Protalix BioTherapeutics, Inc.
Form 10-Q
November 14, 2007

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2007

OR

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

For the transition period from to

001-33357

(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Florida	65-0643773
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

972-4-988-9488

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, par value $0.001 per share	American Stock Exchange

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

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

Large accelerated filer	Accelerated filer	Non-accelerated filer

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

On November 13, 2007, approximately 75,685,318 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 Prota 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 our 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 o subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

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

- the 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 potential rejection of any applications we file with the United States Food and Drug Administration, or other regulatory authorities;
- 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 relationships with collaborators, distributors and partners;
- 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 procedures in which our products are used;

- 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 successfully enforcing them 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 subsidiary, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees, and clinical trial sites.

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In addition, companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. These and other risks and uncertainties are detailed in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2006 and described from time to time in our future reports filed with the Securities and Exchange Commission. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

PROTALIX BIOTHERAPEUTICS, INC.
(A development stage company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	September 30, 2007	December 31, 2006
	(Unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 20,440	$ 15,378
Deposit		7,577
Accounts receivable	1,698	1,336
Deferred issuance cost	407	
Total current assets	22,545	24,291
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	402	293
PROPERTY AND EQUIPMENT, NET	3,763	2,404
Total assets	$ 26,710	$ 26,988
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES –		
Accounts payable and accruals:		
Trade	$ 1,359	$ 892
Other	2,254	1,376
Total current liabilities	3,613	2,268
LONG-TERM LIABILITY		
Liability for employee rights upon retirement	629	436
Total liabilities	4,242	2,704
SHAREHOLDERS' EQUITY*	22,468	24,284
Total liabilities and shareholders' equity	$ 26,710	$ 26,988

* See Note 1a.

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

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PROTALIX BIOTHERAPEUTICS, INC.
(A development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share amounts)
(Unaudited)

	Nine Months Ended September 30,		Three Months Ended September 30,		Period from December 27, 1993* through September 30,
	2007	2006	2007	2006	2007
REVENUES					$ 830
COST OF REVENUES					206
GROSS PROFIT					624
RESEARCH AND DEVELOPMENT EXPENSES(1)	$ 9,537	$ 4,759	$ 3,830	$ 2,148	27,198
less – grants	(1,466)	(1,510)	(385)	(688)	(6,582)
	8,071	3.249	3,445	1,460	20,616
GENERAL AND ADMINISTRATIVE EXPENSES(2)	10,476	2,787	1,986	1,077	19,472
OPERATING LOSS	18,547	6,036	5,431	2,537	39,464
FINANCIAL INCOME – NET	(1,191)	(73)	(685)	(38)	(1,559)
OTHER INCOME	(6)		(6)		
NET LOSS BEFORE CHANGE IN ACCOUNTING PRINCIPLE	17,350	5,963	4,746	2,499	37,899
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE		(37)		(37)	
NET LOSS FOR THE PERIOD	$ 17,350	$ 5,926	$ 4,746	$ 2,499	$ 37,862
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED:					
Prior to cumulative effect of change in accounting principle	$ 0.27	$ 0.28	$ 0.07	$ 0.1	
Cumulative effect of change in accounting principle	**				
	$ 0.27	$ 0.28	$ 0.07	$ 0.1	
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER COMMON STOCK:					
Basic and diluted	65,275,435	21,095,231	65,674,568	25,527,946	
(1) Includes share-based compensation	1,979	511	895	217	3,776
(2) Includes share-based compensation	8,219	1,784	1,218	694	12,358

*

Incorporation date, see Note 1a. ** Represents an amount less than $0.01.

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

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PROTALIX BIOTHERAPEUTICS, INC.
(A development stage company)
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share data)

	Common Stock(2)		Convertible Preferred					
	Shares	Common Stock	Convertible Preferred Shares	Warrants	Additional paid-in capital	Deficit accumulated during development stage	Total	
	Number of shares	Amount						
Balance at December 27, 1993(1)								
Changes during the period from December 27, 1993 through December 31, 2006:								
Common Stock and convertible preferred A, B and C shares and warrants issued for cash (net of issuance costs of $768)	28,856,127	398,227	$ 29	$ 1	$ 1,382		$ 28,156	$ 29,568
Exercise of options granted to employees and non-employees	2,670,403	847	3		394			397
Conversion of convertible preferred shares into Common Stock	24,375,870	(399,074)	24	(1)	(23)			
Change in accounting principle						(37)	$ 37	
Expiration of warrants				(34)	34			
Merger with a wholly owned subsidiary of the Company (net of issuance cost of $642)	583,086	1			240			241
Exercise of warrants	5,296,279	5		(993)	9,658			8,670
Share-based compensation					5,957			5,957
Net loss for the period						(20,549)		(20,549)
Balance at December 31, 2006	61,781,765	62		355	44,379	(20,512)		24,284
Changes during the nine month period ended September 30, 2007 (Unaudited):								
Share-based compensation					10,188			10,188
Exercise of warrants	3,875,416	4		(355)	5,684			5,333
Exercise of options granted to employees	20,137	*			3			3
Restricted Common Stock issued for services(3)	8,000	*			10			10
Net loss for the period						(17,350)		(17,350)
Balance at September 30, 2007 (Unaudited)	65,685,318	—	$ 66	—	—	$ 60,264	$ (37,862)	$ 22,468

*

Represents an amount less than $0.01. (1) Incorporation date, see Note 1a. (2) Common Stock, $0.001 par value; Authorized – as of December 31, 2006 and September 30, 2007 – 150,000,000 shares. (3) The Company issued a total of 8,000 shares of restricted Common Stock in respect of services provided by a member of the Company's Scientific Advisory Board. (See also Note 2(d)).

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

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

	Nine Months Ended September 30,		Period from December 27, 1993* through September 30,
	2007	2007	2006
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss for the period	$ (17,350)	$ (5,926)	$ (37,862)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle	(37)	(37)	
Share based compensation	10,198	2,295	16,134
Depreciation and impairment of fixed assets	530	314	1,710
Changes in accrued liability for employee rights upon retirement	193	103	629
Loss (gain) on amounts funded in respect of employee rights upon retirement	(34)	5	(81)
Capital gain on fixed assets	(6)		(6)
Changes in operating assets and liabilities:			
Increase in accounts receivable	(362)	(579)	(1,647)
Increase in accounts payable and accruals	242	523	2,346
Net cash used in operating activities	$ (6,589)	$ (3,302)	$ (18,814)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	$ (1,072)	$ (639)	$ (4,559)
Investment grant received in respect of fixed assets			38
Proceeds from sale of property and equipment	10		10
Investment in restricted cash deposit			(47)
Amounts funded in respect of employee rights upon retirement	(89)	(85)	(492)
Amounts paid in respect of employee rights upon retirement	14	7	171
Net cash used in investing activities	$ (1,137)	$ (717)	$ (4,879)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Loan and convertible bridge loan received			$ 2,145
Repayment of loan			(1,000)
Issuance of shares and warrants, net of issuance cost	$ 14,869		28,369
Exercise of options and warrants	$ 12,913	30	14,403
Deferred issuance cost	(21)		(21)
Merger with a wholly owned subsidiary of the Company, net of issuance cost	(104)		237
Net cash provided by financing activities	$ 12,788	$ 14,899	$ 44,133
NET INCREASE IN CASH AND CASH EQUIVALENTS	5,062	10,880	20,440
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	15,378	4,741	
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 20,440	$ 15,621	$ 20,440
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the period for interest		**	$ 80
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS			
Conversion of convertible bridge loan into shares			1,145
Purchase of property and equipment	$ 956	$ 31	$ 956
Issuance cost not yet paid	5	$ 23	5
Consultants' and director credit balance converted into shares			80
Issuance cost not yet paid against deferred issuance cost	$ 386		$ 386
Issuance cost paid by a grant of options			$ 21
Merger with a wholly owned subsidiary of the Company:			
Prepaid expenses	4		

*

Incorporation date, see Note 1a. ** 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.
(A development stage company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 1 — SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (formerly Orthodontix, Inc.) (hereinafter, the ‘‘Company’’), through its wholly-owned subsidiary, Protalix Ltd., is a clinical stage biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on its proprietary ProCellEx™ protein expression system. Using its ProCellEx system, the Company is developing a pipeline of proprietary recombinant therapeutic proteins based on its plant cell-based expression technology that target large, established pharmaceutical markets and that rely upon known biological mechanisms of action. The Company’s current commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease, and female infertility disorders. The Company’s business is located in Carmiel, Israel.

On December 31, 2006, the Company consummated the acquisition of Protalix Ltd., a privately-held Israeli biotechnology company incorporated on December 27, 1993, by the merger (the ‘‘Merger’’) of its wholly-owned subsidiary, Protalix Acquisition Co., Ltd., with Protalix Ltd. As a result, Protalix Ltd. is now the Company’s wholly-owned subsidiary, with the former shareholders of Protalix Ltd. acquiring in excess of 99% of the Company’s outstanding shares of common stock, par value $0.001 per share (the ‘‘Common Stock’’) at the closing of the Merger. For accounting purposes, the Merger was treated as a recapitalization of Protalix Ltd. Accordingly, the historical financial statements of the Company reflect the historical operations and financial statements of Protalix Ltd.

The Company has been in the development stage since inception. The successful completion of the Company’s development program and its transition to commercial operations, if at all, is dependent upon obtaining necessary regulatory approvals from the United States Food and Drug Administration (‘‘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’s products will receive regulatory approvals, and a substantial amount of time may pass before the Company achieves a level of sales adequate to support the Company operations, if at all. The Company will also incur substantial expenditures in connection with the regulatory approval process and it will need to raise additional capital 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 other countries and the success of the Company’s clinical trials. The Company cannot predict the outcome of these activities.

Based on its current cash resources and commitments, which includes the proceeds of an underwritten public offering consummated by the Company on October 25, 2007 (see Note 3 below), the Company believes it should be able to maintain its planned research, operating and capital needs for at least the next 24 months. However, the Company currently does not have sufficient resources to complete the commercialization of all of its currently proposed products.

b. Share Based Compensation

For purposes of determining the fair value of the outstanding options and shares of restricted Common Stock held by non-employees that vested during during the fiscal quarter ended September 30, 2007, the Company's management used $5.00 per share, which was the public offering price of the shares of Common Stock sold in the underwritten public offering consummated by the Company on October 25, 2007 (see Note 3 below).

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

c. 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, Statement of Financial Accounting Standards (‘‘SFAS’’) No. 7, ‘‘Accounting and Reporting by Development Stage Enterprises’’, 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. 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, as amended, for the year ended December 31, 2006, filed by the Company with the Securities and Exchange Commission. The comparative balance sheet at December 31, 2006 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.

d. Net Loss per share

Basic and diluted loss per share are computed (in accordance with SFAS No. 128 ‘‘Earnings per Share’’) by dividing net loss by the weighted average number of shares of Common Stock outstanding for each period. Shares of restricted Common Stock, and the shares of Common Stock underlying outstanding options and warrants of the Company, were not included in the computation of diluted loss per share because the effect would be anti-dilutive.

The total weighted average number of shares of Common Stock underlying the convertible preferred shares (on a pre-exchange basis) which have been excluded from the calculations of diluted loss per share were 372,155 and 319,259 for the nine months and for the three months ended September 30, 2006, respectively, and none for each of the nine months and the three months ended September 30, 2007.

The diluted loss per share does not include options, restricted Common Stock and warrants of the Company in the amount of 15,394,256 and 12,233,626 for the nine months ended September 30, 2006 and 2007, respectively, and 16,188,214 and 11,887,934 for the three months ended September 30, 2006 and 2007, respectively.

e. Newly issued and recently adopted Accounting Pronouncements

1) In June 2006, the FASB issued FASB Interpretation (‘‘FIN’’) No. 48, ‘‘Accounting for Uncertainty in Income Taxes’’ (‘‘FIN 48’’), an interpretation of SFAS 109, ‘‘Accounting For Income Taxes.’’ FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction. FIN 48 is effective for fiscal years beginning after December 15, 2006 (January 1, 2007 for the Company). The Company adopted FIN 48 on January 1, 2007. The adoption did not have any impact on the Company’s financial statements.

2) In September 2006, the FASB issued SFAS No. 157, ‘‘Fair Value Measurements’’ (‘‘SFAS 157’’). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for the fiscal year beginning after September 1, 2008. The Company is currently evaluating the impact of the provisions of SFAS 157 on its financial position and results of operations.

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

3) On February 15, 2007, the FASB issued SFAS No. 159, ‘‘The Fair Value Option for Financial Assets and Financial Liabilities’’ (‘‘SFAS 159’’). Under SFAS 159, the Company may elect to report financial instruments and certain other items at fair value on a contract-by-contract basis with changes in value reported in earnings. This election is irrevocable. SFAS 159 provides an opportunity to mitigate volatility in reported earnings that is caused by measuring hedged assets and liabilities that were previously required to use a different accounting method than the related hedging contracts when the complex provisions of SFAS 133 hedge accounting are not met. SFAS 159 is effective for years beginning after November 15, 2007. The Company is currently evaluating the impact of adopting SFAS 159 on its financial position, cash flows, and results of operations.

4) In June 2007, the Emerging Issues Task Force (‘‘EITF’’) issued EITF 07-3, ‘‘Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities’’ (‘‘EITF 07-3’’). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. The EITF concluded that an entity must defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for interim or annual reporting periods in fiscal years beginning after December 15, 2007 (January 1, 2008 for the Company). The Company is currently evaluating the impact of adopting EITF 07-03 on its financial statements and results of operations.

NOTE 2 — STOCK TRANSACTIONS

a. At the closing of the Merger and in accordance with a share purchase agreement entered into in August 2006, the Company issued to Phillip Frost, M.D., and Jane H. Hsiao, Ph.D., both of whom subsequently became directors of the Company, and to one other investor that provides consulting services to the Company, options that are exercisable into 2.5%, 0.5% and 0.5%, respectively, of the Company’s issued and outstanding Common Stock on a fully-diluted basis immediately after the closing of the Merger in consideration for services provided to the Company, including the services provided by each of Dr. Frost and Dr. Hsiao as directors. The options originally vested ratably over a period of 2.5 years, 20% for each six month period while the options are outstanding, commencing upon and subject to certain events (as to changes of the vesting terms see below). The options are exercisable for a ten-year period commencing upon the date of grant. The exercise price of each option is $16.70. The options granted to the directors are accounted for as options granted to employees and the options granted to the other investor are accounted for as options granted to consultants.

In February 2007, the Company’s board of directors approved certain modifications to the vesting periods of such options. The options vest as follows: 40% of the options shall vest on March 1, 2008, and an additional 15% of the options shall vest in four equal installments on each of the following dates: June 30, 2008, December 31, 2008, June 30, 2009, and September 30, 2009.

Modification of the terms of an award is treated as an exchange of the original award for a new award, resulting in the incurrence of additional compensation cost for that incremental value. The incremental value is measured by the

difference between (a) the fair value of the modified option and (b) the value of the old option immediately before its terms are modified. The modification had no effect on the accounting records of the Company.

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(A development stage company)
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(U.S. dollars in thousands, except share data)
(Unaudited)

b. On January 31, 2007, certain warrant holders exercised, in the aggregate, warrants to purchase 3,875,416 shares of Common Stock with an aggregate exercise price of $5,333. Such warrants were issued in connection with the share purchase agreement entered into in August 2006 by such warrant holders.

c. In May 2007, the Company's board of directors approved the grant of options to purchase 204,351 shares of Common Stock to a newly-hired officer of the Company, at an exercise price of $4.33 per share. The options vest over a four-year period and are exercisable for a ten-year period commencing on the date of grant.

The Company estimated the fair value of the options on the date of the grant using the Black-Scholes option-pricing model to be approximately $5,790, based on the following assumptions: dividend yield of 0% for all years; expected volatility of 53.17%; risk-free interest rates of 4.77%; and expected life of six years.

d. In May 2007, the Company's board of directors approved the grant of 8,000 shares of restricted Common Stock to a new member of its Scientific Advisory Board. The shares vest as follows: 25% vest 12 months after the grant date and the remaining 75% of the shares vest over three years in 36 equal monthly installments.

The Company presents restricted Common Stock as ''issued'' and ''outstanding'' in its financial statements.

The estimate fair value of the restricted shares on the date of grant was approximately $215.

e. In July and August 2007, certain former employees of the Company exercised outstanding stock options, which were granted under the Company's 2006 Stock Incentive Plan, for a total of 20,137 shares of Common Stock for aggregate consideration of $3.

NOTE 3 — SUBSEQUENT EVENT

On October 25, 2007, the Company issued and sold 10,000,000 shares of Common Stock in an underwritten public offering at a price of $5.00 per share. In addition, the underwriters have an option to purchase an additional 1,500,000 shares of Common Stock at the public offering price, within 30 days of the offering. The net proceeds to the Company were approximately $46.0 million after deducting underwriting discounts and commissions and offering expenses.

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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 condensed 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, as amended, for the year ended December 31, 2006. 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, as amended, for the year ended December 31, 2006 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 ProCellEx, our proprietary protein expression system. Using our ProCellEx protein expression system, we are developing a pipeline of proprietary 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, and female infertility disorders. 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 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 novel therapeutic proteins.

Our lead product development candidate is prGCD for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. We received authorization from the FDA in April 2007 to commence a pivotal phase III clinical trial of prGCD and subsequently submitted to the FDA a request for a special protocol assessment (SPA) of the final design of the pivotal phase III clinical trial. In July 2007, we reached an agreement with the FDA on the final design that we submitted in the SPA request and in the third quarter of 2007, we initiated enrollment and treatment of patients in our phase III clinical trial of prGCD. prGCD 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. The current standard of care for Gaucher disease is enzyme replacement therapy, a medical treatment in which GCD is replaced for patients in whom the enzyme is lacking or dysfunctional. Although Gaucher is a relatively rare disease, it represents a large commercial market due to the severity of the symptoms and the chronic nature of the disease. The annual worldwide sales of Cerezyme, an enzyme replacement therapy produced by Genzyme and currently the only approved enzyme replacement therapy for Gaucher disease, were approximately $1 billion in 2006, and $546.8 million for the six months ended June 30, 2007, according to public reports by Genzyme.

In addition to prGCD, we are developing an innovative product pipeline using our ProCellEx protein expression system, including therapeutic protein candidates for the treatment of Fabry disease and female infertility disorders. We plan to file an investigational new drug application (IND) with the FDA with respect to at least one additional product during 2008. Because these product candidates are based on well-understood proteins with known biological mechanisms of action, we believe we may be able to reduce the development risks and time to market for such product candidates. 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 our products, if

approved, in North America, the European Union and in other significant markets, including Israel.

Our business is conducted by our wholly owned subsidiary, Protalix Ltd., which we acquired through a reverse merger transaction effective December 31, 2006. The accounting treatment for the

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merger transaction was a recapitalization and as such the results of operations discussed below are those of Protalix Ltd. Prior to the merger transaction, we had not conducted any operations for several years. Protalix Ltd. was originally incorporated in Israel in December 1993. Since its inception in December 1993, Protalix Ltd. has generated significant losses in connection with its research and development, including the clinical development of prGCD. At September 30, 2007, we had an accumulated deficit of $37.9 million. Since we do not generate revenue from any of our product candidates, we expect to continue to generate losses in connection with the continued clinical development of prGCD and the research and development activities relating to our technology and other drug candidates. 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 are likely to be substantial over the next several years. We will need to obtain additional funds to further develop our research and development programs.

Critical Accounting Policies

Our significant accounting policies are described in Note 1 to our condensed consolidated financial statements appearing at the beginning of this Quarterly Report on Form 10-Q.

Results of Operations

Three months ended September 30, 2007 compared to the three months ended September 30, 2006

Research and Development Expenses

Research and development expenses were $3.8 million for the three months ended September 30, 2007, an increase of $1.7 million, or approximately 81%, from $2.1 million for the three months ended September 30, 2006. The increase resulted primarily from a $914,000 increase in salaries for new and existing employees and related consulting and materials associated with research and development and from a $678,000 increase in share-based compensation resulting primarily from a grant made during the three months ended June 30, 2007 to a newly hired executive officer.

We expect research and development expenses to continue to increase as we enter into more advanced stages of clinical trials for our product candidates, especially with respect to the current phase III clinical trial of prGCD.

General and Administrative Expenses

General and administrative expenses were $2.0 million for the three months ended September 30, 2007, an increase of $909,000, or approximately 83%, from $1.1 million for the three months ended September 30, 2006. The increase resulted primarily from a $524,000 increase in share-based compensation resulting from the increase in the fair value of the Common Stock underlying the portions of certain outstanding stock options granted to consultants that vested during the three-month period ended September 30, 2007, and due to certain grants made during the third and fourth quarters of 2006. In addition, the increase resulted, in part, from a $206,000 increase in legal and accounting expenses in the three months ended September 30, 2007.

Financial Expenses and Income

Financial income was $685,000 for the three months ended September 30, 2007, an increase of $647,000, compared to a financial expense of $38,000 for the three months ended September 30, 2006. The increase resulted primarily from the interest income earned on the proceeds generated from the sale of ordinary shares of Protalix Ltd. in

September 2006 and on the proceeds generated from the exercise of certain warrants in January 2007.

Nine months ended September 30, 2007 compared to the nine months ended September 30, 2006

Research and Development Expenses

Research and development expenses were $9.5 million for the nine months ended September 30, 2007, an increase of $4.7 million, or 100%, from $4.8 million for the nine months ended

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September 30, 2006. The increase resulted primarily from a $2.9 million increase in salaries for new and existing employees and related consulting and materials associated with research and development. In addition, the increase resulted from a $1.5 million increase in share-based compensation resulting primarily from a grant made during the three months ended June 30, 2007 to a newly hired executive officer.

We expect research and development expenses to continue to increase as we enter into more advanced stages of clinical trials for our product candidates, especially with respect to the current phase III clinical trial of prGCD.

General and Administrative Expenses

General and administrative expenses were $10.5 million for the nine months ended September 30, 2007, an increase of $7.7 million, or approximately 275%, from $2.8 million for the nine months ended September 30, 2006. The increase resulted primarily from a $6.4 million increase in share-based compensation resulting from the increase in the fair value of the Common Stock underlying the portions of certain outstanding stock options granted to consultants that vested during the nine month period ended September 30, 2007. In addition, the increase resulted, in part, from a $917,000 increase in legal and accounting expenses.

Financial Expenses and Income

Financial income was $1.2 million for the nine months ended September 30, 2007, an increase of $1.1 million, compared to $73,000 for the nine months ended September 30, 2006. The increase resulted primarily from the interest income earned on the proceeds generated from the sale of ordinary shares of Protalix Ltd. in September 2006 and on the proceeds generated from the exercise of certain warrants in January 2007.

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 gross proceeds equal to $31.3 million from the sale of convertible preferred and ordinary shares of Protalix Ltd. and an additional $14.4 million in connection with the exercise of warrants issued in connection with the sale of such preferred and ordinary shares. On October 25, 2007, we generated $46.5 million in connection with an underwritten public offering. We believe that the funds currently available to us are sufficient to satisfy our planned research, operating and capital needs for at least the next 24 months.

Cash Flows

Net cash used in operations was $6.6 million for the nine months ended September 30, 2007. The net loss for the nine months ended September 30, 2007 of $17.4 million includes $10.2 million of non-cash share-based compensation. Net cash used in investing activities for the nine months ended September 30, 2007 was $1.1 million and consisted primarily of purchases of property and equipment. Net cash provided by financing activities for the nine months ended September 30, 2007 was $12.8 million, consisting of the proceeds from the exercise of certain warrants in January 2007.

Net cash used in operations was $3.3 million for the nine months ended September 30, 2006. The net loss for the three months ended September 30, 2006 of $5.9 million was mainly offset by $2.3 million of non-cash share-based compensation. Net cash used in investing activities for the nine months ended September 30, 2006 was $717,000 and consisted primarily of purchases of property and equipment.

Future Funding Requirements

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to the hiring of personnel

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and additional clinical trials. We expect that general and administrative expenses will also increase as we expand our finance and administrative staff, add infrastructure, and incur additional costs related to being a public company in the United States, including the costs of directors' and officers' insurance, investor relations programs, and increased professional fees. In addition, we are considering a new manufacturing facility that would meet the FDA requirements for the manufacture of our product candidates, which would increase our capital expenditures significantly.

We believe that our existing cash and cash equivalents, after giving effect to the proceeds we received in connection with our underwritten public offering on October 25, 2007, will be sufficient to enable us to fund our planned research, operating and capital needs for at least the next 24 months.

We will 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.

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, 2007 or the nine months ended September 30, 2006.

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, 2007 or the nine months ended September 30, 2006.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2007 or September 30, 2006.

Recently Issued Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, ''Fair Value Measurements'' (''SFAS 157''). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for the fiscal year beginning after September 1, 2008. We are currently evaluating the impact of the provisions of SFAS 157 on its financial position and results of operations.

On February 15, 2007, the FASB issued SFAS No. 159, ''The Fair Value Option for Financial Assets and Financial Liabilities'' (''SFAS 159''). Under SFAS 159, we may elect to report financial instruments and certain other items at fair value on a contract-by-contract basis with changes in value reported in earnings. This election is irrevocable. SFAS 159 provides an opportunity to mitigate volatility in reported earnings that is caused by measuring hedged assets and liabilities that were previously required to use a different accounting method than the related hedging contracts when the complex provisions of SFAS 133 hedge accounting are not met. SFAS 159 is effective for years beginning after November 15, 2007. We are currently evaluating the impact of adopting SFAS 159 on our financial position, cash flows and results of operations.

In June 2007, the Emerging Issues Task Force (''EITF'') issued EITF 07-3, ''Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities'' (''EITF 07-3''). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by

a research and development entity for future research and development activities. The EITF concluded that an entity must defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for interim or annual reporting periods in fiscal years beginning after December 15, 2007 (January 1, 2008 for our company). We are currently evaluating the impact of adopting EITF 07-03 on our financial statements and results of operations.

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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. Most 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 our 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 50% of our costs, including salaries, expenses and office expenses, are incurred in New Israeli Shekels, the 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,
	2006	2007	2006
Average rate for period	4.1628	4.5224	4.4565
Rate at period end	4.0130	4.3020	4.2250

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 4T. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures or controls and other procedures that are designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, or Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of September 30, 2007. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of September 30, 2007, our disclosure controls and procedures were effective at providing reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

Changes in Internal Controls over Financial Reporting

During the third quarter of fiscal year 2007, ending on September 30, 2007, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 from the risk factors previously disclosed in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2006.

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

There have been no unregistered sales of equity securities during the quarter ended September 30, 2007 other than the issuance of 20,137 shares of common stock, in the aggregate, on September 12, 2007 to two of our former employees in connection with the exercise of outstanding stock options granted under our 2006 Stock Incentive Plan for aggregate proceeds equal to $3,648. The shares were issued pursuant to exemptions from registration under Section 4(2) of the Securities Act of 1933.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Method of Filing
3 .1	Amended and Restated Articles of Incorporation of the Company	Incorporated by reference to the Company's Registration Statement on Form S-4 filed on March 26, 1998, SEC File No. 333-48677
3 .2	Article of Amendment to Articles of Incorporation dated June 9, 2006	Incorporated by reference to the Company's Registration Statement on Form 8-A filed on March 9, 2007
3 .3	Article of Amendment to Articles of Incorporation dated December 13, 2006	Incorporated by reference to the Company's Registration Statement on Form 8-A filed on March 9, 2007
3 .4	Article of Amendment to Articles of Incorporation dated December 26, 2006	Incorporated by reference to the Company's Registration Statement on Form 8-A filed on March 9, 2007
3 .5	Article of Amendment to Articles of Incorporation dated February 26, 2007	Incorporated by reference to the Company's Registration Statement on Form 8-A filed on March 9, 2007

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Exhibit Number	Exhibit Description	Method of Filing
3 .6	Bylaws of the Company, as amended	Incorporated by reference to the Company's Registration Statement on Form S-4 filed on March 26, 1998
4 .1	Form of Warrant	Incorporated by reference to the Company's Current Report on Form 8-K filed on January 8, 2007
10 .1	Research and License Agreement made on August 8, 2007, by and between Yissum Research Development Company of Jerusalem, the Boyce Thompson Institute and Protalix Ltd.	Filed herewith†
10 .2	Scientific Advisory Board Agreement dated as of August 5, 2007, by and between the Company and Aaron Ciechanover, M.D.	Incorporated by Reference to the Company's Current Report on Form 8-K filed on August 6, 2007
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	Filed herewith
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	Filed herewith
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	Filed herewith
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	Filed herewith

† 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 14, 2007 By: /s/ David Aviezer David Aviezer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer) Date: November 14, 2007 By: /s/ Yossi Maimon Yossi Maimon
Vice President and Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)