

Protalix BioTherapeutics, Inc.  
Form 10-Q  
May 07, 2008

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

**x**

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

**For the quarterly period ended March 31, 2008**

**OR**

**o**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**001-33357**

**(Commission file number)**

**PROTALIX BIOTHERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Florida**

**65-0643773**

(State or other jurisdiction  
of incorporation or organization)

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

**2 Snunit Street  
Science Park  
POB 455  
Carmiel, Israel**

**20100**

(Address of principal executive offices)

(Zip Code)

**972-4-988-9488**

(Registrant's telephone number, including area code)

**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

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

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

(Do not check if a smaller reporting company)

Smaller reporting company

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

On May 1, 2008, approximately 75,883,046 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

---



**FORM 10-Q**

**TABLE OF CONTENTS**

**Page**

**PART I FINANCIAL INFORMATION**

**Cautionary Statement Regarding Forward-Looking Statements**

ii

Item 1.

Financial Statements

Condensed Consolidated Balance Sheets As of March 31, 2008 (Unaudited) and December 31, 2007

1

Condensed Consolidated Statements of Operations (Unaudited) For the Three Months Ended March 31, 2008 and 2007; and for the Period from December 27, 1993 through March 31, 2008

2

Condensed Consolidated Statement of Changes in Shareholders' Equity As of March 31, 2008 (Unaudited) and December 31, 2007

3

Condensed Consolidated Statements of Cash Flows (Unaudited) For the Three Months Ended March 31, 2008 and 2007; and for the Period from December 27, 1993 through March 31, 2008

4

Notes to Condensed Consolidated Financial Statements

6

Item 2.

Management's Discussion and Analysis of Financial Condition and Results of Operations

11

Item 3.

Quantitative and Qualitative Disclosures About Market Risk

15

Item 4.

Controls and Procedures

16

## **PART II OTHER INFORMATION**

Item 1.

Legal Proceedings

17

Item 1A.

Risk Factors

17

Item 2.

Unregistered Sales of Equity Securities and Use of Proceeds

17

Item 3.

Defaults Upon Senior Securities

17

Item 4.

Submission of Matters to a Vote of Security Holders

18

Item 5.

Other Information

18

Item 6.

Exhibits

18



Signatures

20

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 Business, Management's Discussion and Analysis of Financial Condition and Results of Operations, and Risk Factors, and other statements included elsewhere in this Annual 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 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 the FDA, 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 our drug products, if approved;

the possibility of infringing a third party's patents or other intellectual property rights;

the uncertainty of obtaining patents covering our products and processes and in successfully enforcing 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.

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 Section 1A of our Annual Report on Form 10-K for the year ended December 31, 2007, and described from time to time in our future reports to be 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.



**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**PROTALIX BIOTHERAPEUTICS, INC.**

(a development stage company)

**CONDENSED CONSOLIDATED BALANCE SHEETS**

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

**March 31, 2008**

**December 31, 2007**

**(Unaudited)**

**ASSETS**

**CURRENT ASSETS:**

Cash and cash equivalents

\$

57,782

\$

61,813

Accounts receivable

2,096

1,354

Total current assets



59,878

63,167

**FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT**

544

464

**PROPERTY AND EQUIPMENT, NET**

5,404

4,506

Total assets

\$

65,826

\$

68,137

**LIABILITIES AND SHAREHOLDERS EQUITY**

**CURRENT LIABILITIES:**

Accounts payable and accruals:

Trade

\$

1,057

\$

899

Other

3,148

2,863

Total current liabilities

4,205

3,762

**LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT**

872

690

Total liabilities

5,077

4,452

**SHAREHOLDERS EQUITY**

60,749

63,685

Total liabilities and shareholders equity

\$

65,826

\$

68,137

**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 data)

(Unaudited)

**Three Months Ended**

**Period from  
December 27, 1993\*  
through**

**March 31, 2008**

**March 31, 2007**

**March 31, 2008**

**REVENUES**

\$

830

**COST OF REVENUES**

206

**GROSS PROFIT**



624

**RESEARCH AND DEVELOPMENT EXPENSES (1)**

\$

5,653

\$

2,532

37,246

less grants

(1,366

)

(738

)

(7,553

)

4,287

1,794

29,693

**GENERAL AND ADMINISTRATIVE EXPENSES (2)**

1,976

1,987

22,678

**OPERATING LOSS**

6,263

3,781

51,747

**FINANCIAL INCOME NET**

(1,150

)

(331

)

(3,598

)

**OTHER INCOME**