Protalix BioTherapeutics, Inc.
Form 10-Q/A
March 18, 2019

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q/A**

**(Mark One)**

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

**For the quarterly period ended June 30, 2018**

**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)**

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

**2 Snunit Street**

**Science Park**

**20100**

**POB 455**

**Carmiel, Israel**
**(Address of principal executive offices) (Zip Code)**

**+972-4-988-9488**

**(Registrant's telephone number, including area code)**

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

| | | | |
|---|---|---|---|
| Large accelerated filer | ¨ | Accelerated filer | x |
| Non-accelerated filer | ¨ | | |
| Smaller reporting company | ¨ | Emerging growth company | ¨ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

On August 1, 2018, approximately 148,183,591 shares of the Registrant's common stock, $0.001 par value, were outstanding.

*Except where the context otherwise requires, the terms "we," "us," "our" and "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.*

**Explanatory Note**

This Amendment No. 1 to Form 10-Q, or this Amendment, amends the Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018 we originally filed with the Securities and Exchange Commission, or the Commission, on August 9, 2018, or the Original Filing, in connection with the recognition in this Amendment of revenue from a license agreement that was not recognized previously.

All amendments and restatements to the financial statements are non-cash in nature.

**Restatement**

As further discussed in Note 1 to our unaudited condensed consolidated financial statements in Part I, Item 1, "Financial Statements" of this Amendment, on March 14, 2019, we concluded that we would restate our previously issued consolidated financial statements as of and for the three and six months ended June 30, 2018, as set forth in the Original Filing in connection with the recognition in this Amendment of revenue from a license agreement that was not recognized previously.

**Disclosure Controls and Procedures**

Management has reassessed its evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of June 30, 2018. As a result of that reassessment, management has concluded that we did not maintain effective disclosure controls and procedures due to the material weakness in internal control over financial reporting which existed at that date. For a description of the material weakness in internal control over financial reporting and actions taken, and to be taken, to address the material weakness, see Part 1, Item 4 "Controls and Procedures" of this Amendment.

**Amendment**

The purpose of this Amendment is to restate our previously issued unaudited condensed consolidated financial statements and related disclosures as of and for the three and six months ended June 30, 2018 in connection with the recognition in this Amendment of revenue from a license agreement that was not recognized previously. This Amendment also includes (a) an amended Part I, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” to reflect the correction of the errors described above, and (b) an amended Part I, Item 4 “Controls and Procedures” to restate the conclusion on the effectiveness of disclosure controls and procedures. Disclosure controls and procedures were deemed effective in the Original Filing on August 9, 2018 and are deemed ineffective as a result of the material weakness described in Part I, Item 4 “Controls and Procedures” of this Amendment.

Except as expressly set forth herein, including in the notes to the consolidated financial statements, this Amendment does not reflect events occurring after the date of the Original Filing or modify or update any of the other disclosures contained therein in any way other than as required to reflect the amendment discussed above. Accordingly, this Amendment should be read in conjunction with the Original Filing and our other filings with the Commission. Information not affected by the restatement is unchanged and reflects disclosures made at the time of the filing of the Original Filing.

**Items Amended in this Filing**

For reasons discussed above, we are filing this Amendment in order to amend the following items in our Original Filing to the extent necessary to reflect the adjustments discussed above and make corresponding revisions to our financial data cited elsewhere in this Amendment in connection with the recognition in this Amendment of revenue from a license agreement that was not recognized previously:

- Part I, Item 1. Financial Statements
- Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Part I, Item 4. Controls and Procedures

In accordance with applicable Commission rules, this Amendment includes new certifications required by Rule 13a-14 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, from our Chief Executive Officer and Chief Financial Officer dated as of the date of filing of this Amendment.

FORM 10-Q

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**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

The statements set forth under the captions "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and other statements included elsewhere in this Quarterly Report on Form 10-Q, which are not historical, constitute "forward-looking statements" within the meanings of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases import, as they relate to the Company 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, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. 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:

- failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; inability to monitor patients adequately during or after treatment; and or lack of sufficient funding to finance our clinical trials;

- the risk that the results of our clinical trials will not support the applicable claims of superiority, safety or efficacy and that our product candidates will not have the desired effects or will have undesirable side effects or other unexpected characteristics;

- risks relating to our ability to manage our relationship with Chiesi Farmaceutici S.p.A., or Chiesi, and any other collaborator, distributor or partner;

- risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance or satisfy conversions of our outstanding convertible notes or any other indebtedness;

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risks relating to the compliance by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, or the Brazilian MoH, with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement;

- our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services;

- risks relating to our ability to finance our activities and research programs;

- delays in preparing and filing applications for regulatory approval of our product candidates in the United States, the European Union and elsewhere;

- the impact of development of competing therapies and/or technologies by other companies;

- the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, one or more of our product candidate may become be subject to potential marketing and commercialization restrictions;

- risks related to our supply of drug product to Pfizer Inc., or Pfizer, pursuant to our amended and restated exclusive license and supply agreement with Pfizer;

- risks related to the commercialization efforts for taliglucerase alfa in Brazil;

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- risks related to our expectations with respect to the potential commercial value of our product and product candidates;
- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;
- potential product liability risks, and risks of securing adequate levels of product liability and clinical trial insurance coverage;
- the possibility of infringing a third-party's patents or other intellectual property rights;
- the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third-parties;
- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; and
- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the U.S. Food and Drug Administration, or the FDA, or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

These forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These and other risks and uncertainties are detailed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017, and are described from time to time in the reports we file with the Commission.

**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**PROTALIX BIOTHERAPEUTICS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(U.S. dollars in thousands)

| | June 30, 2018 (Unaudited) (as restated) | December 31, 2017 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 28,327 | $ 51,163 |
| Accounts receivable – Trade | 5,248 | 1,721 |
| Other assets | 2,499 | 1,934 |
| Inventories | 6,978 | 7,833 |
| Total current assets | $ 43,052 | $ 62,651 |
| FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT | $ 1,729 | $ 1,887 |
| PROPERTY AND EQUIPMENT, NET | 6,940 | 7,676 |
| Total assets | $ 51,721 | $ 72,214 |
| LIABILITIES NET OF CAPITAL DEFICIENCY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accruals: | | |
| Trade | $ 6,001 | $ 7,521 |
| Other | 9,071 | 9,310 |
| Contracts liability | 3,420 | |
| Convertible notes | | 5,921 |
| Total current liabilities | $ 18,492 | $ 22,752 |
| LONG TERM LIABILITIES: | | |
| Convertible notes | $ 46,742 | $ 46,267 |
| Contracts liability | 21,636 | 25,015 |
| Liability for employee rights upon retirement | 2,335 | 2,586 |
| Other long term liabilities | 5,258 | 5,051 |
| Total long term liabilities | $ 75,971 | $ 78,919 |

| | | |
|---|---|---|
| Total liabilities | $ 94,463 | $ 101,671 |
| COMMITMENTS | | |
| CAPITAL DEFICIENCY | (42,742) | (29,457) |
| Total liabilities net of capital deficiency | $ 51,721 | $ 72,214 |

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

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

| | Six Months Ended | | Three Months Ended | |
|---|---|---|---|---|
| | **June 30, 2018** | June 30, 2017 | **June 30, 2018** | June 30, 2017 |
| | **(as restated)** | | **(as restated)** | |
| REVENUES FROM SELLING GOODS | $6,559 | $9,247 | $2,006 | $6,358 |
| REVENUES FROM LICENSE AND R&D SERVICES | 4,993 | | 2,832 | |
| COST OF GOODS SOLD | (5,107) | (7,611) | (2,183) | (5,523) |
| RESEARCH AND DEVELOPMENT EXPENSES (1) | (14,762) | (15,271) | (7,476) | (9,304) |
| Less – grants | 1,078 | 1,816 | 235 | 478 |
| RESEARCH AND DEVELOPMENT EXPENSES, NET | (13,684) | (13,455) | (7,241) | (8,826) |
| SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2) | (4,656) | (5,351) | (2,158) | (2,814) |
| OPERATING LOSS | (11,895) | (17,170) | (6,744) | (10,805) |
| FINANCIAL EXPENSES | (4,013) | (5,132) | (1,793) | (3,045) |
| FINANCIAL INCOME | 207 | 1,665 | 75 | 40 |
| (LOSS) INCOME FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE | | (38,061) | | 14,260 |
| FINANCIAL (EXPENSES) INCOME, NET | (3,806) | (41,528) | (1,718) | 11,255 |
| NET (LOSS) INCOME FOR THE PERIOD | $(15,701) | $(58,698) | $(8,462) | $450 |
| NET (LOSS) EARNINGS PER SHARE OF COMMON STOCK: | | | | |
| BASIC | | | | |
| **Net (loss) earnings per share of common stock** | $(0.11) | $(0.47) | $(0.06) | $0.00 |
| **DILUTED** | | | | |
| **Net loss per share of common stock** | $(0.11) | $(0.47) | $(0.06) | $(0.06) |
| WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING (LOSS) EARNINGS PER SHARE | | | | |
| BASIC | 145,985,445 | 126,000,782 | 146,644,450 | 127,523,706 |
| **DILUTED** | 145,985,445 | 126,000,782 | 146,644,450 | 192,598,389 |
| (1) Includes share-based compensation | $40 | $120 | $(2) | $55 |
| (2) Includes share-based compensation | $34 | $96 | $14 | $43 |

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

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**PROTALIX BIOTHERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN CAPITAL DEFICIENCY**

(U.S. dollars in thousands)

(Unaudited)

| | Common Stock (1) | Common Stock | Additional Paid–In Capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|
| | Number of shares | **Amount** | | | |
| Balance at December 31, 2016 | 124,134,085 | $124 | $202,575 | $ (212,656 ) | $(9,957 ) |
| Changes during the six-month period ended June 30, 2017: | | | | | |
| Share-based compensation related to stock options | | | 216 | | 216 |
| Reclassification of embedded derivative | | | 43,634 | | 43,634 |
| Convertible notes conversions | 4,948,821 | 5 | 4,132 | | 4,137 |
| Net loss for the period | | | | (58,698 ) | (58,698) |
| Balance at June 30, 2017 | 129,082,906 | 129 | 250,557 | (271,354 ) | (20,668) |
| Balance at December 31, 2017 | 143,728,797 | $144 | $266,495 | $ (296,096 ) | $(29,457) |
| Changes during the six-month period ended June 30, 2018: | | | | | |
| Share-based compensation related to stock options | | | 58 | | 58 |
| Share-based compensation related to restricted stock award | 29,898 | * | 16 | | 16 |
| Convertible notes conversions | 1,811,260 | 2 | 1,190 | | 1,192 |
| Convertible notes exchange | 2,613,636 | 2 | 1,148 | | 1,150 |
| Net loss for the period (as restated) | | | | (15,701 ) | |