into inventory. The increase was further increased by approximately \$1.3 million due to higher level of reimbursement for certain expenses in accordance with the terms and conditions of the Pfizer agreement of during the three months ended September 30, 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 \$1.5 million for the three months ended September 30, 2011, an increase of \$105,000, or 7%, from \$1.4 million for the three months ended September 30, 2010.

Financial Expenses and Income

Financial expense was \$108,000 for the three months ended September 30, 2011, compared to financial income of \$374,000 for the three months ended September 30, 2010. The expense during the three months ended September 30, 2011 resulted mainly due to the devaluation of the New Israeli Shekel against the US dollar.

Nine months ended September 30, 2011 compared to the nine months ended September 30, 2010

Revenues

We recorded revenues of \$6 million during the nine months ended September 30, 2011, an increase of \$558,000, or 10%, from \$5.5 million during the nine months ended September 30, 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, and products delivered to Pfizer under such agreement.

Our share in the Collaboration Agreement

We recorded \$3.7 million of loss as our share in the collaboration under the Pfizer agreement during the nine months ended September 30, 2011, compared to \$1.9 million during the nine months ended September 30, 2010. Our share in the collaboration's loss for the nine months ended September 30, 2011 resulted primarily from our 40% share of the allowance for sales return of taliglucerase alfa Pfizer recorded in connection with the short term supply agreement between Pfizer and the Ministry of Health of Brazil. During the second quarter of 2011, the Ministry of Health of Brazil requested that Pfizer consider the replacement of certain vials that might expire during 2012. As a result, Pfizer recorded an allowance for sales return. The allowance was partially offset by our share in the income generated through sale of taliglucerase alfa via the ATU program in France. Under the terms and conditions of the Pfizer agreement, we record income or loss equal to 40% of the profit or loss realized from sales of taliglucerase alfa and related expenses incurred based on reports we receive from Pfizer summarizing the results of the collaborative activities under the Pfizer agreement for the applicable period. 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 \$28.7 million for the nine months ended September 30, 2011, an increase of \$3.1 million, or 12%, from \$25.6 million for the nine months ended September 30, 2010. The increase resulted primarily from an increase of \$1.9 million in materials and consumables mostly in connection with the capitalization of certain cost incurred during the three months ended on September 30, 2010 into inventory in connection with the deliverables for the short term supply agreement with Brazil. In the absence of a definitive supply agreement or regulatory marketing approval the company does not capitalize costs into inventory. The research and development expenses for both the nine months ended September 30, 2011 and 2010 were partially offset by grants received from the OCS of approximately \$2.6 million, and \$2.6 million of reimbursements for certain expenses in accordance with the terms and conditions of the Pfizer agreement.

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 \$5.3 million for the nine months ended September 30, 2011, an increase of \$1 million, or approximately 23%, from \$4.3 million for the nine months ended September 30, 2010. The increase resulted primarily from an increase of \$321,000 in salaries expense and an increase of \$367,000 in professional fees.

Financial Expenses and Income

Financial income was \$57,000 for the nine months ended September 30, 2011, a decrease of \$591,000, or 91%, from \$648,000 for the nine months ended September 30, 2010. The decrease is mainly due to the devaluation of the New Israeli Shekel against the US dollar.

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 \$14.1 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.

Cash Flows

Net cash used in operations was \$16.9 million for the nine months ended September 30, 2011. The net loss for the nine months ended September 30, 2011 of \$27.6 million decreased mainly due to a decrease of \$2.8 million in accounts receivable and an increase of \$4.4 million in accounts payable and accruals and \$2.7 million in depreciation. Net cash used in investing activities for the nine months ended September 30, 2011 was \$5.1 million and consisted primarily of purchases of property and equipment. Net cash provided from financing activities was \$20.9 million mainly due to the underwritten public offering of our common stock.

Net cash used in operations was \$30.4 million for the nine months ended September 30, 2010. The net loss for the nine months ended September 30, 2010 of \$20.5 million increased primarily from an increase of \$6.7 million in inventories and an increase of \$5.1 million in accounts receivable, and a decrease of \$3.4 million in deferred revenues, but partially offset by \$2.2 million in depreciation and \$2.1 million increase in accounts payable. Net cash used in investing activities for the nine months ended September 30, 2010 was \$6.9 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 if we receive approval, of our lead product candidate, taliglucerase alfa, through milestone payments of up to \$50 million upon certain regulatory approvals that we are entitled to from Pfizer, and ultimately via the successful launch of taliglucerase alfa. 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. 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 two thirds of the anticipated market demand for taliglucerase alfa, if approved. The expansion in its final stage will increase our capital expenditures significantly, and is estimated to cost approximately \$25.0 million in total.

The ability of the Company to continue as a going concern is dependent on either gaining regulatory approval or through raising additional capital. There can be no assurance that the Company will be able to raise the necessary funds if and when needed to finance its ongoing costs. These factors raise substantial doubt about the ability of the Company to continue as a going concern.

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 nine months ended September 30, 2011 or the nine months ended September 30, 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 nine months ended September 30, 2011 or the nine months ended September 30, 2010.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2011 and September 30, 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 currently have no significant source of revenues; therefore we consider the currency of the primary economic environment to be the currency in which we expend cash. Approximately 50% of our expenses and capital expenditures are incurred in dollars, and a significant source of our financing has been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

Approximately 35% of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our income before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Nine months ended September 30,		Year ended December 31,
	2011	2010	2010
Average rate for period	3.5302	3.7707	3.733
Rate at period end	3.7120	3.6650	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. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with

policies or procedures.

Changes in internal controls

There were no changes to our internal controls over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended September 30, 2011 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

We describe certain risk factors below. This description includes certain material changes to and supersedes the description of the risk factors related to regulatory matters disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in Part II, Item 1A of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2011.

Risks Related to Regulatory Matters

We are subject to extensive governmental regulation including the requirement of FDA approval or clearance before our drug candidates may be marketed.

Both before and after approval or clearance of our drug candidates, we, our drug candidates, our suppliers, our contract manufacturers and our contract testing laboratories are subject to extensive regulation by the FDA or comparable foreign regulatory authorities. Failure to comply with applicable requirements of the FDA or comparable foreign regulatory authorities could result in, among other things, any of the following actions:

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in the FDA's or other foreign regulatory authorities' approving or clearing, or the refusal of any regulatory authority to approve or clear, any drug candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

In addition to the approval and clearance requirements, other numerous and pervasive regulatory requirements apply, both before and after approval or clearance, to us, our drug candidates, and our suppliers, contract manufacturers, and contract laboratories. These include requirements related to:

- testing;
- manufacturing;

- quality control;
- labeling;
- advertising;
- promotion;

- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with use of the drug candidate; and
- obtaining additional approvals or clearances for certain modifications to the drug candidate or its labeling or claims.

We also are subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories, and there can be no assurance that the FDA will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. We may be required to make modifications to our manufacturing operations in response to these inspections which may require significant resources and may have a material adverse effect upon our business, financial condition and results of operations.

The approval process for any drug candidate may also be delayed by changes in government regulation, future legislation or administrative action or changes in policy of the FDA and comparable foreign authorities that occur prior to or during their respective regulatory reviews of such drug candidate. Delays in obtaining regulatory approvals with respect to any drug candidate may:

- delay commercialization of, and our ability to derive product revenues from, such drug candidate;
- delay the regulatory-related milestone payments we anticipate receiving from Pfizer;
- require us to perform costly procedures with respect to such drug candidate; or
- otherwise diminish any competitive advantages that we may have with respect to such drug candidate.

Delays in the approval process for any drug candidate may have a material adverse effect upon our business, financial condition and results of operations.

We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our drug candidates in a timely manner, if at all, which would have a material adverse effect on our business, financial condition and results of operations.

We need FDA approval to commercialize our drug candidates in the United States and approvals from foreign regulators to commercialize our drug candidates elsewhere. In order to obtain FDA approval of any of our drug candidates, we must submit to the FDA an NDA or a Biologic License Application (BLA) demonstrating that the drug candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. In the European Union, we must submit an MAA to the EMA. Satisfaction of the FDA's and foreign regulatory authorities' regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the drug candidate and requires substantial resources for research, development and testing. In December 2009, we completed the filing of an NDA for taliglucerase alfa for the treatment of Gaucher disease and received a PDUFA date of February 25, 2011, and in November 2010, we submitted a marketing application to the Israeli MOH and an MAA to each of the EMA and ANVISA for taliglucerase alfa.

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 clinical and chemistry,

manufacturing and controls (CMC). In the clinical section of the CRL, the FDA requested additional data from the ongoing switchover trial and the long-term extension trial relating to taliglucerase alfa. 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. In May 2011, we had a meeting with the FDA to clarify the FDA's requests and in July 2011, we submitted a reply to the CRL. In August 2011, the FDA notified us that it had accepted for review the resubmission of the taliglucerase alfa NDA, had deemed the resubmission a class 2, or 6-month, response and established February 1, 2012 as the new PDUFA date. 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 the FDA's review of our reply 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.

Even if we comply with all the requests of the FDA and comparable foreign authorities, the authorities may ultimately reject the NDA or other filing or submission we filed for taliglucerase alfa or one or more of the NDAs or other filings or submissions we file in the future, if any, or we might not obtain regulatory clearance in a timely manner for taliglucerase alfa or any of our other drug candidates. 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 in preliminary findings or other comparable authorities for such clinical trials. Further, even if favorable testing data is generated by the clinical trials of a drug candidate, the FDA, EMA or other regulatory authority may not accept or approve an NDA, MAA or other comparable submission, as applicable, filed by a pharmaceutical or biotechnology company for the drug candidate. Failure to obtain approval of the FDA or comparable foreign authorities of any of our drug candidates in a timely manner, if at all, will severely undermine our business, financial condition and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues.

Our research and clinical efforts may not result in drugs that the FDA or foreign regulatory authorities consider safe for humans and effective for indicated uses, which would have a material adverse effect on our business, financial condition and results of operations. After clinical trials are completed for any drug candidate, if at all, the FDA and foreign regulatory authorities have substantial discretion in the drug approval process of the drug candidate in their respective jurisdictions and may require us to conduct additional clinical testing or perform post-marketing studies which would cause us to incur additional costs. Incurring such costs may have a material adverse effect on our business, financial condition and results of operations.

We currently have no significant product revenues and may need to raise additional capital to operate our business, which may not be available on favorable terms, or at all, and which will have a dilutive effect on our shareholders.

To date, we have generated no significant revenues from product sales and only minimal revenues from research and development services and other fees, other than the milestone payments we received in connection with our license and supply agreement with Pfizer. Drug development and commercialization is very capital intensive. Until we receive approval from the FDA and other regulatory authorities for our drug candidates, we cannot generate significant sales from our drugs and will not have product revenues, or milestone payments under the Pfizer agreement which we expect to earn upon FDA and EMA approval. The ability of the Company to continue as a going concern is dependent on either gaining regulatory approval or through raising additional capital. There can be no assurance that the Company will be able to raise the necessary funds if and when needed to finance its ongoing costs. These factors raise substantial doubt about the ability of the Company to continue as a going concern.

We may seek additional financing to implement and fund product development, preclinical studies and clinical trials for the drugs in our pipeline, as well as additional drug candidates and other research and development projects. If we are unable to secure additional financing in the future on acceptable terms, or at all, we may be unable to commence or complete planned preclinical and clinical trials or obtain approval of our drug candidates from the FDA and other regulatory authorities. In addition, we may be forced to reduce or discontinue product development or product licensing, reduce or forego sales and marketing efforts and other commercialization activities or forego attractive business opportunities in order to improve our liquidity and to enable us to continue operations which would have a material adverse effect on our business and results of operations. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our shareholders.

If we receive orphan drug designation for any of our drug candidates there can be no assurance that the drug will be able to obtain orphan drug market exclusivity. If our competitors are able to obtain orphan drug exclusivity for any products that are competitive with our products, we may be precluded from selling or obtaining approval of our competing products by the applicable regulatory authorities for a significant period of time.

In the United States, orphan drug status may be designated for a drug that has the potential to treat a “rare disease or condition,” which generally is a disease or condition that affects fewer than 200,000 individuals within the United States. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a drug candidate which has orphan drug designation subsequently receives the first approval for the indication in a jurisdiction for which it has such designation, the drug candidate is entitled to orphan exclusivity in that jurisdiction, meaning that the applicable regulatory authority may not approve any other application to market the same drug for the same indication, except in very limited circumstances, for seven years. There can be no assurance that a drug candidate that receives orphan drug designation will receive orphan drug marketing exclusivity. More than one drug can have orphan designation for the same indication. Foreign regulations regarding orphan drugs are similar to those in the United States but there are several conceptual differences. For example, the exclusivity period in the EU is generally 10 years. From time to time, we may apply to the FDA or any comparable foreign regulatory authority for orphan drug designation for any one or more of our drug candidates. For example, 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 EMA, after reviewing all relevant clinical data, recommended that the European Commission grant Orphan Drug designation to taliglucerase alfa for the treatment of Gaucher disease. However, none of our other drug candidates have been designated as an orphan drug and there is no guarantee that the FDA will grant such designation in the future. In addition, neither orphan drug designation nor orphan drug exclusivity prevents competitors from developing or marketing different drugs for that indication. Even if we obtain orphan drug exclusivity for one or more indications for one of our drug candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our drug candidate is shown to be clinically superior to our product, any orphan drug exclusivity we may have obtained will not block the approval of that competitive product. Failure to obtain or maintain orphan drug exclusivity for certain drug candidates may have a material adverse effect on our business, financial condition and results of operation. If another drug receives orphan drug exclusivity in any jurisdiction for an indication for a product that competes with one of the indications for one of our drug candidates, we may be prevented from marketing the drug candidate in the jurisdiction during the applicable exclusivity period which will have a material adverse effect on our business, financial condition and results of operation.

Clinical trials are very expensive, time-consuming and difficult to design and implement and may result in unforeseen costs which may have a material adverse effect on our business and results of operations.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. Other than taliglucerase alfa and our acetylcholinesterase product, our drug candidates are in the preclinical studies or research stages. Other, ongoing clinical trials of taliglucerase alfa and our acetylcholinesterase product, and anticipated clinical trials of our other potential drug candidates which have not yet been initiated, will take at least several years to complete. Preliminary and initial results from a clinical trial do not necessarily predict final results, and failure can occur at any stage of the trials. We may encounter problems that cause us to abandon or repeat preclinical studies or clinical trials. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. Failure or delay in the commencement or completion of our clinical trials may be caused by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and
- lack of sufficient funding to finance the clinical trials.

Any failure or delay in commencement or completion of any clinical trials may have a material adverse effect on our business and results of operations. In addition, we or the FDA or other regulatory authorities may suspend any clinical trial at any time if it appears that we are exposing participants in the trial to unacceptable safety or health risks or if the FDA or such other regulatory authorities, as applicable, find deficiencies in our IND submissions or the conduct of the trial. Any suspension of a clinical trial may have a material adverse effect on our business, financial condition and results of operations.

If the results of our clinical trials do not support our claims relating to any drug candidate or if serious side effects are identified, the completion of development of such drug candidate may be significantly delayed or we may be forced to abandon development altogether, which will significantly impair our ability to generate product revenues.

The results of our clinical trials with respect to any drug candidate might not support our claims of safety or efficacy, the effects of our drug candidates may not be the desired effects or may include undesirable side effects or the drug candidates may have other unexpected characteristics. Further, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our drug candidates are safe for humans and effective for indicated uses. In addition, our clinical trials may involve a specific and small patient population. Results of early clinical trials conducted on a small patient population may not be indicative of future results. Adverse or inconclusive results may cause us to abandon a drug candidate and may delay

development of other drug candidates. Any delay in, or termination of, our clinical trials will delay the filing of NDAs with the FDA, or other filings with other regulatory authorities, and, ultimately, significantly impair our ability to commercialize our drug candidates and generate product revenues which would have a material adverse effect on our business, financial condition and results of operations.

We have only limited experience in regulatory affairs, and some of our drug candidates may be based on new technologies. These factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals for medical devices and drug candidates. Moreover, some of the drug candidates that are likely to result from our development programs may be based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of drug candidates may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any products that we develop.

We may find it difficult to enroll patients in our clinical trials, which could cause significant delays in the completion of such trials or may cause us to abandon one or more clinical trials.

Many of the diseases or disorders that our drug candidates are intended to treat are relatively rare and we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Given that each of our drug candidates, other than taliglucerase alfa and our acetylcholinesterase product, is in the preclinical or research stages, we may not be able to initiate clinical trials for any of our drug candidates if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA and/or other foreign regulatory authorities. The requirements of our clinical trials generally mandate that a patient cannot be involved in another clinical trial for the same indication. We are aware that our competitors have ongoing clinical trials for products that are competitive with our drug candidates and subjects who would otherwise be eligible for our clinical trials may be involved in such testing, rendering them unavailable for testing of our drug candidates. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether, which will have a material adverse effect on our business, financial condition and results of operations.

Patients may discontinue their participation in our clinical trials, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Patients enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged related to our drug candidates under evaluation. If a large number of patients in any one of our studies discontinue their participation in the study, the results from that study may not be positive or may not support a filing for regulatory approval of the applicable drug candidate, which would have a material adverse effect on our business, financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities during the three months ended September 30, 2011.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Reserved and Removed)

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Date	
3.1	Amended and Restated Articles of Incorporation of the Company	S-4	333-48677	3.4	March 26, 1998	
3.2	Article of Amendment to Articles of Incorporation dated June 9, 2006	8-A	001-33357	3.2	March 9, 2007	
3.3	Article of Amendment to Articles of Incorporation dated December 13, 2006	8-A	001-33357	3.3	March 9, 2007	
3.4	Article of Amendment to Articles of Incorporation dated December 26, 2006	8-A	001-33357	3.4	March 9, 2007	
3.5	Article of Amendment to Articles of Incorporation dated February 26, 2007	8-A	001-33357	3.5	March 9, 2007	
3.6	Amended and Restated Bylaws of the Company	10-Q	001-33357	3.6	August 5, 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
101.INS	XBRL INSTANCE FILE					X
101.SCH	XBRL SHEMA FILE					X

101.CAL	XBRL CALCULATION FILE	X
101.DEF	XBRL DEFINITION FILE	X
101.LAB	XBRL LABEL FILE	X
101.PRE	XBRL PRESENTATION FILE	X

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November [7], 2011

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

Date: November [7], 2011

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