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 eq