

PTC THERAPEUTICS, INC.
Form 8-K
January 07, 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): January 7, 2019

PTC THERAPEUTICS, INC.

(Exact Name of Company as Specified in Charter)

Delaware 001-35969 04-3416587

(State or Other Jurisdiction (Commission (IRS Employer
of Incorporation) File Number) Identification No.)

100 Corporate Court

South Plainfield, NJ 07080

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (908) 222-7000

Not applicable

(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 communications 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 January 7, 2019, PTC Therapeutics, Inc. (the “Company”) issued a press release (the “press release”) announcing certain preliminary (unaudited) financial information for its fiscal year ending December 31, 2018, including that the Company expects to report (i) Translarna™ (ataluren) net product revenue for the treatment of nonsense mutation Duchenne muscular dystrophy (nmDMD) of approximately \$171 million; (ii) EMFLAZA™ (deflazacort) net product revenue for the treatment of Duchenne muscular dystrophy (DMD) of approximately \$91 million; and (iii) ending cash and cash equivalents of approximately \$227 million. Final results are subject to completion of the Company’s year-end audit.

Item 7.01. Regulation FD Disclosure.

The Company also announced financial guidance for its fiscal year ending December 31, 2019 in the press release, including that the Company anticipates (i) full-year net product revenues to be between \$285 and \$305 million and (ii) GAAP R&D and SG&A expense for the full year 2019 to be between \$395 and \$405 million with non-GAAP R&D and SG&A expense for the full year 2019 to be between \$360 and \$370 million, excluding estimated non-cash, stock-based compensation expense of approximately \$35 million.

The Company announced that on Tuesday, January 8th at 5:00 pm PT at the 37th Annual J.P. Morgan Healthcare Conference (the “Conference”), the Company will present its 2019 strategic priorities, preliminary 2018 financial results, and 2019 financial guidance. The presentation will be webcast live and the accompanying slide deck has been posted on the Events and Presentations page under the Investors section of the Company’s website. A copy of the slide deck, which the Company intends to utilize in various meetings at the Conference, is also attached as Exhibit 99.2. This Current Report on Form 8-K and Exhibits 99.1 and 99.2 include a forward-looking financial measure that was not prepared in accordance with accounting principles generally accepted in the United States (GAAP), non-GAAP R&D and SGA expenses (which excludes non-cash stock-based compensation expense). Management uses this measure when assessing and identifying operational trends and, in management’s opinion, this non-GAAP measure is useful to investors and other users of its financial statements by providing greater transparency into the historical and projected operating performance of PTC and the Company’s future outlook. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Forward Looking Statements: All statements, other than those of historical fact, contained in this Current Report on Form 8-K, are forward-looking statements, including preliminary (unaudited) financial information for fiscal year 2018 and financial guidance for fiscal year 2019. The Company's actual results, performance or achievements could differ materially from those expressed or implied by forward-looking statements it makes as a result of a variety of risks and uncertainties, including those related to the preliminary nature of the Company's 2018 financial information, which is subject to completion of the Company's year-end audit; the assumptions underlying the Company's financial guidance for 2019; and the factors discussed in the “Risk Factors” section of the Company's Annual Report on Form 10-K for the year ended December 31, 2017, Quarterly Reports on Form 10-Q for the periods ended March 31, 2018, June 30, 2018 and September 30, 2018 and Exhibit 99.2 to PTC's Current Report on Form 8-K filed on August 24, 2018 as well as any updates to these risk factors filed from time to time in the Company's other filings with the SEC. You are urged to carefully consider all such factors. The forward-looking statements contained herein and the exhibits hereto represent the Company's views only as of the date of this Current Report on Form 8-K and the Company does not undertake or plan to update or revise any such forward-looking statements to reflect actual results or changes in plans, prospects, assumptions, estimates or projections, or other circumstances occurring after the date of this Current Report on Form 8-K except as required by law. All website addresses given in this Current Report on Form 8-K or incorporated herein by reference are for information only and are not intended to be an active link or to incorporate any website information into this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

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Exhibit No. Description

99.1 Press Release, dated January 7, 2019 issued by PTC Therapeutics, Inc.

99.2 Corporate Presentation - 37th Annual J.P. Morgan Healthcare Conference

Signature

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.

PTC Therapeutics, Inc.

Date: January 7, 2019 By: /s/ Christine Utter

Name: Christine Utter

Title: Principal Financial Officer