

Protalix BioTherapeutics, Inc.  
Form 10-Q  
November 07, 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 September 30, 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 65-0643773  
(State or other jurisdiction (I.R.S. Employer  
of incorporation or organization) Identification No.)

2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel 20100  
(Address of principal executive offices) (Zip Code)

+972-4-988-9488

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

N/A

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  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):

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

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

On November 4, 2012, approximately 93,465,169 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

## FORM 10-Q

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*Except where the context otherwise requires, the terms, "we," "us," "our" or "the Company," refer to the business of Protalix BioTherapeutics, Inc. and its consolidated subsidiaries, and "Protalix" or "Protalix Ltd." refers to the business of Protalix Ltd., our wholly-owned subsidiary and sole operating unit.*

## **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

The statements set forth under the captions "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," and other statements included elsewhere in this Quarterly Report on Form 10-Q which are not historical constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "plan" and "intend" and words or phrases of similar import, as they relate to our company, our subsidiaries and our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

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

- risks related to the commercialization efforts for taliglucerase alfa in the United States and Israel;
- the risk of significant delays in the commercial introduction of taliglucerase alfa in the United States, Israel and other markets as planned, if at all;
- 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;
- risks related to the acceptance and use of taliglucerase alfa by physicians, patients and third-party payors;
- risks related to the market exclusivity issued to Shire plc for velaglucerase alfa in the European Union and the effects thereof;

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 and Israel;

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

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 and Israel;

the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, will be subject to potential marketing and commercialization restrictions;

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

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

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 any other collaborator, distributor or partner;

- 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; and

the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the FDA or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

These forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These and other risks and uncertainties are detailed under the heading "Risk Factors" beginning Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 and in Section 1A, under the heading "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2011, and are described from time to time in the reports we file with the Securities and Exchange Commission, or the Commission.

**PART I – FINANCIAL INFORMATION**

## Item 1. Financial Statements

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

(U.S. dollars in thousands)

|   | September 30,<br>2012<br>(Unaudited) | December 31,<br>2011 |
|---|--------------------------------------|----------------------|
| <b>ASSETS</b>   |                                      |                      |
| <b>CURRENT ASSETS:</b>  |                                      |                      |
| Cash and cash equivalents   | \$ 50,216                            | \$ 27,001            |
| Accounts receivable:  |                                      |                      |
| Trade   | 4,025                                | 1,374                |
| Other   | 3,281                                | 3,837                |
| Inventories   | 2,058                                | 279                  |
| Total current assets  | 59,580                               | 32,491               |
| FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT                     | 1,134                                | 1,043                |
| PROPERTY AND EQUIPMENT, NET   | 16,664                               | 18,271               |
| Total assets  | \$ 77,378                            | \$ 51,805            |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)</b> |                                      |                      |
| <b>CURRENT LIABILITIES:</b>   |                                      |                      |
| Accounts payable and accruals:  |                                      |                      |
| Trade   | \$ 4,427                             | \$ 5,032             |
| Other   | 11,444                               | 7,540                |
| Deferred revenues   | 4,564                                | 6,121                |
| Total current liabilities   | 20,435                               | 18,693               |
| <b>LONG TERM LIABILITIES:</b>   |                                      |                      |
| Deferred revenues   | 47,499                               | 50,923               |
| Long term liability   | 2,794                                | 6,566                |
| Liability for employee rights upon retirement                           | 1,878                                | 1,700                |
| Total long term liabilities   | 52,171                               | 59,189               |
| Total liabilities   | 72,606                               | 77,882               |
| <b>COMMITMENTS</b>  |                                      |                      |
| SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)                               | 4,772                                | (26,077 )            |
| Total liabilities and shareholders' equity (net of capital deficiency)  | \$ 77,378                            | \$ 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)

|   | Nine Months Ended     |                       | Three Months Ended    |                       |
|---|-----------------------|-----------------------|-----------------------|-----------------------|
|   | September<br>30, 2012 | September 30,<br>2011 | September<br>30, 2012 | September 30,<br>2011 |
| REVENUES  | \$33,698              | \$ 6,024              | \$3,724               | \$ 1,132              |
| COMPANY'S SHARE IN COLLABORATION<br>AGREEMENT   | 678                   | (3,745                | ) 1,666               | (235                  |
| COST OF REVENUES (1)  | (6,966                | ) (1,130              | ) (2,367              | ) (220                |
| GROSS PROFIT  | 27,410                | 1,149                 | 3,023                 | 677                   |
| <b>RESEARCH AND DEVELOPMENT<br/>EXPENSES (2)</b>  | (27,717               | ) (28,671             | ) (8,326              | ) (9,340              |
| less – grants and reimbursements  | 5,655                 | 5,163                 | 1,963                 | 1,422                 |
| RESEARCH AND DEVELOPMENT<br>EXPENSES, NET   | (22,062               | ) (23,508             | ) (6,363              | ) (7,918              |
| <b>GENERAL AND ADMINISTRATIVE<br/>EXPENSES (3)</b>  | (7,353                | ) (5,314              | ) (2,220              | ) (1,526              |
| <b>OPERATING LOSS</b>   | (2,005                | ) (27,673             | ) (5,560              | ) (8,767              |
| FINANCIAL INCOME (EXPENSES) – NET   | 264                   | 57                    | 81                    | (108                  |
| NET LOSS FOR THE PERIOD   | \$(1,741              | ) \$ (27,616          | ) \$(5,479            | ) \$ (8,875           |
| LOSS PER SHARE OF COMMON STOCK:   |                       |                       |                       |                       |
| BASIC AND DILUTED   | \$(0.02               | ) \$ (0.33            | ) \$(0.06             | ) \$ (0.10            |
| WEIGHTED AVERAGE NUMBER OF<br>SHARES OF COMMON STOCK USED IN<br>COMPUTING LOSS PER SHARE: |                       |                       |                       |                       |
| BASIC AND DILUTED   | 90,491,421            | 84,351,420            | 91,929,445            | 85,585,777            |
| (1) Includes share-based compensation   | 220                   | 0                     | 220                   | 0                     |
| (2) Includes share-based compensation   | 3,690                 | 348                   | 1,247                 | 92                    |
| (3) Includes share-based compensation   | 2,155                 | 382                   | 840                   | 117                   |

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<br>Stock (1)<br>Number | Common<br>Stock<br>Amount | Additional<br>paid-in<br>capital | Accumulated<br>deficit | Total      |
|---|-------------------------------|---------------------------|----------------------------------|------------------------|------------|
| Balance at December 31, 2010  | 81,248,472                    | \$81                      | \$ 124,044                       | \$ (135,448 )          | \$(11,323) |
| <b>Changes during the nine-month period ended<br/>September 30, 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 related to stock options                                     |                               |                           | 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) |
| Balance at December 31, 2011  | 85,630,157                    | \$86                      | \$ 145,814                       | \$ (171,977 )          | \$(26,077) |
| <b>Changes during the nine-month period ended<br/>September 30, 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 related to stock options                                     |                               |                           | 4,217                            |                        | 4,217      |
| Exercise of options granted to employees  | 1,156,184                     | 1                         | 1,136                            |                        | 1,137      |
| Share-based compensation related to restricted stock award                            | 1,500,000                     | 1                         | 1,847                            |                        | 1,848      |
| Net loss for the period   |                               |                           |                                  | (1,741 )               | (1,741 )   |
| Balance at September 30, 2012 (Unaudited)   | 93,461,341                    | \$93                      | \$ 178,397                       | \$ (173,718 )          | \$4,772    |

(1) Common Stock, \$0.001 par value; Authorized – as of September 30, 2012 and September 30, 2011 - 150,000,000 shares.

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

**PROTALIX BIOTHERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

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

|   | Nine Months Ended        |                       |
|---|--------------------------|-----------------------|
|   | September<br>30,<br>2012 | September 30,<br>2011 |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>  |                          |                       |
| Net loss  | \$(1,741 )               | \$ (27,616 )          |
| Adjustments required to reconcile net loss to net cash used in operating activities |                          |                       |
| Share based compensation  | 6,065                    | 730                   |
| Depreciation and write down of fixed assets   | 2,772                    | 2,698                 |
| Financial income, net (mainly exchange differences)                                 | 14                       | 156                   |
| Changes in accrued liability for employee rights upon retirement                    | 218                      | 115                   |
| Gain on amounts funded in respect of employee rights upon retirement                | (24 )                    | (12 )                 |
| Loss on sale of fixed assets  |                          | 2                     |
| Changes in operating assets and liabilities:  |                          |                       |
| Decrease in deferred revenues (including non-current portion)                       | (4,981 )                 | (991 )                |
| Decrease (increase) in accounts receivable  | (2,099 )                 | 2,810                 |
| Decrease (increase) in inventories  | (1,779 )                 | 762                   |
| Increase in accounts payable and accruals (including long term)                     | 369                      | 4,388                 |
| Net cash used in operating activities   | \$(1,186 )               | \$ (16,958 )          |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>  |                          |                       |
| Purchase of property and equipment  | \$(1,817 )               | \$ (5,001 )           |
| Proceeds from sale of property and equipment  |                          | 2                     |
| Amounts funded in respect of employee rights upon retirement, net                   | (93 )                    | (122 )                |
| Net cash used in investing activities   | \$(1,910 )               | \$ (5,121 )           |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>  |                          |                       |
| Issuance of shares, net of issuance cost  | \$25,328                 | \$ 20,650             |
| Exercise of options   | 1,096                    | 263                   |
| Net cash provided by financing activities   | \$26,424                 | \$ 20,913             |
| <b>EFFECT OF EXCHANGE RATE CHANGES ON CASH</b>                                      | <b>\$(113 )</b>          | <b>\$ (170 )</b>      |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>                         | <b>23,215</b>            | <b>(1,336 )</b>       |
| <b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>                  | <b>27,001</b>            | <b>35,900</b>         |
| <b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>                        | <b>\$50,216</b>          | <b>\$ 34,564</b>      |

**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

|  | Nine Months Ended |           |
|--|-------------------|-----------|
|  | September         | September |
|  | 30,               | 30,       |
|  | 2012              | 2011      |
| <b>SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES</b> |                   |           |
| <b>NOT INVOLVING CASH FLOWS:</b>                                       |                   |           |
| Purchase of property and equipment                                     | \$ 821            | \$ 1,477  |
| Issuance cost not yet paid and accruals – other                        |                   | \$ 60     |
| Exercise of options granted to employees                               | \$ 72             | \$ 12     |

**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**

- |           |                |
|-----------|----------------|
| <b>a.</b> | <b>General</b> |
| <b>1.</b> | Operation      |

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the "Company"), and its wholly-owned subsidiary, Protalix Ltd., are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx<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 the European Union. The Company's two subsidiaries are referred to collectively herein as the "Subsidiaries."

On May 1, 2012, the U.S. Food and Drug Administration ("FDA") approved taliglucerase alfa for injection, the Company's first approved drug product, as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Taliglucerase alfa is a proprietary, recombinant form of glucocerebrosidase (GCD) that the Company developed using ProCellEx. Taliglucerase alfa was also approved by the Israeli Ministry of Health (the "Israeli MOH") in September 2012. Taliglucerase alfa is the first plant cell-based recombinant therapeutic protein approved by each of the FDA and the Israeli MOH.

Taliglucerase alfa is being marketed in the United States under the brand name ELELYSO<sup>™</sup> by Pfizer Inc. ("Pfizer"), the Company's commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd. and Pfizer (the "Pfizer Agreement"). The Company, through Protalix Ltd., markets ELELYSO in Israel.

Protalix Ltd. granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement, but retained those rights in Israel. The Company has agreed to a specific allocation between Protalix Ltd. and Pfizer regarding the responsibilities for the continued development efforts for taliglucerase alfa. To date, the Company has received an upfront payment of \$60.0 million in connection with the execution of the Pfizer Agreement and shortly thereafter an additional \$5.0 million clinical development-related milestone payment. The Company received an additional \$25.0 million milestone payment in connection with the FDA's approval of taliglucerase alfa in the United States, which was considered to be a substantive milestone for purposes of revenue

recognition, and, accordingly, was recorded as revenue during the period in which the milestone was achieved. The agreement provides that the Company share with Pfizer the net profits or loss related to the development and commercialization of taliglucerase alfa on a 40% and 60% basis, respectively, except with respect to the profits and losses related to commercialization efforts in Israel. In calculating the net profits under the agreement, there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold.

The Company is cooperating with Pfizer to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. Currently, marketing authorization applications have been filed for Brazil and other countries. The European Commission issued a Commission Decision refusing the marketing authorization for taliglucerase alfa in the European Union. This decision is an endorsement of the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) June 2012 opinion recommending against the marketing authorization of taliglucerase alfa. While the CHMP gave a positive risk-benefit assessment for taliglucerase alfa, its recommendation was based solely on the orphan market exclusivity granted to VPRIV<sup>®</sup>, Shire plc's Gaucher disease treatment. It was not based on the safety and efficacy profile of taliglucerase alfa.



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

(Unaudited)

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

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

Currently, patients are being treated with taliglucerase alfa on a commercial basis in the United States, and are anticipated to be treated on a commercial basis in Israel shortly. In addition, patients are being treated globally through the Company's clinical trials and related studies, compassionate use programs, special access agreements, named patient provisions and other programs designed to ensure that treatments are available to Gaucher patients in light of recent shortages of approved treatments. On July 13, 2010, the Company announced that the French regulatory authority had granted an Autorisation Temporaire d'Utilisation (ATU), or Temporary Authorization for Use, for taliglucerase alfa for the treatment of Gaucher disease. An ATU is the regulatory mechanism used by the French Health Products and Safety Agency to make non-approved drugs available to patients in France when a genuine public health need exists. This ATU allows Gaucher patients in France to receive treatment with taliglucerase alfa before marketing authorization for the product is granted in the European Union. Payment for taliglucerase alfa has been secured through government allocations to hospitals. Notwithstanding the EC's decision not to approve the market authorization of taliglucerase alfa in the EU, the Company, together with Pfizer, will continue to supply taliglucerase alfa as required by physicians under the ATU process for as long as it is authorized by the French regulatory authorities. 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 Brazilian Ministry of Health 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. During the third quarter of 2012 resupply for certain vials was completed. 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.

In addition to the FDA approval of taliglucerase alfa, successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining the foreign regulatory approvals required to sell its products internationally. In accordance with the terms and conditions of the Pfizer Agreement, the Company received a \$25.0 million milestone payment in connection with the FDA's approval of taliglucerase alfa in the United States. A substantial amount of time may pass before the Company achieves a level of revenues adequate to support its operations, if at all and the Company also expects to incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during their respective developmental periods. Obtaining marketing approval with respect to any product candidate is directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain such approval in the United States and in other countries. The Company cannot reasonably predict the outcome of these activities.

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

(Unaudited)

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

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

**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.

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

Diluted LPS does not include 7,498,026 and 7,169,035 shares of Common Stock underlying outstanding options and restricted shares of Common Stock for the nine months ended September 30, 2011 and 2012, respectively, and 7,428,201 and 7,508,240 shares of Common Stock underlying outstanding options and restricted shares of Common Stock for the three months ended September 30, 2011 and 2012, respectively.

**NOTE 2 – INVENTORIES**

Inventory at September 30, 2012 and December 31, 2011 consisted of the following:

|                  | September<br>30,<br>2012    | December 31,<br>2011 |
|------------------|-----------------------------|----------------------|
|                  | (U.S. dollars in thousands) |                      |
| Raw materials    | \$ 1,294                    | \$ 279               |
| Work in progress | 298                         | -                    |
| Finished goods   | 466                         | -                    |
| Total inventory  | \$ 2,058                    | \$ 279               |

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

(Unaudited)

**NOTE 2 – INVENTORIES (continued):**

Prior to the FDA's approval of taliglucerase alfa, manufacturing costs related to taliglucerase alfa were not capitalized; rather, such costs were expensed as research and development expenses. Effective as of the FDA approval of taliglucerase alfa on May 1, 2012, the Company capitalizes all manufacturing costs associated with taliglucerase alfa.

**NOTE 3 - STOCK TRANSACTIONS**

On February 22, 2012, the Company issued and sold 5,175,000 shares of Common Stock in an underwritten public 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 nine months ended September 30, 2012, the Company issued a total of 1,156,184 shares of Common Stock in connection with the exercise of a total of 1,156,184 options by certain officers and employees of the Company. The Company received aggregate cash proceeds equal to approximately \$1,137,000 in connection with such exercises.

Following FDA approval of taliglucerase alfa on May 1, 2012, the Company started recognizing compensation costs in relation to performance-based awards that were granted in February 2010 to certain officers and employees of the Company, which vest over a three-year period commencing upon the FDA's approval of taliglucerase alfa. During the second and third quarter of 2012, the Company recorded an expense in the amount of approximately \$3,900,000 for the cumulative period from the date of grant.

On July 16, 2012, the Company's Board of Directors approved the grant of 1,500,000 shares of restricted Common Stock to its officers and certain other employees. Of such restricted shares, 1,100,000 of the shares were issued to the Company's named executive officers and vest in 16 equal, quarterly increments over a four-year period, commencing upon the date of grant, and are subject to a 24-month lock-up period, commencing upon the applicable vesting dates. Immediately and automatically in the event of a Change in Control, as such term is defined in the Company's 2006 Stock Incentive Plan, as amended, all of the shares of restricted Common Stock issued to the named executive officers shall vest, and the lock-up periods shall terminate, subject to certain exceptions. The remaining 400,000 shares of restricted Common Stock were issued to other employees of the Company and vest in 12 equal, quarterly increments over a three-year period, commencing upon the date of grant. The Company

estimated the fair value of the restricted stock on the date of grant to be approximately \$8,580,000.

**NOTE 4 - SUBSEQUENT EVENTS**

During October and November 2012, the Company issued a total of 3,828 shares of Common Stock in connection with the exercise of options to purchase 3,828 shares of Common Stock by an employee of the Company. The aggregate cash proceeds in connection with the exercise of the options were \$5,187.

## 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, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2012 and June 30, 2012 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 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### **Overview**

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx<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 for injection, which is being marketed under the brand name ELELYSO<sup>™</sup>, as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. The Israeli Ministry of Health, or the Israeli MOH, approved taliglucerase alfa in September 2012. 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 plant cell-based recombinant therapeutic protein to be approved by each of the FDA and the Israeli MOH. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. Gaucher patients suffer from mutations in or deficiencies of GCD, an enzyme that is naturally found in human cells.

Since May 2012, taliglucerase alfa has been marketed in the United States by Pfizer, our commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd., our wholly-owned subsidiary,

and Pfizer, which we refer to as the Pfizer Agreement. We granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement, but retained those rights in Israel. We have agreed to a specific allocation between Protalix Ltd. and Pfizer of the responsibilities for the continued development efforts for taliglucerase alfa outside of Israel. 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 payment in connection with a clinical development-related milestone. We also received a \$25.0 million milestone payment from Pfizer in connection with the FDA's approval of taliglucerase alfa in the United States. The agreement provides that we share with Pfizer the future net profits or loss for the development and commercialization of taliglucerase alfa worldwide (except in Israel) on a 40% and 60% basis, respectively. In calculating the net profits under the agreement, there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold.

We are cooperating with Pfizer to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. Currently, marketing authorization applications have been filed with the National Sanitary Vigilance Agency, or ANVISA, an agency of the Brazilian Ministry of Health, as well as in other countries. In November 2012, we announced that the European Commission issued a Commission Decision refusing the marketing authorization for taliglucerase alfa in the European Union. This decision is an endorsement of the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) June 2012 opinion recommending against the marketing authorization of taliglucerase alfa. While the CHMP gave a positive risk-benefit assessment for taliglucerase alfa, its recommendation was based solely on the orphan market exclusivity granted to VPRIV<sup>®</sup>, Shire plc's, or Shire's, Gaucher disease treatment. It was not based on the safety and efficacy profile of taliglucerase alfa.



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 good manufacturing practices, or GMP, or similar requirements that the FDA or foreign regulators establish. 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 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 our 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. 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®, which is produced by Genzyme Corporation, or Genzyme (A Sanofi-Aventis company), 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. The switchover study demonstrates that taliglucerase alfa is an alternative treatment for adult patients with Gaucher disease.

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 by the end of 2012. The primary endpoint of the study was change in hemoglobin concentration, and the secondary endpoints were change of spleen volume, liver volume, platelet count and chitotriosidase activity. Patients were enrolled in clinics in Israel, Paraguay and South Africa. Patients that completed the trial continued treatment in the extension trial. Preliminary data regarding pediatric patients that were treated for 12 months was released in July 2012. After 12 months of treatment with taliglucerase

alfa, improvements were seen in the primary endpoint and all secondary endpoints. The majority of treatment-related adverse events were mild or moderate in intensity, and transient in nature. The preliminary results of this study suggest that taliglucerase alfa has the potential to provide alternative therapy in pediatric patients with Gaucher disease, as with adults. We expect to report the data from the study shortly after the conclusion of the study.

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. 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.

Currently, patients are being treated with taliglucerase alfa on a commercial basis in the United States, and, we anticipate that patients will be treated on a commercial basis in Israel shortly. Globally, patients are being treated through our clinical trials and related studies, compassionate use programs, special access agreements, named patient provisions and other programs designed to ensure that treatments are available to Gaucher patients in light of recent shortages of approved treatments. On July 13, 2010, 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 Brazilian Ministry of Health pursuant to which Protalix and Pfizer have provided taliglucerase alfa to the Brazilian Ministry of Health for the treatment of Gaucher patients. During the remainder of 2010 and the first quarter of 2011, we and Pfizer completed the supply of products deliverable under the short-term supply agreement. During 2011, 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. As such vials are replaced, revenues are recorded upon the supply of the 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. During the third quarter of 2012, we and Pfizer resupplied a portion of the returned vials for which an allowance for return was made during 2011 and, as a result, Pfizer reversed the allowance related to such resupplied vials. 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 Brazilian Ministry of Health 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 supply the Brazilian Ministry of Health taliglucerase alfa until we receive marketing approval of taliglucerase alfa from 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) an orally-administered glucocerebrosidase enzyme for the treatment of Gaucher patients utilizing oral delivery of the recombinant enzyme produced within carrot cells; (4) PRX-106, or pr-antiTNF, a plant cell expressed recombinant fusion protein made from the soluble form of the human TNF receptor (TNFR) and an antibody portion, which is being developed as a treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, spondylitis, psoriatic arthritis and plaque psoriasis; 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 the first half of 2013. 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 August 2012, the FDA accepted and approved our IND for a phase I/II clinical study of PRX-102 in Fabry patients. We expect to initiate the trial before the end 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. We plan to apply, by the end of 2012, for regulatory approval of the initiation of a clinical trial in Gaucher patients designed to demonstrate safety and achieve the first ever proof in concept regarding orally-administrated glucocerebrosidase enzyme. In December 2011, we held a pre-IND meeting with respect to PRX-106 and we expect to submit an IND during the first half of 2013.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Israel) which we licensed to Pfizer, we hold the worldwide commercialization rights to our proprietary development candidates. We have built an internal marketing team designed to serve the Israeli market for taliglucerase alfa and we intend to establish internal commercialization and marketing teams for our other product candidates in North America, the European Union and in other significant markets, including Israel, subject to required marketing approvals, as the need arises. In addition, we continuously evaluate potential strategic marketing partnerships.

### **Critical Accounting Policies**

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 September 30, 2012 compared to the three months ended September 30, 2011***

#### *Revenues*

We recorded revenues of \$3.7 million during the three months ended September 30, 2012, an increase of \$2.6 million, or 229%, from revenues of \$1.1 million for the three months ended September 30, 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 revenues recognized during the three months ended on September 30, 2012 for drugs supplied to Pfizer at cost.

*Our share in the Collaboration Agreement*

We recorded revenue of \$1.7 million as our share in net income from the collaboration under the Pfizer Agreement during the three months ended September 30, 2012, compared to loss of \$235,000 for the three months ended September 30, 2011. Our share in the collaboration agreement recorded during the three months ended September 30, 2012 represents our 40% share of the net income generated during the period, which was primarily the result of revenues generated by Pfizer in the United States and resupply in Brazil which exceeded the expenses during such period. Our share in the collaboration includes a loss generated during the three months ended September 30, 2011 which resulted primarily from certain clinical-related expenses. Under the terms and conditions of the Pfizer Agreement, financial information of Pfizer's subsidiaries that operate outside the United States is included based on the fiscal year ending November 30, while financial information for the U.S. entity is included based on the fiscal year ending December 31.

*Cost of Revenues*

Cost of revenues was \$2.4 million and \$220,000 for the three months ended September 30, 2012 and September 30, 2011, respectively. Cost of revenues for the three months ended September 30, 2012 includes approximately \$2.1 million primarily for certain fixed costs relating to our manufacturing facility, including rent, depreciation, salary and maintenance expenses, and to a much lesser extent, the direct cost of products delivered to Pfizer for which revenues were recognized during the period. Cost of revenues also includes \$314,000, representing royalties due to the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the OCS, and to a certain academic institution in connection with gross sales of taliglucerase alfa during the period. Prior to the FDA's approval of taliglucerase alfa, manufacturing costs related to taliglucerase alfa were not capitalized; rather, such costs were expensed as research and development expenses. Effective as of the FDA approval of taliglucerase alfa on May 1, 2012, we capitalize all manufacturing costs associated with taliglucerase alfa.

*Research and Development Expenses, Net*

Research and development expenses were \$6.4 million for the three months ended September 30, 2012, a decrease of \$1.5 million, or 20%, from \$7.9 million for the three months ended September 30, 2011. The decrease resulted primarily from a decrease of \$789,000 in rent and other overhead costs and \$630,000 in materials which have been classified as cost of revenues or capitalized as inventory after the FDA's approval of taliglucerase alfa in May 2012, and due to \$366,000 in costs related to consulting and subcontractors associated with research and development activities. The decrease was partially offset by an increase of \$598,000 in salaries expense resulting primarily from bonuses paid in connection with the FDA's approval of taliglucerase alfa on May 1, 2012 and share-based compensation. The decrease also resulted from increased reimbursement of expenses equal to \$1.2 million in accordance with the terms and conditions of the Pfizer Agreement during the three months ended September 30, 2012, compared to the total reimbursement of approximately \$564,000 from Pfizer, during the three months ended September 30, 2011.

We expect research and development expenses for our various development programs to continue to be our primary expense.

*General and Administrative Expenses*

General and administrative expenses were \$2.2 million for the three months ended September 30, 2012, an increase of \$694,000, or 45%, from \$1.5 million for the three months ended September 30, 2011. The increase resulted primarily from an increase of \$856,000 in salaries expense primarily due to share-based compensation.

*Financial Income, Net*

Financial income was \$81,000 for the three months ended September 30, 2012, compared to financial expenses of \$108,000 for the three months ended September 30, 2011 primarily due to the exchange rate differences between the NIS and the US dollar.

*Nine months ended September 30, 2012 compared to the nine months ended September 30, 2011*

*Revenues*

We recorded revenues of \$33.7 million during the nine months ended September 30, 2012, an increase of \$27.7 million from revenues of \$6.0 million for the nine months ended September 30, 2011. The revenues represent the \$25.0 million payment we received from Pfizer under the Pfizer Agreement in connection with the FDA approval of taliglucerase alfa on May 1, 2012 and a pro rata amortization of the \$65.0 million upfront and milestone payments of \$1.1 million in each quarterly period and the cost of drug supplied to Pfizer during the relevant period.

*Our share in the Collaboration Agreement*

We recorded revenue of \$678,000 as our share in net income from the collaboration under the Pfizer Agreement during the nine months ended September 30, 2012, compared to loss of \$3.7 million for the nine months ended September 30, 2011. Our share in the collaboration agreement recorded during the nine months ended September 30, 2012 represents our 40% share of the net income generated during the period, which was primarily the result of revenues generated by Pfizer in the United States and the resupply in Brazil, which exceeded the expenses during such period. Our share in the collaboration includes a loss generated during the nine months ended September 30, 2011 which resulted primarily from certain clinical-related expenses. Under the terms and conditions of the Pfizer Agreement, financial information of Pfizer's subsidiaries that operate outside the United States is included based on the fiscal year ending November 30, while financial information for the U.S. entity is included based on the fiscal year ending December 31.



*Cost of Revenues*

Cost of revenues was \$7.0 million and \$1.1 million for the nine months ended September 30, 2012 and September 30, 2011, respectively. Cost of revenues for the nine months ended September 30, 2012 includes approximately \$2.1 million for royalties due to the OCS and a certain academic institution in connection with gross sales of taliglucerase alfa during the period and \$4.9 million primarily for certain fixed costs relating to our manufacturing facility, including rent, depreciation, salary and maintenance expenses, and to a much lesser extent, the direct cost of products delivered to Pfizer during the period. Cost of revenues for the nine months ended September 30, 2011 includes primarily the direct cost of products delivered to Pfizer during the period. Prior to the FDA's approval of taliglucerase alfa, manufacturing costs related to taliglucerase alfa were not capitalized; rather, such costs were expensed as research and development expenses. Effective as of the FDA approval of taliglucerase alfa on May 1, 2012, we capitalize all manufacturing costs associated with taliglucerase alfa.

*Research and Development Expenses, Net*

Research and development expenses were \$22.1 million for the nine months ended September 30, 2012, a decrease of \$1.4 million, or 6%, from \$23.5 million for the nine months ended September 30, 2011. The decrease resulted primarily from a decrease of \$1.1 million in costs related to consulting and subcontractors associated with research and development activities, a decrease of \$647,000 representing costs related to materials and \$2.2 million in certain expenses, such as rent, depreciation and maintenance, that were classified as cost of revenues or capitalized as inventory after the FDA's approval of taliglucerase alfa. The decrease was partially offset by \$3.3 million in salaries expense resulting primarily from bonuses paid in connection with the FDA's approval of taliglucerase alfa on May 1, 2012 and share-based compensation. The decrease was also the result of grants received from the OCS of approximately \$3.2 million during the nine months ended September 30, 2012, compared to the total of grants of \$2.6 million received from the OCS, during the nine months ended September 30, 2011.

We expect research and development expenses for our various development programs to continue to be our primary expense.

*General and Administrative Expenses*

General and administrative expenses were \$7.4 million for the nine months ended September 30, 2012, an increase of \$2.1 million, or 38%, from \$5.3 million for the nine months ended September 30, 2011. The increase resulted primarily from an increase of \$2.5 million in salaries expense primarily due to bonuses paid in connection with the FDA's approval of taliglucerase alfa on May 1, 2012 and share-based compensation. The increase was partially offset by a decrease of \$423,000 in legal and accounting expenses.

*Financial Income, Net*

Financial income was \$264,000 for the nine months ended September 30, 2012, compared to financial income of \$57,000 for the nine months ended September 30, 2011.

**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 in the United States and the September 2012 approval by the Israeli MOH) to generate significant product sales revenue, we have not been profitable, with the exception of the second quarter of 2012, for which profits were recorded that were primarily the result of the \$25.0 million milestone payment we received in connection with the FDA's approval of taliglucerase alfa on May 1, 2012, 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 shares of our 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. In addition, we received a \$25.0 million milestone payment in connection with the FDA's approval of taliglucerase alfa in May 2012. Protalix Ltd. is entitled to payments equal to 40% of the net profits earned by Pfizer on Pfizer's sales of taliglucerase alfa. 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 \$1.2 million for the nine months ended September 30, 2012. The net loss for the nine months ended September 30, 2012 of \$1.7 million decreased primarily due to \$6.1 million in share-based compensation and \$2.8 million in depreciation, which was partially offset by a decrease of \$5.0 million in deferred revenues and increase of \$2.1 million in accounts receivable and increase of \$1.8 million in inventory. Net cash used in investing activities for the nine months ended September 30, 2012 was \$1.9 million and consisted primarily of purchases of property and equipment. Net cash provided by financing activities was \$26.4 million, consisting primarily of net proceeds from our February 2012 underwritten public offering of common stock.

Net cash used in operations was \$17.0 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 March 2011 underwritten public offering of our common stock.

### *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 as Pfizer's commercialization efforts for taliglucerase alfa progress after the FDA's approval in May 2012, and as we begin to generate revenues from the commercialization of taliglucerase alfa in Israel after the Israeli MOH' approval in September 2012. We also anticipate that we will generate additional revenues to offset any losses after additional anticipated marketing approvals of taliglucerase alfa are granted outside of the United States and Israel, including, primarily, in Brazil. We expect to continue 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 administrative staff, add infrastructure and incur additional costs related to the continued progression of the commercialization of taliglucerase alfa.

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

Our future capital requirements will depend on many factors, including the progress of Pfizer's commercialization efforts in the United States, the progress of our commercialization efforts in Israel and, if anticipated marketing approvals of taliglucerase alfa are granted in other jurisdictions, the progress of Pfizer's global commercialization efforts, the progress and results of our clinical trials, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

We may need to finance our future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. Any sale of additional equity or debt securities will likely result in dilution to our shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

### **Effects of Inflation and Currency Fluctuations**

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2012 or the nine months ended September 30, 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 nine months ended September 30, 2012 or the nine months ended September 30, 2011.

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

We have no off-balance sheet arrangements as of each of September 30, 2012 and September 30, 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:

|                         | Nine months ended |       | Year ended   |
|-------------------------|-------------------|-------|--------------|
|                         | September 30,     |       | December 31, |
|                         | 2012              | 2011  | 2011         |
| Average rate for period | 3.861             | 3.530 | 3.578        |
| Rate at period end      | 3.912             | 3.712 | 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 September 30, 2012 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.



## **PART II – OTHER INFORMATION**

### Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

### Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

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

#### **Unregistered Sales of Equity Securities**

There were no unregistered sales of equity securities during the nine months ended September 30, 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  | 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, as amended July 15, 2012   | 8-K                       | 001-33357   | 3.1     | July 18, 2012  |                |
| 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, 2012 By: /s/ David Aviezer  
David Aviezer, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 7, 2012 By: /s/ Yossi Maimon  
Yossi Maimon  
Chief Financial Officer, Treasurer and Secretary  
(Principal Financial and Accounting Officer)