

Protalix BioTherapeutics, Inc.  
Form 10-Q  
May 09, 2012

**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 March 31, 2012**

**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 <b>(State or other jurisdiction of incorporation or organization)</b>	<b>65-0643773 (I.R.S. Employer Identification No.)</b>
<b>2 Snunit Street Science Park POB 455 Carmiel, Israel (Address of principal executive offices)</b>	<b>20100 (Zip Code)</b>

**+972-4-988-9488**

**(Registrant's telephone number, including area code)**

**N/A**

**(Former name, former address and former fiscal year, if changed since last report)**

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

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>

(Do not check if a 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 May 3, 2012, approximately 91,891,578 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

FORM 10-Q

TABLE OF CONTENTS

	<b>Page</b>
<b>PART I – FINANCIAL INFORMATION</b>	
Cautionary Statement Regarding Forward-Looking Statements	ii
Item 1. Financial Statements	
Condensed Consolidated Balance Sheets – As of March 31, 2012 (Unaudited) and December 31, 2011	1
Condensed Consolidated Statements of Operations (Unaudited) – For the Three Months Ended March 31, 2012 and 2011	2
Condensed Consolidated Statement of Changes in Shareholders’ Equity (Capital Deficiency) (Unaudited) – For the Three Months Ended March 31, 2012 and 2011	3
Condensed Consolidated Statements of Cash Flows (Unaudited) – For the Three Months Ended March 31, 2012 and 2011	4
Notes to Condensed Consolidated Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3. Quantitative and Qualitative Disclosures About Market Risk	16
Item 4. Controls and Procedures	17
<b>PART II – OTHER INFORMATION</b>	
Item 1. Legal Proceedings	18
Item 1A. Risk Factors	18
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	21
Item 3. Defaults Upon Senior Securities	21
Item 4. Mine Safety Disclosures	21
Item 5. Other Information	21
Item 6. Exhibits	21
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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms “anticipate,” “believe,” “estimate,” “expect” and “intend” and words or phrases of similar import, as they relate to our company or our subsidiaries or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the following:

the risk of a significant delay in the commercial introduction of taliglucerase alfa in the United States and other markets as planned, if at all;

delays in the approval or the potential rejection of any application filed with or submitted to the regulatory authorities reviewing taliglucerase alfa outside of the United States, including the marketing application we submitted to the Israeli Ministry of Health, or the Israeli MOH, and the Marketing Authorization Application (MAA) submitted to each of the European Medicines Agency, or the EMA, the National Sanitary Vigilance Agency, or ANVISA, an agency of the Ministry of Health of Brazil, and the Australian Therapeutic Goods Administration, or the Australian TGA, for taliglucerase alfa;

risks relating to our ability to finance our research programs, the expansion of our manufacturing capabilities and the ongoing costs in the case of delays in regulatory approvals for taliglucerase alfa outside of the United States;

the effect of the orphan drug designation granted by the EMA/European Commission to VPRIV<sup>®</sup> in the European Union on the marketing of taliglucerase alfa in the European Union;

risks relating to potential restrictions on the marketing and sale of certain of our product candidates in certain territories due to the orphan drug status that may be granted to competing products;

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;

the impact of development of competing therapies and/or technologies by other companies;

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

delays in our preparation and filing of applications for regulatory approval of our other product candidates in the United States, the European Union, Israel, Brazil, Australia and elsewhere;

any lack of progress of our research and development activities and our clinical activities with respect to any product candidate;

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 Teva, or with any other collaborator, distributor or partner;

- our ability to obtain, on a timely basis, if at all, sufficient patient enrollment in our clinical trials;
- risks relating to biosimilar legislation and/or healthcare reform in the United States or elsewhere;
- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;

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

- the possibility of infringing a third party's patents or other intellectual property rights;

the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties;

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; and

- other risks and uncertainties detailed in Part II, Section 1A of this Quarterly Report on Form 10-Q.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the FDA or foreign regulatory authorities may not accept or approve an NDA or MAA, as applicable, filed by a pharmaceutical or biotechnology company for the drug product. These and other risks and uncertainties are detailed under the heading "Risk Factors" in this Quarterly Report on Form 10-Q and are described from time to time in the reports we file with the Securities and Exchange Commission, or the Commission.

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, 2011, Section 1A, under the heading “Risk Factors,” and as described from time to time in our future reports to be filed with the SEC.



**PART I – FINANCIAL INFORMATION**

## Item 1. Financial Statements

**PROTALIX BIOTHERAPEUTICS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS**

(U.S. dollars in thousands)

	March 31, 2012 (Unaudited)	December 31, 2011
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 45,605	\$ 27,001
Accounts receivable:		
Trade	815	1,374
Other	3,154	3,837
Inventories	263	279
Total current assets	49,837	32,491
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,120	1,043
PROPERTY AND EQUIPMENT, NET	17,507	18,271
Total assets	\$ 68,464	\$ 51,805
<b>LIABILITIES NET OF CAPITAL DEFICIENCY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accruals:		
Trade	\$ 4,568	\$ 5,032
Other	8,298	7,540
Deferred revenues	4,858	6,121
Total current liabilities	17,724	18,693
<b>LONG TERM LIABILITIES:</b>		
Deferred revenues	49,781	50,923
Long term liability	5,623	6,566
Liability for employee rights upon retirement	1,793	1,700
Total long term liabilities	57,197	59,189
Total liabilities	74,921	77,882
<b>COMMITMENTS</b>		
CAPITAL DEFICIENCY	(6,457	) (26,077
Total liabilities net of capital deficiency	\$ 68,464	\$ 51,805

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

**PROTALIX BIOTHERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

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

(Unaudited)

	Three Months Ended	
	March 31, 2012	March 31, 2011
REVENUES	\$3,861	\$ 4,128
COMPANY'S SHARE IN COLLABORATION AGREEMENT	(133 )	1,872
COST OF REVENUES	(1,320 )	(778 )
GROSS PROFIT	2,408	5,222
<b>RESEARCH AND DEVELOPMENT EXPENSES (1)</b>	<b>(8,847 )</b>	<b>(10,563 )</b>
less – grants and reimbursements	2,003	2,292
RESEARCH AND DEVELOPMENT EXPENSES, NET	(6,844 )	(8,271 )
<b>GENERAL AND ADMINISTRATIVE EXPENSES (2)</b>	<b>(1,629 )</b>	<b>(1,989 )</b>
OPERATING LOSS	(6,065 )	(5,038 )
FINANCIAL (Expenses) INCOME – NET	161	(14 )
NET LOSS FOR THE PERIOD	\$(5,904 )	\$ (5,052 )
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED:	\$0.07	\$ 0.06
<b>WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE of common stock, basic and diluted</b>	<b>87,821,078</b>	<b>81,744,547</b>

(1) Research and development expenses include share-based compensation of \$61 and \$104 for the three-month periods ended March 31, 2012 and March 31, 2011, respectively.

(2) General and administrative expenses include share-based compensation of \$68 and \$138 for the three-month periods ended March 31, 2012 and March 31, 2011, 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) <b>Number</b>	Common Stock <b>Amount</b>	Additional paid-in capital	Accumulated deficit	Total
Balance at December 31, 2010	81,248,472	\$ 81	\$ 124,044	\$ (135,448 )	\$(11,323)
<b>Changes during the three-month period ended March 31, 2011 (Unaudited):</b>					
Common stock issued for cash (net of issuance costs of \$1,410)	4,000,000	4	20,586		20,590
Share-based compensation			242		242
Exercise of options granted to employees and non-employees	329,475	1	247		248
Net loss for the period				(5,052 )	(5,052 )
Balance at March 31, 2011 (Unaudited)	85,577,947	\$ 86	\$ 145,119	\$ (140,500 )	\$4,705
Balance at December 31, 2011	85,630,157	\$ 86	\$ 145,814	\$ (171,977 )	\$(26,077)
<b>Changes during the three-month period ended March 31, 2012 (Unaudited):</b>					
Common stock issued for cash (net of issuance costs of \$1,780) (see note 3a)	5,175,000	5	25,383		25,388
Share-based compensation			129		129
Exercise of options granted to employees	17,095	*	7		7
Net loss for the period				(5,904 )	(5,904 )
Balance at March 31, 2012 (Unaudited)	90,822,252	\$ 91	\$ 171,333	\$ (177,881 )	\$(6,457 )

(1) Common Stock, \$0.001 par value; Authorized – as of March 31, 2012 and March 31, 2011 - 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)

	Three Months Ended	
	March 31, 2012	March 31, 2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (5,904 )	\$ (5,052 )
Adjustments required to reconcile net loss to net cash used in operating activities		
Share based compensation	129	242
Depreciation and write down of fixed assets	930	878
Financial expenses (income), net (mainly exchange differences)	(114 )	64
Changes in accrued liability for employee rights upon retirement	44	33
Gain on amounts funded in respect of employee rights upon retirement	(5 )	(7 )
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non- current portion)	(2,405 )	(1,141 )
Decrease (increase) in accounts receivable	1,270	(1,654 )
Decrease in inventories	16	88
Increase (decrease) in accounts payable and accruals (including long term)	(242 )	2,561
Net cash used in operating activities	\$ (6,281 )	\$ (3,988 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	\$ (810 )	\$ (2,604 )
Amounts funded in respect of employee rights upon retirement, net	(42 )	(46 )
Net cash used in investing activities	\$ (852 )	\$ (2,650 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Issuance of shares, net of issuance cost	\$ 25,538	\$ 20,680
Exercise of options	36	256
Net cash provided by financing activities	\$ 25,574	\$ 20,936
EFFECT OF EXCHANGE RATE CHANGES ON CASH	\$ 163	\$ 29
NET INCREASE IN CASH AND CASH EQUIVALENTS	18,604	14,327
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	27,001	35,900
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 45,605	\$ 50,227

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

**PROTALIX BIOTHERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(U.S. dollars in thousands)  
(Unaudited)

(Continued) - 2

**SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING  
ACTIVITIES NOT INVOLVING CASH FLOWS:**

	Three Months Ended	
	March 31, 2012	March 31, 2011
Purchase of property and equipment	\$ 829	\$ 1,194
Issuance cost not yet paid and accruals – other	\$ 150	\$ 90
Exercise of options granted to employees	\$ 2	\$ 1

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

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES**

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the “Company”), and its wholly-owned subsidiary, Protalix Ltd. (the “Israeli Subsidiary” or “Protalix Ltd.”), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company’s proprietary ProCellEx<sup>®</sup> protein expression system (“ProCellEx”). In September 2009, Protalix Ltd. formed another wholly-owned subsidiary under the laws of the Netherlands, Protalix B.V, in connection with the European Medicines Agency (“EMA”) application process in Europe. The Company’s two subsidiaries are referred to collectively herein as the “Subsidiaries.”

On May 1, 2012, the FDA approved taliglucerase alfa, the Company’s first approved drug product, for injection, as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Taliglucerase alfa will be marketed under the brand name ELELYSO<sup>™</sup>. Taliglucerase alfa is a proprietary, recombinant form of glucocerebrosidase (GCD) that the Company developed using ProCellEx. Taliglucerase alfa is the first FDA-approved plant cell-based recombinant therapeutic protein.

Taliglucerase alfa will be marketed in the United States by Pfizer Inc. (“Pfizer”), the Company's commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd., the Company's wholly-owned subsidiary, and Pfizer (the “Pfizer Agreement”). Protalix Ltd. granted to Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement but retained those rights in Israel. The Company has agreed to a specific allocation between Protalix Ltd. and Pfizer regarding the responsibilities for the continued development efforts for taliglucerase alfa. To date, the Company has received an upfront payment of \$60.0 million, in connection with the execution of the Pfizer agreement and shortly thereafter an additional \$5.0 million upon the Company’s filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMA. Upon the FDA's approval of taliglucerase alfa in the United States, an additional \$25.0 million milestone payment became payable and, in addition, the Company is eligible to receive potential milestone payments equal to \$25.0 million for matters relating to the successful achievement of regulatory approval of taliglucerase alfa in the EU. The agreement provides that the Company share with Pfizer the future revenues and expenses for the development and commercialization of taliglucerase alfa on a 40% and 60% basis, respectively.

The Company is cooperating with Pfizer to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. In the fourth quarter of 2010, Pfizer filed a Marketing Authorization Application, or MAA, for taliglucerase alfa with the European Medicines Agency, or EMA. As part of its ongoing review of the MAA, the EMA delivered a list of outstanding points to be addressed by the applicant. Among the topics currently in discussion, is the orphan drug designation and exclusivity granted by the EMA/European Commission to VPRIV, Shire plc's, or Shire's,

Gaucher disease treatment, which could prevent the marketing authorization of taliglucerase alfa in the European Union for a 10-year market exclusivity period commencing as of the August 2010 marketing authorization of VPRIV in the European Union. As part of the MAA procedure, Pfizer, with The Company's cooperation, is challenging VPRIV's orphan market protection with respect to taliglucerase alfa pursuant to the EU orphan drug regulation. The EU orphan drug regulation provides for the possibility of such a challenge, and for an exception to this exclusivity to be granted, based on a number of factors, including contribution to patient care, clinical, supply, capacity and others.

In addition to taliglucerase alfa, the Company is developing certain other products using ProCellEx.



**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

Following the submission of the taliglucerase alfa MAA to the EMA, a good manufacturing practices ("GMP") audit of the Company's manufacturing facility was performed and it was found compliant with EMA GMP in December 2011. In addition, marketing applications have been submitted for taliglucerase alfa with each of the Israeli Ministry of Health, or the Israeli MOH, the National Sanitary Vigilance Agency, or ANVISA, an agency of the Ministry of Health of Brazil, and the Australian Therapeutic Goods Administration, or the Australian TGA.

In January 2010, the EMA's Committee for Orphan Medicinal Products, after reviewing all relevant clinical data, recommended that the European Commission grant orphan drug designation to taliglucerase alfa for the treatment of Gaucher disease and in March 2010, the European Commission granted orphan designation to taliglucerase alfa. In September 2009, the FDA's Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status.

Although commercial sales of taliglucerase alfa in the United States have not yet been commenced, and taliglucerase alfa has not yet been approved for commercial sale outside of the United States, patients are being treated with taliglucerase alfa, both in the framework of the Company's clinical trials and related studies and in compassionate use programs, special access agreements, named patient provisions and other programs designed to ensure that treatments are available to Gaucher patients in light of recent shortages of approved treatments. In July 2009, following a request by the FDA, the Company 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 the Company is continuing to treat patients in the United States under this protocol. On July 13, 2010, the Company announced that the French regulatory authority had granted an Autorisation Temporaire d'Utilisation (ATU), or Temporary Authorization for Use, for taliglucerase alfa for the treatment of Gaucher disease. An ATU is the regulatory mechanism used by the French Health Products and Safety Agency to make non-approved drugs available to patients in France when a genuine public health need exists. This ATU allows Gaucher patients in France to receive treatment with taliglucerase alfa before marketing authorization for the product is granted in the European Union. Payment for taliglucerase alfa has been secured through government allocations to hospitals. In addition to the United States and France, taliglucerase alfa is currently being provided to Gaucher patients under special access agreements or Named Patient provisions in Brazil and in other countries.

On August 10, 2010, Pfizer entered into a 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 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 2011, Pfizer recorded an allowance for sales returns in connection with the supply agreement because the Brazilian Ministry of Health requested that Pfizer consider the replacement of certain vials that might expire during 2012. Revenue, net of allowance for sales returns, generated from the Brazilian Ministry of Health was recorded by Pfizer, and the Company recorded its share of such revenues in accordance with the terms and conditions of the Pfizer Agreement.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

**2.** Liquidity and Financial Resources

In addition to the FDA approval, successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining necessary foreign regulatory approvals must be obtained to sell its products internationally. Pursuant to the Pfizer agreement, upon the FDA's approval of taliglucerase alfa in the United States, a \$25.0 million milestone payment became payable. In addition, the Company is eligible to receive potential milestone payments equal to \$25.0 million, in the aggregate, for matters relating to the successful achievement of regulatory approval of taliglucerase alfa in the EU. Notwithstanding the FDA's approval of taliglucerase alfa, there can be no assurance that the Company will receive regulatory approval of taliglucerase alfa in the EU or any other jurisdiction, nor is there any assurance that the Company will receive regulatory approval of any of its other 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 their respective developmental periods. Obtaining marketing approval will be directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. The Company cannot predict the outcome of these activities.

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

**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, 2011, filed by the Company with the Securities and Exchange Commission. The comparative balance sheet at December 31, 2011 has been derived from the audited financial statements at that date.

**c. Net loss per share**

Basic and diluted loss per share (“LPS”) are computed by dividing net loss by the weighted average number of shares of the Company’s common stock, par value \$.001 per share (the “Common Stock”), outstanding for each period.

**PROTALIX BIOTHERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

Diluted LPS does not include options to purchase 7,373,768 and 7,643,024 shares of Common Stock for the three months ended March 31, 2012 and 2011, respectively, because the effect would be anti-dilutive.

**NOTE 2 - INVENTORIES**

Inventory as of each of March 31, 2012 and December 31, 2011 consisted solely of raw materials.

**NOTE 3 - STOCK TRANSACTIONS**

On February 22, 2012, the Company issued and sold 5,175,000 shares of Common Stock in an underwritten public **a.** offering at a price to the public of \$5.25 per share. The net proceeds to the Company were approximately \$25,388,000 (net of underwriting commissions and issuance costs of approximately \$1,780,000).

During the three months ended March 31, 2012, the Company issued a total of 17,095 shares of Common Stock in **b.** connection with the exercise of a total of 17,095 options by certain employees and non-employees of the Company. The Company received aggregate cash proceeds equal to approximately \$7,000 in connection with such exercises.

**NOTE 4 - SUBSEQUENT EVENTS**

During April and May, 2012, the Company issued a total of approximately 1,069,326 shares of Common Stock in connection with the exercise of options to purchase approximately 1,069,326 shares of Common Stock by certain employees and officers of the Company. The aggregate cash proceeds in connection with the exercise of these options are equal to approximately \$1,017,010.



## 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, 2011. 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, 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 ProCellEx<sup>®</sup> protein expression system, or ProCellEx. Using our ProCellEx system, we are developing a pipeline of proprietary and biosimilar versions of recombinant therapeutic proteins based on our plant cell-based expression technology that 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.

On May 1, 2012, the FDA approved taliglucerase alfa, which will be marketed under the brand name ELELYSO<sup>™</sup>, for injection, as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Taliglucerase alfa, our first approved drug product, is a proprietary, recombinant form of glucocerebrosidase (GCD) that we developed using ProCellEx. Taliglucerase alfa is the first FDA-approved plant cell-based recombinant therapeutic protein. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. Gaucher patients suffer from mutations in or deficiencies of GCD, which is an enzyme that is naturally found in human cells.

Taliglucerase alfa will be marketed in the United States by Pfizer, our commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd., our wholly-owned subsidiary, and Pfizer, which we refer to as the Pfizer Agreement. We granted to Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement but retained those rights in Israel. We have agreed to a specific allocation between Protalix Ltd. and Pfizer regarding the responsibilities for the continued development

efforts for taliglucerase alfa. To date, we have received an upfront payment of \$60.0 million, in connection with the execution of the Pfizer agreement and shortly thereafter an additional \$5.0 million upon our filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMA. Upon the FDA's approval of taliglucerase alfa in the United States, an additional \$25.0 million milestone payment became payable and, in addition, we are eligible to receive potential milestone payments equal to \$25.0 million, in the aggregate, for matters relating to the successful achievement of regulatory approval of taliglucerase alfa in the EU. The agreement provides that we share with Pfizer the future revenues and expenses for the development and commercialization of taliglucerase alfa on a 40% and 60% basis, respectively. Pfizer has informed us that it expects to commence commercial sales of taliglucerase alfa in the United States during May 2012.

We are cooperating with Pfizer to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. In the fourth quarter of 2010, Pfizer filed a Marketing Authorization Application, or MAA, for taliglucerase alfa with the European Medicines Agency, or EMA. As part of its ongoing review of the MAA, the EMA delivered a list of outstanding points to be addressed by the applicant. Among the topics currently in discussion, is the orphan drug designation and exclusivity granted by the EMA/European Commission to VPRIV, Shire plc's, or Shire's, Gaucher disease treatment, which could prevent the marketing authorization of taliglucerase alfa in the European Union for a 10-year market exclusivity period commencing as of the August 2010 marketing authorization of VPRIV in the European Union. As part of the MAA procedure, Pfizer, with our cooperation, is challenging VPRIV's orphan market protection with respect to taliglucerase alfa pursuant to the EU orphan drug regulation. The EU orphan drug regulation provides for the possibility of such a challenge, and for an exception to this exclusivity to be granted, based on a number of factors, including contribution to patient care, clinical, supply, capacity and others.



Following the submission of the taliglucerase alfa MAA to the EMA, a good manufacturing practices, or GMP, audit of our manufacturing facility was performed and it was found compliant with EMA GMP in December 2011.

In January 2010, the EMA's Committee for Orphan Medicinal Products, or COMP, after reviewing all relevant clinical data, recommended that the European Commission grant orphan drug designation to taliglucerase alfa for the treatment of Gaucher disease and in March 2010, the European Commission granted orphan designation to taliglucerase alfa.

In addition, marketing applications have been submitted for taliglucerase alfa with each of the Israeli Ministry of Health, or the Israeli MOH, the National Sanitary Vigilance Agency, or ANVISA, an agency of the Ministry of Health of Brazil, and the Australian Therapeutic Goods Administration, or the Australian TGA.

The FDA and foreign regulators require manufacturers of drug products to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. In February 2010, the Israeli MOH completed a successful GMP audit of our manufacturing facilities in Carmiel, Israel. 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 December 2011, following the submission of the taliglucerase alfa MAA to the EMA, the Irish Medicines Board, or IMB, completed a successful GMP audit of our facility and issued a Certificate of GMP Compliance of a Manufacturer for the facility. The IMB certificate is accepted by all health authorities in the European Union under the European Union's centralized marketing authorization procedure, and by authorities of several other countries that recognize EU certification.

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. Eligible patients who completed nine months of treatment in our phase III clinical trial were offered the opportunity to participate in the extension study and continue to receive taliglucerase alfa at the same dose they received in the phase III clinical trial for an additional 15 months in a blinded manner. In February 2012, we announced data from 26 adult patients enrolled in the trial. According to the data, after 24 months, patients continued to demonstrate statistically significant improvement in all parameters with a similar safety profile as seen in the phase III clinical trial. Furthermore, those patients who were followed specifically for their bone parameters using Quantitative Chemical Shift Imaging (QCSI) MRI continued to show bone marrow improvement over time. We have also initiated a home care treatment program for patients enrolled in the extension study.

In the second quarter of 2011, we successfully completed a nine-month, worldwide, multi-center, open-label, switch-over clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated with

Cerezyme<sup>®</sup>, which is produced by Genzyme Corporation, or Genzyme (which was been acquired by Sanofi-Aventis, or Sanofi, in April 2011), with taliglucerase alfa. The results of the switchover trial demonstrate that over the nine-month treatment period, patients remained stable with regard to spleen volume, liver volume, platelet count and hemoglobin concentration, the efficacy endpoints of the switchover trial, after switching from Cerezyme to taliglucerase alfa. The safety analysis of the switchover trial demonstrated that taliglucerase alfa was well tolerated, and no drug-related serious adverse events were reported. In December 2009, we filed a proposed pediatric investigation plan to the Pediatric Committee of the EMA, which was approved during the first quarter of 2010. We have since concluded enrollment all of the naïve and switchover pediatric patients required according to the study protocol. All of the naïve patients have concluded the study and we anticipate that the remaining patients will conclude the study around year end. Patients in the extension trial and the switchover trial are still being treated with taliglucerase alfa.

The current standard of care for Gaucher patients is enzyme replacement therapy with either Cerezyme or, since its U.S. approval in February 2010, VPRIV. 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 commercial sales of taliglucerase alfa in the United States have not yet been commenced, and taliglucerase alfa has not yet been approved for commercial sale outside of the United States, patients are being treated with taliglucerase alfa, both in the framework of our clinical trials and related studies and in compassionate use programs, special access agreements, named patient provisions and other programs designed to ensure that treatments are available to Gaucher patients in light of recent shortages of approved treatments. In 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. 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 Gaucher patients in France to receive treatment with taliglucerase alfa before marketing authorization for the product is granted in the European Union. Payment for taliglucerase alfa has been secured through government allocations to hospitals. In addition to the United States and France, taliglucerase alfa is currently being provided to Gaucher patients under special access agreements or Named Patient provisions in Brazil and in other countries. Hundreds of patients, in the aggregate, have been treated with taliglucerase alfa.

On August 10, 2010, Pfizer entered into a \$30 million short-term supply agreement with the 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 remainder of 2010 and the first quarter of 2011, we and Pfizer completed the supply of products deliverable under the short-term supply agreement. During 2011, Pfizer recorded an allowance for sales returns in connection with the supply agreement because the Brazilian Ministry of Health requested that Pfizer consider the replacement of certain vials that might expire during 2012. Revenue, net of allowance for sales returns, generated from the Brazilian Ministry of Health was recorded by Pfizer, and we recorded our share of such revenues in accordance with the terms and conditions of the Pfizer Agreement. 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 ANVISA, if at all.

In September 2009, the FDA's Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status. 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.

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) PRX-106, or pr-antiTNF, a plant cell expressed recombinant fusion protein made from the soluble form of the human TNF receptor (TNFR) and an antibody portion, which is being developed as a treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, spondylitis, psoriatic arthritis and plaque psoriasis; (4) an orally-administered glucocerebrosidase enzyme for the treatment of Gaucher patients utilizing oral delivery of the recombinant enzyme produced within carrot cells; and (5) two additional undisclosed therapeutic proteins, both of which are being evaluated in animal studies. We participated in a pre-investigational new drug, or IND, meeting with respect to one of the undisclosed product candidates in the first quarter of 2012 and a pre-IND meeting for the second candidate is planned for later this year. 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-IND meeting with the FDA with respect to PRX-102. We completed preclinical trials in small and large animals with respect to PRX-102, and we expect to submit an IND to the FDA during the second quarter of 2012 in connection with an anticipated phase I/II clinical study of PRX-102 in Fabry patients, and to initiate the trial once the IND is approved, if at all. In December 2011 we held a pre-IND meeting with respect to PRX-106 and we expect to submit an IND around the fourth quarter of 2012. 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 rights to commercialize taliglucerase alfa worldwide (other than Israel) which we licensed 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.

### **Critical Accounting Policies**

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing in this Quarterly Report. There have not been any changes to our significant accounting policies since the Annual Report on Form 10-K for the year ended December 31, 2011.

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

judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

## **Results of Operations**

### ***Three months ended March 31, 2012 compared to the three months ended March 31, 2011***

#### *Revenues*

We recorded revenues of \$3.9 million during the three months ended March 31, 2012, a decrease of \$267,000, or 6%, from revenues of \$4.1 million for the three months ended March 31, 2011. The revenues represent a pro rata amortization of the \$65.0 million upfront and milestone payments of \$1.1 million in each quarterly period and \$2.8 million for the quarter ended March 31, 2012 in connection with products delivered to Pfizer under our license agreement.

*Our share in the Collaboration Agreement*

We recorded \$133,000 of loss as our share in the collaboration under the Pfizer Agreement during the three months ended March 31, 2012 compared to income of \$1.9 million for the three months ended March 31, 2011. Our share in income for the three months ended March 31, 2011 was primarily the result of Pfizer's completion of the supply of products deliverable under the short-term supply agreement with the Brazilian Ministry of Health during that 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, Net*

Research and development expenses were \$8.8 million for the three months ended March 31, 2012, a decrease of \$1.7 million, or 16%, from \$10.6 million for the three months ended March 31, 2011. The decrease resulted primarily from a decrease of \$1.2 million in costs related to consulting and subcontractors associated with research and development activities. Such decrease was partially offset by the total of grants received from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, the OCS, of approximately \$1.6 million and of reimbursement for certain expenses in accordance with the terms and conditions of the Pfizer Agreement of \$434,000 during the three months ended March 31, 2012 compared to the total of grants of \$936,000 from the OCS, and of reimbursement of approximately \$1.4 million from Pfizer during the three months ended March 31, 2011.

We expect research and development expenses to continue to be our primary expense after we start to generate revenues from Pfizer's sales of taliglucerase alfa in the United States.

*General and Administrative Expenses*

General and administrative expenses were \$1.6 million for the three months ended March 31, 2012, a decrease of \$360,000, or 18%, from \$2.0 million for the three months ended March 31, 2011. The decrease resulted primarily from a decrease of \$118,000 in salaries expense and a decrease of \$234,000 in legal and accounting expenses.

*Financial Expenses and Income*

Financial income was \$161,000 for the three months ended March 31, 2012, compared to financial expense of \$14,000 for the three months ended March 31, 2011. Financial income resulted primarily from the devaluation of the New Israeli Shekel, or NIS, against the U.S. dollar.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

As a result of our significant research and development expenditures and the lack of any approved product (prior to the May 2012 approval of taliglucerase alfa) to generate significant 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, 2008. 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; on March 23, 2011, we generated gross proceeds of \$22.0 million in connection with an underwritten public offering of our common stock; and on February 22, 2012, we generated gross proceeds of \$27.2 million in connection with an underwritten public offering of our common stock. In 2012, the OCS awarded us a grant of up to approximately \$4.3 million for the calendar years 2011 and 2012. The OCS awarded the grant to promote the advancement of our drug development programs.

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. As a result of the FDA's approval of taliglucerase alfa in the United States, a \$25.0 million milestone payment became payable. In addition, we are eligible to receive milestone payments of \$25.0 million, in the aggregate, for matters relating to the receipt of regulatory approval of taliglucerase alfa in the EU, if at all. Protalix Ltd. is entitled to payments equal to 40% of the net profits earned by Pfizer on its sales of taliglucerase alfa, if any. In calculating net profits there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold.



We believe that the funds currently available to us as are sufficient to satisfy our capital needs for at least the next 12 months.

### *Cash Flows*

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

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

### *Future Funding Requirements*

We expect to continue to incur operating losses in the near future. However, we anticipate that we will generate revenues to offset any such losses upon Pfizer's commercial launch of taliglucerase alfa. 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 the progression of taliglucerase alfa into the commercial phase.

We believe that our existing cash and cash equivalents together with the \$25.0 million that became payable to us from Pfizer upon the FDA's approval of taliglucerase alfa in the United States will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including the progress of the commercialization efforts by Pfizer in the United States, and 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, 2012 or the three months ended March 31, 2011.

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services. We do not believe currency fluctuations have had a material effect on our results of operations during the three months ended March 31, 2012 or the three months ended March 31, 2011.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of each of March 31, 2012 and March 31, 2011.

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

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

	Three months ended		Year ended
	March 31,		December 31,
	2012	2011	2011
Average rate for period	3.771	3.601	3.578
Rate at period end	3.715	3.481	3.821

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects due to the impact of inflation in Israel.

### **Interest Rate Risk**

Our exposure to market risk is confined to our cash and cash equivalents. We consider all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents. The primary objective of our investment activities is to preserve principal while maximizing the interest income we receive from our investments, without increasing risk. We invest any cash balances primarily in bank deposits and investment grade interest-bearing instruments. We are exposed to market risks resulting from changes in interest rates. We do not use derivative financial instruments to limit exposure to interest rate risk. Our interest gains may decline in the future as a result of changes in the financial markets.

Item 4. Controls and Procedures

**Evaluation of Disclosure Controls and Procedures**

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the Commission, and that material information relating to our company and our consolidated subsidiary is made known to management, including the Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

**Inherent Limitations on Effectiveness of Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with

policies or procedures.

#### Changes in internal controls

There were no changes to our internal controls over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended March 31, 2012 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

17

## **PART II – OTHER INFORMATION**

### Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

### Item 1A. Risk Factors

We describe certain risk factors below. In addition to the risks, uncertainties and other factors set forth below and elsewhere in this Quarterly Report on Form 10-Q, see, the “Risk Factors” section contained in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

#### **Risks Related to the Commercialization of taliglucerase alfa**

**We received marketing approval of taliglucerase alfa from the FDA in May 2012 and Pfizer has not yet launched commercial sales of taliglucerase alfa; accordingly, we cannot predict our share in net income we will receive from Pfizer's sales of taliglucerase alfa, if at all.**

We received marketing approval of taliglucerase alfa from the FDA on May 1, 2012 and we have no other products approved for marketing. As we have invested a significant portion of our efforts and financial resources in the development of taliglucerase alfa, our ability to generate product revenue, depends heavily on the successful development and commercialization of taliglucerase alfa. In November 2009, we granted to Pfizer an exclusive worldwide license to develop and commercialize taliglucerase alfa except in Israel. We retained such rights in Israel. Pfizer has not yet launched commercial sales of taliglucerase alfa. Sales of taliglucerase alfa worldwide (except Israel) will be dependent upon Pfizer's sales and marketing efforts, which we do not control and may not be able to effectively influence, and on the actions and decisions of foreign regulatory authorities. Pfizer may experience a delay in, or be unable to achieve, the commercial introduction of taliglucerase alfa in the United States or in other markets upon the receipt of marketing approval in other jurisdictions, if at all, which would have a material adverse effect on our business, results of operations and financial condition.

Our future revenues under our collaboration with Pfizer from Pfizer's sales of taliglucerase alfa, if any, will depend on a number of factors, including:

- the number of Gaucher patients who will seek treatment with taliglucerase alfa;
- competition from Cerezyme and VPRIV, other approved treatments of Gaucher disease;
- Pfizer's efforts under the Pfizer Agreement and the effectiveness of Pfizer's commercial strategy and its execution of that strategy, including its pricing strategy and the effectiveness of its efforts to obtain adequate third-party reimbursements;
- obtaining marketing approvals from foreign regulatory authorities outside of the United States;
- a continued acceptable safety and efficacy profile of our product candidates following approval;
- the successful audit of our facilities by additional regulatory authorities;
- maintaining the cGMP compliance of our manufacturing facility or establishing manufacturing arrangements with third parties; and
- the capacity of physicians and health care providers to provide treatment to Gaucher patients.

Over the next several years, the revenues we generate under our collaboration with Pfizer, if any, will also depend, in part, on the receipt of marketing approval for taliglucerase alfa in the EU, Brazil, Australia and in the rest of the world. We cannot accurately predict the amount of revenues we will generate under our collaboration with Pfizer in future periods, if any. Any failure to commercialize taliglucerase alfa or the experience of significant delays in doing so will have a material adverse effect on our business, results of operations and financial condition.

The market share and/or other indicators of market acceptance of taliglucerase alfa may not meet the expectations of investors or public market analysts, which would have a material adverse effect on our business, results of operations and financial condition and the market price of our common stock would likely decline.



**If safety issues regarding taliglucerase alfa that were not known at the time of approval are discovered, or if we or Pfizer fail to comply with continuing United States and applicable foreign regulations, commercialization efforts for taliglucerase alfa could be negatively affected and taliglucerase alfa could lose its approval or its sales could be suspended.**

Drug products remain subject to continuing regulatory oversight after they are approved for marketing, including the review of additional safety information. Drugs are more widely used by patients once approval has been obtained and therefore side-effects and other problems may be observed after approval that were not seen or anticipated, or were not as prevalent or severe, during pre-approval clinical trials or nonclinical studies. The subsequent discovery of previously unknown problems with a product could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market. The reporting of adverse safety events involving taliglucerase alfa or public speculation about such events could cause our stock price to decline or experience periods of volatility and will have a material adverse effect on our business, results of operations and financial condition.

If we or Pfizer fail to comply with applicable continuing regulatory requirements, we or Pfizer may be subject to fines and/or criminal prosecutions, and taliglucerase may become subject to suspension or withdrawal of regulatory approval, product recalls and seizures and operating restrictions. In addition, the manufacturers we and Pfizer engage to produce taliglucerase alfa and the manufacturing facilities in which taliglucerase alfa is made are subject to periodic review and inspection by the FDA and foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or manufacturing facilities, it could result in our inability to use the facility to make our product or a determination that inventories are not safe for commercial sale, which may have a material adverse effect on our business, results of operations and financial condition.

**If physicians, patients, third party payors and others in the medical community do not accept and use of taliglucerase alfa, or any of our other product candidates, if approved, our ability to generate revenue from product sale will be materially impaired.**

Physicians and patients, and other healthcare providers, may not accept and use taliglucerase alfa or any of our other product candidates, if approved for marketing. Future acceptance and use of taliglucerase alfa or any of our other product candidates, if approved, will depend upon a number of factors including:

- perceptions by physicians, patients, third party payors and others in the medical community about the safety and effectiveness of our drug candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the prevalence and severity of any side effects, including any limitations or warnings contained in our products' approved labeling;
- pharmacological benefits of our products relative to competing products and products under development;

- the efficacy and potential advantages relative to competing products and products under development;
  - relative convenience and ease of administration;
- effectiveness of education, marketing and distribution efforts by us and our licensees and distributors, if any;
  - publicity concerning our products or competing products and treatments;
  - coverage and reimbursement of our products by third party payors; and
- the price for our products and competing products.

Because we expect sales of taliglucerase alfa or any of our other product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, any lack of market acceptance of taliglucerase alfa or any other approved product candidate would have a material adverse effect on our business, results of operations and financial condition, and revenues from sales of our products would be materially impaired.

**Coverage and reimbursement may not be available for taliglucerase alfa or any of our other product candidates, if approved, which could diminish our sales or affect our ability to sell taliglucerase alfa or any other products profitably.**

Market acceptance and sales of taliglucerase alfa or any of our other product candidates, if approved, will depend on worldwide coverage and reimbursement policies. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that coverage and reimbursement will be available for taliglucerase alfa or any of our other product candidates, if approved for marketing and sale. Obtaining reimbursement approval for an approved product from governments and other third party payors is a time consuming and costly process that requires our collaborators or us, as the case may be, to provide supporting scientific, clinical and cost-effectiveness data for the use of our products, if and when approved, to every payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of approved products, if any, to such payors' satisfaction. Such studies might require our collaborators or us to commit a significant amount of management time and financial and other resources. Even if a payor determines that taliglucerase alfa, or any other approved product, if any, is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other regulatory authorities. In addition, there is a risk that full reimbursement may not be available for high priced products. Moreover, eligibility for coverage does not imply that any approved product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Also, limited reimbursement amounts may reduce the demand for, or the price of, our product candidates. Except with respect to taliglucerase alfa, we have not commenced efforts to have our product candidates covered and reimbursed by government or third-party payors. If coverage and reimbursement are not available or are available only to limited levels, the sales of our products, if approved may be diminished or we may not be able to sell such products profitably.

**We and our collaborating partners may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. If we or our collaborating partners are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.**

All marketing activities associated with taliglucerase alfa in the United States, as well as marketing activities in the United States related to any other products for which we obtain regulatory approval, if any, will be, directly or indirectly through our customers, subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products in the United States, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and HIPAA. These laws may impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to

include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of co-payments and deductibles, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other state or federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The “qui tam” provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of \$5,500 to \$11,000 for each separate false claim.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. Moreover, to the extent that taliglucerase alfa, or any of our products, if approved for marketing, will be sold in a foreign country, we and our collaborators, including Pfizer, may be subject to similar foreign laws and regulations. If we or any of our collaborators are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business, results of operations and financial condition.

## 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, 2012.

## Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	<b>Incorporated by Reference</b>				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	

21

Edgar Filing: Protalix BioTherapeutics, Inc. - Form 10-Q

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: May 9, 2012 By: /s/ David Aviezer  
David Aviezer, Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

Date: May 9, 2012 By: /s/ Yossi Maimon  
Yossi Maimon

Chief Financial Officer, Treasurer and Secretary

(Principal Financial and Accounting Officer)