Protalix BioTherapeutics, Inc.
Form 10-Q
November 08, 2010

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

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

For the transition period from _____ to _____

001-33357
(Commission file number)

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

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

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

On November 1, 2010, approximately 81,211,718 shares of the Registrant s common stock, $0.001 par value, were outstanding.

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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 Management s Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors, and other statements included elsewhere in this Quarterly Report on Form 10-Q, which are not historical, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms anticipate, believe, estimate, expect and intend and words or phrases of similar import, as they relate to us or our subsidiaries or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

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

- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;
- delays in our preparation and filing of applications for regulatory approval;
- delays in the approval or the potential rejection of any applications we file with the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities, including the New Drug Application (NDA) we have filed with the FDA for taliglucerase alfa;
- any lack of progress of our research and development (including the results of clinical trials we are conducting);
- obtaining on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- our ability to obtain additional financing required to fund our research programs;
- the risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all;
- our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationship with Pfizer Inc., Teva Ltd. or with any other collaborator, distributor or partner;
- potential product liability risks and risks of securing adequate levels of product liability and clinical trial insurance coverage;
- the availability of reimbursement to patients from health care payors for any of our product candidates, if approved;
- the possibility of infringing a third party s patents or other intellectual property rights;
- the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties; and

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

In addition, companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated by clinical trials of a drug product, the FDA might not accept or approve an NDA filed by a pharmaceutical or biotechnology company for the drug product. These and other risks and uncertainties are detailed in our Annual Report on Form 10-K for the year ended December 31, 2009, Section 1A, under the heading Risk Factors and are described from time to time in the reports we file with the Securities and Exchange Commission. 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.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2010 (Unaudited)	December 31, 2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 44,401	$ 81,266
Accounts receivable	8,943	2,144
Inventories	5,097	
Total current assets	58,441	83,410
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	866	724
PROPERTY AND EQUIPMENT, NET	15,841	14,537
Total assets	$ 75,148	$ 98,671
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals		
Trade	$ 5,667	$ 3,406
Other	10,257	13,561
Deferred revenues	4,563	4,563
Total current liabilities	20,487	21,530
LONG-TERM LIABILITIES:		
Deferred revenues	56,627	60,049
Liability for employee rights upon retirement	1,575	1,209
Total long term liabilities	58,202	61,258
COMMITMENTS		
Total liabilities	78,689	82,788
SHAREHOLDERS EQUITY (CAPITAL DEFICIENCY)	(3,541)	15,883
Total liabilities and shareholders equity	$ 75,148	$ 98,671

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

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

	Nine months ended		Three Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
REVENUES	$ 5,466		$ 3,184	
COMPANY S SHARE IN COLLABORATION AGREEMENT	(1,887)		(1,065)	
RESEARCH AND DEVELOPMENT EXPENSES (1)	(23,032)	$ (17,330)	(4,440)	$ (6,034)
less grants	2,640	4,223	894	1,423
	(20,392)	(13,107)	(3,546)	(4,611)
GENERAL AND ADMINISTRATIVE EXPENSES (2)	(4,305)	(3,847)	(1,421)	(1,435)
OPERATING LOSS	(21,118)	(16,954)	(2,848)	(6,046)
FINANCIAL INCOME NET	648	450	374	152
NET LOSS FOR THE PERIOD	$ (20,470)	$ (16,504)	$ (2,474)	$ (5,894)
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED:	$ 0.25	$ 0.22	$ 0.03	$ 0.08
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:				
Basic and diluted	80,879,843	76,236,399	80,914,930	76,564,441
(1) Includes share-based compensation	431	1,026	213	363
(2) Includes share-based compensation	456	976	142	475

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

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

	Common Stock (1)	Common Stock*	Additional paid in capital	Accumulated deficit	Total
	Number	Amount			
Balance at December 31, 2008	**75,938,059**	**$ 76**	**$ 119,281**	**$ (75,010)**	**$ 44,347**
Changes during the nine month period ended September 30, 2009					
(Unaudited):					
Share-based compensation			2,002		2,002
Exercise of options granted to employees (includes Net Exercise)	745,004	1	231		232
Net loss for the period				(16,504)	(16,504)
Balance at September 30, 2009 (Unaudited)	**76,683,063**	**$ 77**	**$ 121,514**	**$ (91,514)**	**$ 30,077**
Balance at December 31, 2009	**80,841,237**	**$ 81**	**$ 122,252**	**$ (106,450)**	**$ 15,883**
Changes during the nine month period ended September 30, 2010					
(Unaudited):					
Share-based compensation			$ 887		$ 887
Exercise of options granted to employees (includes Net Exercise)	172,300	*	159		159
Net loss for the period				(20,470)	(20,470)
Balance at September 30, 2010 (Unaudited)	**81,013,537**	**$ 81**	**$ 123,298**	**$ (126,920)**	**$ (3,541)**

(1) Common Stock, $0.001 par value; Authorized as of September 30, 2010 and September 30, 2009 150,000,000 shares.

* Represents an amount less than $1.

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

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

	Nine months ended	
	September 30, 2010	**September 30, 2009**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,470)	$ (16,504)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities		
Share based compensation	887	2,002
Depreciation of fixed assets	2,244	1,407
Financial expenses net (mainly exchange differences)	(331)	(164)
Changes in accrued liability for employee rights upon retirement	330	195
Loss on amounts funded in respect of employee rights upon retirement	(16)	(59)
Loss on sale of fixed assets	11	10
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non-current portion)	(3,422)	
Increase in accounts receivable	(6,702)	(1,724)
Increase in Inventories	(5,097)	
Increase in accounts payable, accruals other long-term liabilities	2,133	171
Net cash used in operating activities	$ (30,433)	$ (14,666)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (6,816)	$ (5,648)
Proceeds from sale of property and equipment		75
Amounts funded in respect of employee rights upon retirement, net	(101)	(60)
Net cash used in investing activities	$ (6,917)	$ (5,633)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of options	$ 159	$ 200
Net cash provided by financing activities	$ 159	$ 200
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 326	$ 113
NET DECREASE IN CASH AND CASH EQUIVALENTS	(36,865)	(19,986)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	81,266	42,596
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 44,401	$ 22,610

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

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

(Continued) 2

	Nine months ended	
	September 30, 2010	**September 30, 2009**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 1,268	$ 2,047
Issuance cost not yet paid and accruals other	$ 5	$ 5
Exercise of options granted to employees		$ 32

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

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PROTALIX BIOTHERAPEUTICS, INC.

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

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES

a. General

1. Operation

Protalix BioTherapeutics, Inc. and its wholly-owned subsidiary, Protalix Ltd. (Protalix Ltd., and collectively with Protalix BioTherapeutics, Inc., the Company), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company s proprietary ProCellEx[tm] protein expression system (ProCellEx). In September 2009, the Company formed another wholly-owned subsidiary under the laws of the Netherlands in connection with the European Medicines Agency, or EMEA, application process in Europe. The Company s lead product development candidate is taliglucerase alfa for the treatment of Gaucher disease, which the Company is developing using its ProCellEx protein expression system.

In September 2009, the Company successfully completed its phase III pivotal trial of taliglucerase alfa. In July 2010, the U.S. Food and Drug Administration (FDA) notified the Company that it had accepted the Company s new drug application (NDA) for taliglucerase alfa for the treatment of Gaucher disease and that it granted to taliglucerase alfa a Prescription Drug User Fee Act (PDUFA) action date of February 25, 2011. In addition to its phase III clinical trial, the Company initiated a clinical study in December 2008 to evaluate the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with taliglucerase alfa. This switchover-study is not a prerequisite for the marketing approval of taliglucerase alfa.

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

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

On July 13, 2010 the French regulatory authority granted an Autorisation Temporaire d Utilisation (ATU), or Temporary Authorization for Use, for taliglucerase alfa for the treatment of Gaucher disease. An ATU is the regulatory mechanism used by the French Health Products and Safety Agency to make non-approved drugs available to patients in France when a genuine public health need exists. This ATU allows patients with Gaucher disease in France to receive treatment with taliglucerase alfa before marketing authorization for the product is granted in the European Union. Payment for taliglucerase alfa has been secured through government allocations to hospitals.

On August 10, 2010, Pfizer entered into a $30 million short-term supply agreement with the Ministry of Health of Brazil pursuant to which the Company and Pfizer will provide taliglucerase alfa to Gaucher disease patients in such country.

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

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):

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

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

2. Subsequent Events

The Company has evaluated events through the date of issuance of the financial statements. See Note 4.

b. General Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial information and Article 10 of Regulation S-X under the Securities Exchange Act of 1934. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year. Prior to December 2009, the Company was a development stage company as defined under the guidance for Development Stage Enterprises. The Company has determined that, as of November 30, 2009, it is no longer a development stage company.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2009, filed by the Company with the Securities and Exchange Commission. The comparative balance sheet at December 31, 2009 has been derived from the audited financial statements at that date, but does not include all of the information and notes required under GAAP for complete financial statements.

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

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):

c. Inventories

Inventories are valued at the lower of cost or market. Cost of raw and packaging materials and purchased products is determined using the moving average basis. Cost of finished products and products in process is determined as follows: the value of the raw and packaging materials component is determined primarily on a using the moving average basis; the value of the labor and overhead component is determined on an average basis over the production period.

d. Revenue Recognition

The Company recognizes revenue when the earnings process is complete, which is when revenue is realized or realizable and earned, there is persuasive evidence a revenue arrangement exists, delivery of goods or services has occurred, the sales price is fixed or determinable and collectability is reasonably assured.

1. Revenues from the license and supply agreement with Pfizer

The Company earns revenue under collaboration agreements with third parties to develop and produce drug candidates. The Company recognizes revenue and milestone payments in accordance with guidance regarding revenue recognition and accounting for revenue arrangements with multiple deliverables. Pursuant to this guidance, the Company determines whether an arrangement involves multiple revenue-generating deliverables that should be accounted for as a combined unit of accounting or separate units of accounting for revenue recognition purposes. If it is determined that there are multiple units of accounting, the consideration from the arrangement is allocated among the separate units based on a relative fair value allocation. If the arrangement represents a single unit of accounting, the revenue is recognized over the performance obligation period. Non-refundable, up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each collaboration agreement and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances.

2. Company s share in the collaboration agreement

Under the terms and conditions of the Pfizer Agreement, the Company is entitled to 40% of the profits or loss from sales of taliglucerase alfa, and related expenses incurred, under the Pfizer Agreement. The Company recognizes its share of net profit or loss from the Pfizer Agreement based on reports it receives from Pfizer summarizing the results of the collaborative activities under the agreement for the applicable period. Under the terms of the Pfizer Agreement, for its subsidiaries operating outside the United States, financial information 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.

3. Revenues from selling products to Pfizer

The Company recognizes revenues received from products sold to Pfizer at the time the Company delivers the product to Pfizer. The revenues represent the Company s cost with respect to the products.

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

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):

e. Research and Development Costs

Reimbursements received from Pfizer and other research foundations are recognized when the reimbursements become receivable provided there is reasonable assurance that the Company will comply with the conditions attached to the reimbursements and there is reasonable assurance the reimbursements will be received. The reimbursements are deducted from the related research and development expenses as the applicable costs are incurred.

f. Net loss per share

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

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

Diluted LPS does not include options in the amount of 11,364,973 and 7,729,307shares of Common Stock for the nine months ended September 30, 2009 and 2010, respectively, and 11,127,112 and 7,954,811 shares of Common Stock for the three months ended September 30, 2009 and 2010, respectively.

g. Newly Issued Accounting Pronouncements

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

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

h. Reclassifications

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

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

NOTE 2 INVENTORIES

Inventory at September 30, 2010 consisted of the following:

	September 30, 2010
Raw materials	$ 1,720
Work in process	2,366
Finished goods	1,011
Total inventory	$ 5,097

NOTE 3 STOCK TRANSACTIONS

a. During the nine months ended September 30, 2010, the Company issued a total of 172,300 shares of Common Stock in connection with the exercise of a total of 186,605 options by certain employees of the Company. The Company received aggregate cash proceeds equal to approximately $159 in connection with such exercises, and 20,312 of the options were exercised on a net exercise basis.

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

c. In February 2010, the Company s Board of Directors approved the grant of options to purchase 1,016,000 shares of Common Stock, in the aggregate, to certain officers and employees of the Company with an exercise price equal to $6.90 per share. The options vest quarterly over three years, commencing after the FDA s approval of taliglucerase alfa, if at all. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $5,700, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 75.74%; risk-free interest rates of 3.69%; and expected life of 10 years. The Company will start charging these expenses following the FDA s approval of taliglucerase alfa, if at all.

d. In September 2010, the Company s Board of Directors approved the grant of options to purchase 160,000 shares of Common Stock to a new executive officer of the Company with an exercise price equal to $7.55 per share and options to purchase 40,000 shares of Common Stock to a new employee of the Company with an exercise price equal to $6.32 per share. The options vest over a four-year period, with the first 25% to vest on the first anniversary of the applicable date of the grant and the remaining 75% in equal tranches on a quarterly basis for three years thereafter. The options are exercisable over a 10-year period commencing on the applicable date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $987 based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 73%; risk-free interest rates of 1.68%; and expected life of six years.

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

NOTE 3 STOCK TRANSACTIONS (Continued):

e. In September 2010, the Company s Board of Directors modified the terms of the options previously granted to an executive in 2001, by extending the life of the options until 2021. At the date of modification, all of the options were fully vested. The Company concluded that there was no incremental increase in the value of the awards and therefore no accounting charges need to be recorded in connection with the modifications.

NOTE 4 SUBSEQUENT EVENTS

a. During October 2010, the Company issued a total of 198,181 shares of Common Stock in connection with the exercise of options to purchase 205,950 shares of Common Stock by certain officers and employees of the Company. The Company received aggregate cash proceeds equal to approximately $279 in connection with the exercise of 128,181 options and 77,769 of such options were exercised on a net-exercise basis.

b. In November 2010, the Company s Board of Directors approved the grant of options to purchase 68,000 shares of Common Stock to a new executive officer of the Company with an exercise price equal to $9.66 per share. The options vest over a four-year period, with the first 25% to vest on the first anniversary of the applicable date of the grant and the remaining 75% in equal tranches on a quarterly basis for three years thereafter. The options are exercisable over a 10-year period commencing on the applicable date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $421 based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 72%; risk-free interest rates of 1.54%; and expected life of six years.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the consolidated financial statements and the related notes included elsewhere in this Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2009. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2009 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx™ protein expression system, or ProCellEx. Using our ProCellEx system, we are developing a pipeline of proprietary and biosimilar or generic versions of recombinant therapeutic proteins based on our plant cell-based expression technology that target large, established pharmaceutical markets and that rely upon known biological mechanisms of action. Our initial commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease. We believe our ProCellEx protein expression system will enable us to develop proprietary recombinant proteins that are therapeutically equivalent or superior to existing recombinant proteins currently marketed for the same indications. Because we are primarily targeting biologically equivalent versions of highly active, well-tolerated and commercially successful therapeutic proteins, we believe our development process is associated with relatively less risk compared to other biopharmaceutical development processes for completely novel therapeutic proteins.

Our lead product development candidate is taliglucerase alfa for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. Taliglucerase alfa is our proprietary recombinant form of glucocerebrosidase (GCD), an enzyme naturally found in human cells that is mutated or deficient in patients with Gaucher disease. In July 2007, we reached an agreement with the U.S. Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of taliglucerase alfa, through the FDA s special protocol assessment (SPA) process. The phase III clinical trial was completed in September 2009 and, on October 15, 2009, we announced positive top-line results from the trial. On December 9, 2009, we filed our New Drug Application (NDA) for taliglucerase alfa, and in January 2010 the FDA requested additional data regarding the Chemistry, Manufacturing and Controls (CMC) section of our NDA. We provided the requested data in April 2010 and in July 2010 we received notification from the FDA that it had accepted the filing of our NDA and assigned a PDUFA date of February 25, 2011 to taliglucerase alfa.

In March 2010, the Israeli Ministry of Health completed a successful audit of our manufacturing facilities in Carmiel, Israel. The audit was performed as part of the Ministry of Health s evaluation of our manufacturing process for taliglucerase alfa.

In addition to our recently completed phase III clinical trial, during the third quarter of 2008, we initiated a double-blind, follow-on extension study as part of the trial. We also initiated a home care treatment program for patients enrolled in the extension study and in December 2008, we initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with taliglucerase alfa. The current standard of care for Gaucher patients is enzyme replacement therapy with Cerezyme™ which is produced by Genzyme Corporation and, until the recent approval of VPRIV™ by Shire plc in February 2010, the only approved enzyme replacement therapy for Gaucher disease. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional. The switch-over study is not a prerequisite for approval of taliglucerase alfa by the FDA. In December 2009 we filed a proposed pediatric investigation plan to the Pediatric Committee of the European Medicines Agency, or EMEA, which was approved during the second quarter of 2010.

On November 30, 2009, Protalix Ltd. and Pfizer Inc., or Pfizer, entered into an exclusive license and supply agreement pursuant to which Pfizer was granted an exclusive, worldwide license to develop and commercialize

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taliglucerase alfa. Under the terms and conditions of the Pfizer agreement, Protalix Ltd. retained the right to commercialize taliglucerase alfa in Israel. In connection with the execution of the Pfizer agreement, Pfizer made an upfront payment to Protalix Ltd. of $60.0 million in connection with the execution of the agreement and subsequently paid Protalix Ltd. an additional $5.0 million upon our filing of a proposed pediatric investigation plan to the Pediatric Committee of the EMEA. Protalix Ltd. is also eligible to receive potential milestone payments totaling $50.0 million for the successful achievement of other developmental milestones and to royalties equal to 40% of the net profits earned on Pfizer s sales of taliglucerase alfa, if any. Pfizer and Protalix Ltd. have agreed to a specific allocation of the responsibilities for the continued development efforts for taliglucerase alfa.

In July 2009, following a request by the FDA, we submitted a treatment protocol 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. In September 2009, the FDA s Office of Orphan Product Development granted taliglucerase alfa Orphan Drug Status. In January 2010, the Committee for Orphan Medicinal Products (COMP) of the EMEA, after reviewing all relevant clinical data, recommended that the European Commission grant orphan drug designation to taliglucerase alfa for the treatment of Gaucher disease.

On July 13, 2010, we announced that the French regulatory authority has granted an Autorisation Temporaire d Utilisation (ATU), or Temporary Authorization for Use, for taliglucerase alfa for the treatment of Gaucher disease. An ATU is the regulatory mechanism used by the French Health Products and Safety Agency to make non-approved drugs available to patients in France when a genuine public health need exists. This ATU allows patients with Gaucher disease in France to receive treatment with taliglucerase alfa before marketing authorization for the product is granted in the European Union. Payment for taliglucerase alfa has been secured through government allocations to hospitals.

On August 10, 2010, Pfizer entered into a $30 million short-term supply agreement with the ministry of health of a Latin American country pursuant to which we and Pfizer will provide taliglucerase alfa to Gaucher disease patients in such country.

The Orphan Drug designation in the United States for taliglucerase alfa for the treatment of Gaucher disease provides special status to taliglucerase alfa provided that it meets certain criteria. As a result of the orphan designation, we are qualified for the tax credit and marketing incentives of the Orphan Drug Act of 1983. A marketing application for a prescription drug product that has been designated as a drug for a rare disease or condition is not subject to a prescription drug user fee unless the application includes an indication for other than a rare disease or condition.

In addition to taliglucerase alfa, we are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates, therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, an acetylcholinesterase enzyme-based therapy for biodefense, antiTNF, a plant cell expressed recombinant fusion protein made from the soluble form of the human TNF receptor (TNFR) which is being developed as a treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis and others, and additional undisclosed therapeutic proteins and intoxication treatments, all of which are currently being evaluated in animal studies. In March 2010, we initiated a phase I clinical trial of PRX-105, our plant cell expressed pegylated recombinant acetylcholinesterase product candidate for biodefense indications, which we completed in June 2010. We are currently preparing for further efficacy trials in larger animals.

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

Our common stock has been listed for trade on the NYSE Amex (formerly, the American Stock Exchange), since March 12, 2007 and, since September 6, 2010, traded on the Tel Aviv Stock Exchange. Our business is conducted by our wholly-owned subsidiary, Protalix Ltd., which we acquired through a reverse merger transaction effective December 31, 2006. Since its inception in December 1993, Protalix Ltd. has generated significant losses in connection

with its research and development, including the clinical development of taliglucerase alfa. Since we currently do not generate significant revenue from any of our product candidates, we expect to continue to generate losses over the next several years in connection with research and development activities relating to our pipeline of product candidates and the commercialization costs associated with the expected launch of taliglucerase alfa in

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Israel. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe that our operating losses may be substantial over the next several years. We may need to obtain additional funds to continue the research and clinical development of our programs.

Critical Accounting Policies

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

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate such estimates and judgments, including those described in greater detail below, on an on-going basis. 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, 2010 compared to the three months ended September 30, 2009

Revenues

We recorded revenues of $3.2 million during the three months ended September 30, 2010. The revenues include the pro rata amortization of the $60.0 million upfront payment and $5.0 million milestone payment we received in connection with our license and supply agreement with Pfizer of $1.1 million. In addition, the revenues include approximately $2.1 million that represents the cost we incurred in connection with the taliglucerase alfa vials delivered to Pfizer under the Pfizer Agreement. No revenues were recorded during the three months ended September 30, 2009.

Our share in the collaboration agreement

We recorded approximately $1.1 million of loss as our share in the collaboration under the Pfizer Agreement during the three months ended September 30, 2010. The share in the collaboration represents our 40% share of the collaboration s profit and loss calculation. During the three months ended September 30, 2010, Pfizer s revenue under the Pfizer Agreement resulted from the first shipment of taliglucerase alfa to France made pursuant to the ATU, with the associated operating costs. The associated costs are not allowed to exceed the higher of a certain fixed amount or a percentage of sales and our cost of goods sold, which also may not exceed a certain percentage of revenue. Under the terms of the Pfizer Agreement, for its subsidiaries operating outside the United States, financial information 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. No company s share in collaboration was recorded during the three months ended September 30, 2009.

Research and Development Expenses

Research and development expenses were $4.4 million for the three months ended September 30, 2010, a decrease of $1.6 million, or 27.0%, from $6.0 million for the three months ended September 30, 2009. The decrease resulted primarily from our capitalization of certain expenses into approximately $5.1 million of inventory, which was recognized on September 30, 2010 for the first time. The decrease was partially offset as the result of the increased number of clinical sites and patients enrolled in our ongoing clinical trials during the three months ended September 30, 2010 when compared to the three months ended September 30, 2009, and to the increase in the number of projects we have initiated since the beginning of 2010. The decrease was partially offset by grants of $894,000 from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the OCS, during the three months ended September 30, 2010, a decrease of approximately $529,000, or 38%, compared to grants equal to $1.4 million received from the OCS during the three months ended September 30, 2009.

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

General and Administrative Expenses

General and administrative expenses were $1.4 million for the three months ended September 30, 2010, same as for the three months ended September 30, 2009.

Financial Expenses and Income

Financial income was $374,000 for the three months ended September 30, 2010, compared to a financial income of $152,000 for the three months ended September 30, 2009, mainly due to higher cash balance during the three months ended September 30, 2010.

Nine months ended September 30, 2010 compared to the nine months ended September 30, 2009

Revenues

We recorded revenues of $5.5 million during the nine months ended September 30, 2010. The revenues include the pro rata amortization of the $60.0 million upfront payment and $5.0 million milestone payment we received in connection with our license and supply agreement with Pfizer of approximately $3.4 million. In addition, the revenues include approximately $2.1 million that represents the cost we incurred in connection with the vials of taliglucerase alfa delivered to Pfizer under the Pfizer Agreement. No revenues were recorded during the nine months ended September 30, 2009.

Our share in the collaboration agreement

We recorded approximately $1.9 million of loss as our share in the collaboration under the Pfizer Agreement during the nine months ended September 30, 2010. The share in the collaboration agreement represents our 40% share of the collaboration s profit and loss calculation. During the nine months ended September 30, 2010, Pfizer s revenue under the Pfizer Agreement resulted from the first shipment of taliglucerase alfa to France made pursuant to the ATU, with the associated operating costs. The associated costs are not allowed to exceed the higher of a certain fixed amount or a percentage of sales and our cost of goods sold, which also may not exceed a certain percentage of revenue. Under the terms of the Pfizer Agreement, for its subsidiaries operating outside the United States, financial information 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. No company s share in collaboration was recorded during the nine months ended September 30, 2009.

Research and Development Expenses

Research and development expenses were $23.0 million for the nine months ended September 30, 2010, an increase of $5.7 million, or 32.9% from $17.3 million for the nine months ended September 30, 2009. The increase resulted from the increased number of clinical sites and patients enrolled in our ongoing clinical trials during 2010, when compared to 2009, and the increase in the number of projects we have initiated since the beginning of 2010. The increase was partially offset by the capitalization of certain expenses into approximately $5.1 million of inventory which was recognized on September 30, 2010 for the first time. The increase was also partially offset by grants of $2.6 million from the OCS during the nine months ended September 30, 2010, a decrease of approximately $1.6 million, or 38.1%, compared to grants equal to $4.2 million received from the OCS during the nine months ended September 30, 2009.

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

General and Administrative Expenses

General and administrative expenses were $4.3 million for the nine months ended September 30, 2010, an increase of $458,000, or approximately 12.1%, from $3.8 million for the nine months ended September 30, 2009. The increase resulted primarily from an increase of $354,000 in salaries expense.

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Financial Expenses and Income

Financial income was $648,000 for the nine months ended September 30, 2010 compared to $450,000 for the nine months ended September 30, 2009, primarily the result of a higher cash balance during the nine months ended September 30, 2010.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since our inception. To date, we have funded our operations primarily with proceeds equal to $31.3 million from the private sale of our shares of common stock and from sales of convertible preferred and ordinary shares of Protalix Ltd., and an additional $14.2 million in connection with the exercise of warrants issued in connection with the sale of such ordinary shares, through December 31, 2009. In addition, on October 25, 2007, we generated gross proceeds of $50.0 million in connection with an underwritten public offering of our common stock.

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

We believe that the funds currently available to us, as well as the funds we except to receive in connection with our anticipated share in profit from contracts and/or shipments of taliglucerase alfa already made and future milestone payments, will be sufficient to satisfy our capital needs for the foreseeable future.

Cash Flows

Net cash used in operations was $30.4 million for the nine months ended September 30, 2010. The net loss for the nine months ended September 30, 2010 of $20.5 million increased primarily from an increase of $5.1 million in inventories and an increase of $6.7 million in accounts receivable, and a decrease of $3.4 million in deferred revenues, but partially offset by $2.2 million in depreciation and $2.1 million increase in accounts payable. Net cash used in investing activities for the nine months ended September 30, 2010 was $6.9 million and consisted primarily of purchases of property and equipment.

Net cash used in operations was $14.7 million for the nine months ended September 30, 2009. The net loss for the nine months ended September 30, 2009 of $16.5 million was partially offset by $2.0 million of non-cash share-based compensation and $1.4 million of depreciation expense. In addition, net loss increased due to an increase of $1.7 million in accounts receivable. Net cash used in investing activities for the nine months ended September 30, 2009 was $5.6 million and consisted primarily of purchases of property and equipment. Net cash provided from financing activities for the nine months ended September 30, 2009 was approximately $200,000, consisting of exercise price paid in connection with certain exercise of stock options.

Future Funding Requirements

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

We believe that the funds currently available to us, as well as the funds we except to receive in connection with our anticipated share in profit from contracts and/or shipments of taliglucerase alfa already made and future milestone payments, will be sufficient to satisfy our capital needs for the foreseeable future. We have based this

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estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

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

Effects of Inflation and Currency Fluctuations

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2010 or the nine months ended September 30, 2009.

Currency fluctuations could affect us by increased or decreased costs mainly for goods and services acquired outside of Israel. We do not believe currency fluctuations have had a material effect on our results of operations during the nine months ended September 30, 2010 or the nine months ended September 30, 2009.

Recently Issued Accounting Pronouncements

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

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

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2010 and September 30, 2009.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Currency Exchange Risk

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

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

	Nine months ended September 30,		Year ended December 31,
	2010	2009	2009
Average rate for period	3.7707	3.9885	3.933
Rate at period end	3.6650	3.7580	3.775

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

Interest Rate Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and

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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 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, 2010. The changes relate to the processes associated with the evaluation of our new revenue contracts and accounting for inventories.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

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

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities during the three months ended September 30, 2010.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Reserved and Removed)

Item 5. Other Information

None.

Item 6. Exhibits

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File Number**	**Exhibit**	**Date**	**Filed Herewith**
3.1	Amended and Restated Articles of Incorporation of the Company	S-4	333-48677	3.4	March 26, 1998	
3.2	Article of Amendment to Articles of Incorporation dated June 9, 2006	8-A	001-33357	3.2	March 9, 2007	
3.3	Article of Amendment to Articles of Incorporation dated December 13, 2006	8-A	001-33357	3.3	March 9, 2007	
3.4	Article of Amendment to Articles of Incorporation dated December 26, 2006	8-A	001-33357	3.4	March 9, 2007	
3.5	Article of Amendment to Articles of Incorporation dated February 26, 2007	8-A	001-33357	3.5	March 9, 2007	
3.6	Amended and Restated Bylaws of the Company	10-Q	001-33357	3.6	August 8, 2008	
10.1	Employment Agreement by and between Protalix Ltd., and Tzvi Palash dated as of August 29, 2010	8-K	001-33357	10.1	September 7, 2010	

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Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	File Number	Exhibit Date	
10.2	License Agreement between Protalix Biotherapeutics Ltd. and Virginia Tech Intellectual Properties, Inc.				X
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

Portions of this exhibit were omitted and have been filed separately with the Secretary of the Securities and Exchange Commission pursuant to the Registrant s application requesting confidential treatment under Rule 24b-2 of the Exchange Act.

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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 8, 2010

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

Date: November 8, 2010

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