

Protalix BioTherapeutics, Inc.
Form 10-Q
May 15, 2007

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended March 31, 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

**(State or other jurisdiction
of incorporation or organization)**

65-0643773

**(I.R.S. Employer
Identification No.)**

**2 Snunit Street
Science Park
POB 455**

Carmiel, Israel 21000

(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

**Common stock, par value \$0.001 per
share**

**Name of each exchange on which
registered
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):

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

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 May 1, 2007, approximately 65,657,181 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

FORM 10-Q TABLE OF CONTENTS

	<u>Page</u>
PART I - FINANCIAL INFORMATION	
	ii
Item 1	1
Item 2	9
Item 3	12
Item 4	12
Item 1	13
Item 1A	13
Item 2	13
Item 3	13
Item 4	13
Item 5	13
Item 6	13
Signatures	16

i

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 the expectations, beliefs, intentions or strategies for the future. When used in this report, the terms anticipate, believe, estimate, expect and intend and words or phrases of similar import, as they relate to our or our subsidiaries or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. 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:

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

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 FDA, or other health regulatory authorities;

any lack of progress of our research and development (including the results of clinical trials being conducted by us);

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 financings 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 in 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 operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, couriers, collaborative partners, licensees, and clinical trial sites.

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 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.

ii

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2007	December 31, 2006
	(Unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 24,896	\$ 15,378
Deposit		7,577
Accounts receivable	2,244	1,336
	27,140	24,291
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	320	293

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

PROPERTY AND EQUIPMENT, NET	2,898	2,404
	<u> </u>	<u> </u>
Total assets	\$ 30,358	\$ 26,988
	<u> </u>	<u> </u>
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	\$ 788	\$ 892
Other	1,442	1,376
	<u> </u>	<u> </u>
Total current liabilities	2,230	2,268
	<u> </u>	<u> </u>
LONG-TERM LIABILITY		
Liability for employee rights upon retirement	510	436
	<u> </u>	<u> </u>
Total liabilities	2,740	2,704
	<u> </u>	<u> </u>
SHAREHOLDERS EQUITY *	27,618	24,284
	<u> </u>	<u> </u>
Total liabilities and shareholders equity	\$ 30,358	\$ 26,988
	<u> </u>	<u> </u>

* See Note 1a.

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

1

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

	Three Months Ended		Period from
	March 31, 2007	March 31, 2006	December 27, 1993* through March 31, 2007
	<u> </u>	<u> </u>	<u> </u>
REVENUES			\$ 830
COST OF REVENUES			206
			<u> </u>
GROSS PROFIT			624
			<u> </u>
RESEARCH AND DEVELOPMENT EXPENSES (1)	\$ 2,532	\$ 1,236	\$ 20,193
less - grants	(738)	(373)	(5,854)
	<u> </u>	<u> </u>	<u> </u>
	1,794	863	14,339
	<u> </u>	<u> </u>	<u> </u>
GENERAL AND ADMINISTRATIVE EXPENSES (2)	1,987	774	10,983

OPERATING LOSS	3,781	1,637	24,698
FINANCIAL INCOME - NET	(331)	(41)	(699)
NET LOSS BEFORE CHANGE IN ACCOUNTING PRINCIPLE	3,450	1,596	23,999
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE		(37)	(37)
NET LOSS FOR THE PERIOD	\$ 3,450	\$ 1,559	\$ 23,962
NET LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED:			
Prior to cumulative effect of change in accounting principle	\$ 0.05	\$ 0.08	
Cumulative effect of change in accounting principle		**	
	\$ 0.05	\$ 0.08	
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER COMMON STOCK:			
Basic and diluted	64,365,376	18,801,527	
(1) Includes share-based compensation	206	143	2,003
(2) Includes share-based compensation	1,245	527	5,384

* 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.

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	Convertible 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:	28,856,127	398,227	\$ 29	\$ 1	\$ 1,382	\$ 28,156		\$ 29,568

	Common Stock (2)	Convertible Preferred Shares	Common Stock	Convertible Preferred Shares	Warrants	Additional paid-in capital	Deficit accumulated during development stage	Total
Common Stock and convertible preferred A, B and C shares and warrants issued for cash (net of issuance costs of \$768)								
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 three month period ended March 31, 2007 (Unaudited):								
Share-based compensation						1,451		1,451
Exercise of warrants	3,875,416		4		(355)	5,684		5,333
Net loss for the period							(3,450)	(3,450)
Balance at March 31, 2007 (Unaudited)	65,657,181		\$ 66			\$ 51,514	\$ (23,962)	\$ 27,618

(1) Incorporation date, see Note 1a.

(2) Common Stock, \$0.001 par value; Authorized - as of December 31, 2006 and March 31, 2007 - 150,000,000 shares.

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

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

	Three Months Ended		Period from December 27, 1993* through March 31, 2007
	March 31, 2007	March 31, 2006	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss for the period	\$ (3,450)	\$ (1,559)	\$ (23,962)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle		(37)	(37)

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

	Three Months Ended		Period from December 27, 1993* through 7,387 March 31, 2007,312
Share based compensation	1,451	670	
Depreciation and impairment of fixed assets	132	98	
Changes in accrued liability for employee rights upon retirement	74	36	510
Loss (gain) on amounts funded in respect of employee rights upon retirement	(5)	11	(52)
Changes in operating assets and liabilities:			
Increase in accounts receivable	(908)	(383)	(2,193)
Increase (decrease) in accounts payable and accruals	(113)	27	1,991
Net cash used in operating activities	\$ (2,819)	\$ (1,137)	\$ (15,044)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	\$ (516)	\$ (183)	\$ (4,003)
Investment grant received in respect of fixed assets			38
Proceeds from sale of property and equipment	4		4
Investment in restricted cash deposit			(47)
Amounts funded in respect of employee rights upon retirement	(30)	(24)	(433)
Amounts paid in respect of employee rights upon retirement	8		165
Net cash used in investing activities	\$ (534)	\$ (207)	\$ (4,276)
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		(10)	28,369
Exercise of options and warrants	\$ 12,910	6	14,400
Merger with a wholly owned subsidiary of the Company, net of issuance cost	(39)		302
Net cash provided by (used in) financing activities	\$ 12,871	\$ (4)	\$ 44,216
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	9,518	(1,348)	24,896
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	15,378	4,741	
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 24,896	\$ 3,393	\$ 24,896

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

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

(Concluded) - 2

	Three Months Ended		Period from December 27, 1993* through March 31, 2007
	March 31, 2007	March 31, 2006	
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	\$ 249	\$ 164	\$ 249
Issuance cost not yet paid	5	5	5
Consultants and director credit balance converted into shares			80
Issuance cost paid by a grant of options			\$ 21
Merger with a wholly owned subsidiary of the Company:			
Prepaid expenses			4
Issuance cost setoff against accounts payable	\$ 65		\$ 65

* Incorporation date, see Note 1a.

** Represents an amount less than \$1.

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

(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES**a. General**

Protalix BioTherapeutics, Inc. (formerly Orthodontix, Inc.) (hereinafter, the Company) is engaged through its wholly owned subsidiary, Protalix Ltd. in the biotechnology field. In recent years, Protalix Ltd. has been engaged in the research and development of plant-derived human proteins, with its main product under development, prGCD, being a plant-derived protein being developed as a treatment for Gaucher Disease. The Company has completed a Phase I clinical trial on prGCD, has received an approval to initiate phase III study in April 2007, and expects to initiate it in mid 2007. 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). For accounting purposes, the Merger was accounted for 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.

The Company currently does not have sufficient resources to complete the commercialization of any of its proposed products. Based on its current cash resources and commitments, the Company believes it should be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 18 months, although no assurance can be given that it will not need additional cash prior to such time. Unexpected increases in general and administrative expenses and research and development expenses may cause the Company to need additional financing during the next 18 months.

b. Share Based Compensation

The Company's management evaluated the fair value of its Common Stock for the purposes of determining the fair value of the options granted to consultants and non-employees, based on a retrospective valuation of the fair value of the Common Stock at March 31, 2007, conducted by a third-party specialist. The valuation specialist used various valuation methodologies and determined retrospectively that the fair value of the shares of Common Stock underlying the options granted to consultants and non-employees at March 31, 2007 was \$6.19 per share.

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 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 (LPS)

Basic and diluted LPS 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.

Convertible preferred shares, options, and warrants were not included in the computation of diluted LPS because the effect would be anti-dilutive.

The total weighted average (on a pre-exchange basis) number of shares of Common Stock related to the convertible preferred shares has been excluded from the calculations of diluted loss per share were 398,235 and 0 for the three months ended March 31, 2006 and 2007, respectively.

The diluted loss per share also does not include options and warrants of the Company in the amount of 15,026,538 and 13,008,658 for the three months ended March 31, 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.

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued)

- 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.
- 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.

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., 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.

- b. On January 31, 2007, certain warrant holders exercised, in the aggregate, warrants for 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.

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 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 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

Our only 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 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.

We are a clinical stage biopharmaceutical company currently in the development stage that is focused on developing and producing recombinant therapeutic proteins that are expressed through our proprietary plant cell system. Recombinant therapeutic proteins are proteins that are produced by different genetically modified organisms following the insertion of the relevant DNA into their genome and are the basis of

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

most biopharmaceutical drugs currently under development. We are leveraging our plant cell culture and bioreactor technology for the production of recombinant therapeutic proteins, and we are currently developing several such biotherapeutic products. Our patented plant cell system enables the expression in plant cells of specific human genes, most often genes coding for proteins of pharmaceutical or therapeutic value. Once the plant cells produce a therapeutic protein, such protein may be grown on an industrial scale in our proprietary bioreactor system. Subsequently, the protein is extracted from the cells and purified to a clinical grade. Our system presents a proprietary method for the production of recombinant proteins that we believe is safe and scalable and may allow for the cost-effective industrial scale production of such recombinant human therapeutic proteins.

Our lead product candidate, prGCD, is a proprietary plant cell expressed recombinant Glucocerebrosidase enzyme-based protein for the treatment of Gaucher Disease. In July 2005, we received FDA approval of our Investigational New Drug application, or IND, for prGCD, allowing us to initiate an FDA-approved clinical development program for prGCD. The Phase I clinical trial was completed in June 2006 and in April 2007 we received written notice from the FDA that we may initiate a Phase III clinical trial in the United States. We expect to commence the Phase III clinical trial mid-2007.

We believe that we have demonstrated the potential of our plant cell manufacturing platform to become a safe and efficacious expression technology for the manufacturing of a wide variety of biopharmaceutical products. Accordingly, we are employing a two-pronged business strategy that enables us to pursue our goal of becoming a fully integrated biopharmaceutical company. In addition to our development of prGCD, we are using our protein expression technology to develop an innovative proprietary product pipeline. We are evaluating and initiating additional internal research programs through collaboration agreements with academic institutions, such as the Yeda Research and Development Company Limited, the technology transfer arm of the Weizmann Institute of Science. In addition, we continually review and consider development and commercialization alliances with corporate partners in specific and identified markets worldwide for products or territories in order to enable us to optimize our resources and effectively penetrate target markets. We entered into such an agreement with Teva Pharmaceutical Industries Ltd. in September 2006.

Since its inception in December 1993, Protalix Ltd. has generated significant losses in connection with the research and development of its technology, including the clinical development of prGCD, and at March 31, 2007, we had an accumulated deficit of \$24.0 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

9

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 Form 10-Q.

Results of Operations

Three months ended March 31, 2007 compared to the three months ended March 31, 2006

Research and Development Expenses

Research and development expenses were \$2.5 million for the three months ended March 31, 2007, an increase of \$1.3 million, or 104%, from \$1.2 million for the three months ended March 31, 2006. The increase resulted primarily from the increase of \$1 million in salaries and related consulting and materials associated with research and development. This increase was partially offset by \$365,000 from grants from the Office of the Chief Scientist, the OCS, equal to \$738,000 during the three months ended March 31, 2007, compared to grants equal to \$373,000 during the three months ended March 31, 2006.

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

General and Administrative Expenses

General and administrative expenses were \$2.0 million for the three months ended March 31, 2007, an increase of \$1.2 million, or approximately 156%, from \$774,000 for the three months ended March 31, 2006. The increase resulted primarily from a \$718,000 increase in share-based compensation in connection with additional stock option awards granted in the second half of 2006.

Financial Expenses and Income

Financial income was \$331,000 for the three months ended March 31, 2007, an increase of \$290,000, compared to \$41,000 for the three months ended March 31, 2006. The increase resulted primarily from a higher balance of cash and cash equivalents as of March 31, 2007, which primarily resulted from the interest income earned on the proceeds generated from the sale of ordinary shares of Protalix Ltd. in September 2006 and the exercise of 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 ordinary shares. We believe that the funds currently available to us as are sufficient to satisfy our capital needs for the next 18 months.

Cash Flows

Net cash used in operations was \$2.8 million for the three months ended March 31, 2007. The net loss for the three months ended March 31, 2007 of \$3.5 million was partially offset by \$1.5 million of non-cash share-based compensation but was increased due to an increase in accounts receivable of \$1.0 million, mainly due to grants to

be received from the OCS. Net cash used in investing activities for the three months ended March 31, 2007 was \$534,000 and consisted primarily of purchases of property and equipment. Net cash provided by financing activities for the three months ended March 31, 2007 was \$12.9 million, consisting of the proceeds from the exercise of certain warrants.

Net cash used in operations was \$1.1 million for the three months ended March 31, 2006. The net loss for the three months ended March 31, 2006 of \$1.6 million was mainly offset by \$670,000 of non-cash share-based compensation and depreciation equal to \$98,000. Net cash used in investing activities for the three months ended March 31, 2006 was \$207,000 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 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 will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least for the next 18 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 three months ended March 31, 2007 or the three months ended March 31, 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 three months ended March 31, 2007 and the three months ended March 31, 2006.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of March 31, 2007 and March 31, 2006.

Recently Issued Accounting Pronouncements

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 fiscal years beginning after November 15, 2007. Early adoption within 120 days of the beginning of our 2007 fiscal year is permissible, provided a company has not yet issued interim financial statements for 2007 and has adopted SFAS 157. We do not intend to adopt SFAS 157 early, and we are currently evaluating the impact of adopting SFAS 159 on our financial position, cash flows, and results of operations.

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:

	Year Ended December 31,		
	2004	2005	2006
Average rate for period	4.4820	4.4878	4.4565
Rate at year-end	4.3080	4.6030	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

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

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 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.

12

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 March 31, 2007. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of March 31, 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 first quarter of fiscal 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.

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 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 March 31, 2007 other than those disclosed in our Current Report on Form 8-K dated as of January 31, 2007.

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, SEC File No. 001-33357
13		
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, SEC File No. 001-33357
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, SEC File No. 001-33357
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, SEC File No. 001-33357
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, SEC File No. 333-48677
4.1	Form of Warrant	Incorporated by reference to the Company's Current Report on Form 8-K filed on January 8, 2007, SEC File No. 000-27836
10.11	Stock Option Award Agreement by and between the Registrant and Phillip Frost, dated as of December 31, 2006	Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 30, 2007, SEC File No. 001-33357
10.12	Stock Option Award Agreement by and between the Registrant and Jane Hsiao, dated as of December 31, 2006	Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 30, 2007, SEC File No. 001-33357
10.13	Stock Option Award Agreement grant by and between the Registrant and Steven Rubin, dated as of December 31, 2006	Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 30, 2007, SEC File No. 001-33357

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

10.14	First Amendment to the December 31, 2006 Stock Option Award Agreement by and between the Registrant and Phillip Frost, effective as of February 28, 2007	Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 30, 2007, SEC File No. 001-33357
10.15	First Amendment to the December 31, 2006 Stock Option Award Agreement by and between the Registrant and Jane Hsiao, effective as of February 28, 2007	Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 30, 2007, SEC File No. 001-33357
10.16	First Amendment to the December 31, 2006 Stock Option Award Agreement by and between the Registrant and Steven Rubin, effective as of February 28, 2007	Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 30, 2007, SEC File No. 001-33357
10.17	Employment Agreement between Protalix Ltd. and Iftah Katz, effective as of February 28, 2007	Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 30, 2007, SEC File No. 001-33357

14

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

15

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: May 15, 2007

By: /s/ David Aviezer

David Aviezer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

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

Date: May 15, 2007

By: /s/ Yossi Maimon

Yossi Maimon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)