

Protalix BioTherapeutics, Inc.
Form 8-K
March 18, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): March 18, 2019 (March 14, 2019)

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33357
(Commission File Number)

65-0643773
(IRS Employer
Identification No.)

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

Registrant's telephone number, including area code +972-4-988-9488

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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. "

Item 2.02 Results of Operations and Financial Condition

On March 18, 2019, Protalix BioTherapeutics, Inc. (the “Company”) issued a press release announcing its financial results for full-year ended December 31, 2018, and providing a corporate update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 4.02 Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

On March 14, 2019, the Company concluded, through its Board of Directors and its Audit Committee, that it will restate its first, second and third quarter 2018 financial statements in connection with the recognition of revenues from license agreements that were not recognized previously. The Company expects to recognize revenues equal to \$2.2 million, \$2.8 million and \$11.7 million over the first, second and third quarter of 2018 respectively. The restatement is expected to decrease the Company’s net loss for each of those periods.

As a result of the restatement, investors should no longer rely upon the Company’s previously issued financial statements for the periods set forth above.

The decision to restate these financial statements is based on the Company’s conclusion that it needs to recognize certain revenues generated under the Company’s license agreements with Chiesi Farmaceutici S.p.A. that were not recognized for purposes of the first, second and third quarter 2018 financial statements. Previously, the Company had identified a single performance obligation with regard to its promises under each of the agreements. The Company subsequently concluded that there are two performance obligations under each of the agreements as follows: (i) the license together with research and development services and (ii) a contingent performance obligation regarding future manufacturing. As such, the Company will recognize revenue for the combined performance obligations (the license and the research and development services) for the first, second and third quarter 2018 financial statements for the satisfaction of the performance obligations that occurred during those periods. Following filing this Current Report on Form 8-K, the Company will promptly file restated Form 10-Q/As for the quarterly periods ended March 31, 2018, June 30, 2018 and September 30, 2018. All amendments and restatements to the financial statements are non-cash in nature and had no impact to total cash flows from operations for each period.

In connection with the restatement, the Company has determined that a material weakness exists in its internal control over financial reporting related to accounting for revenue recognition. Management, with the oversight of the Audit Committee of the Board of Directors, has updated, and will continue to update, the Company's revenue recognition processes and controls with respect to complex revenue contracts, and intends to implement additional control procedures. These additional control procedures are intended both to address the identified material weakness and to enhance the Company's overall financial control environment.

The Audit Committee of the Board of Directors has discussed the matters disclosed in this Item 4.02 with Kesselman & Kesselman, Certified Public Accountants (Isr.), a member of PricewaterhouseCoopers International Limited, the Company's independent registered public accounting firm.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "expect," "anticipate," "believe," "estimate," "project," "plan," "should" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. These statements are based on our current beliefs and expectations as to such future outcomes. Examples of such forward-looking statements include, but are not limited to, statements of our expectations regarding the Company's intended actions, timing and assessment related to the restatement of the Company's financial statements for the restated periods described above; the expected impact of the restatement for each of the restated periods; and other factors described in our filings with the U.S. Securities and Exchange Commission. Although the Company believes that the expectations underlying any of these forward-looking statements are reasonable, these expectations may prove to be incorrect and all of these statements are subject to risks and uncertainties. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated March 18, 2019.

SIGNATURES

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

Date: March 18, 2019 **PROTALIX
BIOTHERAPEUTICS, INC.**

By: /s/ Yossi Maimon
Name: Yossi Maimon

Title: Vice President and
Chief Financial Officer