Edgar Filing: PTC THERAPEUTICS, INC. - Form 8-K

PTC THERAPEUTICS, INC.

Form 8-K

January 08, 2018

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 8, 2018

PTC THERAPEUTICS, INC.

(Exact Name of Company as Specified in Charter)

Delaware 001-35969 04-3416587 (State or Other Jurisdiction of Incorporation) Given the File Number of Identification No.)

100 Corporate Court

South Plainfield, NJ 07080 (Address of Principal Executive Offices) (Zip Code)

Company'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):

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

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. o

Item 2.02. Results of Operations and Financial Condition.

On January 8, 2018, PTC Therapeutics, Inc. (the "Company") issued a press release (the "press release") announcing certain preliminary (unaudited) financial information for its fourth quarter and fiscal year ending December 31, 2017, including that the Company expects to report (i) TranslarnaTM (ataluren) net product revenue for the treatment of nonsense mutation Duchenne muscular dystrophy (nmDMD) of approximately \$145 million; (ii) EMFLAZATM (deflazacort) net product revenue for the treatment of Duchenne muscular dystrophy (DMD) of approximately \$29 million; and (iii) ending cash and cash equivalents of approximately \$191 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, 2018 in the press release, including that the Company anticipates (i) full-year net product revenues to be between \$260 and \$295 million, with Translarna net product revenue for the full year 2018 to be between \$170 and \$185 million and EMFLAZA net product revenue for the full year 2018 to be between \$90 and \$110 million and (ii) GAAP R&D and SG&A expense for the full year 2018 to be between \$280 and \$290 million with non-GAAP R&D and SG&A expense for the full year 2018 to be between \$250 and \$260 million, excluding estimated non-cash, stock-based compensation expense of approximately \$30 million.

This Current Report on Form 8-K and Exhibit 99.1 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 stock-based compensation expense). Management uses this measure to assess its operations 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 expected operating performance at 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 Exhibit 99.1, 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 2017 and financial guidance for 2018. 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 2017 financial information, which is subject to completion of the Company's year-end audit; the assumptions underlying the Company's financial guidance for 2018; and the factors discussed in the "Risk Factors" section of the Company's most recent Quarterly Report on Form 10-Q 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 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

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Exhibit No. Description

99.1 Press Release, dated January 8, 2018

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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.

/s/

Date: January 8, 2018 By: Christine

Utter

Name: Christine

Utter

Principal

Title: Financial

Officer