

PTC THERAPEUTICS, INC.
Form 8-K
January 29, 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 27, 2018

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)

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):

- 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 7.01. Regulation FD Disclosure.

On January 27, 2018, PTC Therapeutics, Inc. (the "Company") issued a press release (the "press release") announcing the presentation of preliminary data from Part 1 of the FIREFISH trial in Type 1 SMA infants at the International Scientific Congress on Spinal Muscular Atrophy in Krakow, Poland. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Report"). A copy of the presentation is also attached to this Report as Exhibit 99.2 and is incorporated by reference into this Item 7.01. Additionally, copies of three posters that were presented at the conference, 1) Mercuri et al. (L. Servais as presenting author), "Updated pharmacodynamic and safety data from SUNFISH Part 1, a study evaluating the oral SMN2 splicing modifier RG7916 in patients with Type 2 or 3 spinal muscular atrophy" (the "SUNFISH poster"), 2) Chiriboga et al. (D. Kraus as presenting author) "Preliminary Evidence for Pharmacodynamics Effects of RG7916 in JEWELFISH, a Study in Patients with Spinal Muscular Atrophy who Previously Participated in a Study with Another SMN2-Splicing Targeting Therapy" (the "JEWELFISH poster"), and 3) Poirier et al. (L. Mueller as presenting author), "Relationship Between Central and Peripheral SMN Protein Increase Upon Treatment with RO7034067 (RG7916)" (the "SMN protein poster"), are attached to this Report as Exhibits 99.3, 99.4 and 99.5, respectively, and are incorporated by reference into this Item 7.01.

The presentation was authored and given by Dr. Giovanni Baranello from the Fondazione Istituto Neurologico Carlo Besta in Milan, Italy, who is a third-party investigator in the trial, and was neither prepared nor presented by or on behalf of the Company. The SUNFISH poster was authored by Dr. Eugenio Mercuri from the Paediatric Neurology and Nemo Center at Catholic University and Policlinico Gemelli in Rome, Italy, who is a third-party investigator in the trial. The JEWELFISH poster was authored by Dr. Claudia A. Chiriboga from the Department of Neurology at Columbia University Medical Center in New York, NY, who is a third-party investigator in the trial. The SMN protein poster was authored by Dr. Agnes Poirier from the Roche Innovation Center in Basel, Switzerland. The SUNFISH poster and the JEWELFISH poster were neither prepared nor presented by or on behalf of the Company. The Company is providing the presentation and the posters as a convenience for investors for informational purposes.

The information in this Current Report on Form 8-K, including Exhibits 99.1, 99.2, 99.3, 99.4 and 99.5 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, including those contained in Exhibits 99.1, 99.2, 99.3, 99.4 and 99.5, are forward-looking statements, including regarding any advancement of the joint development program in SMA with PTC, Roche, and SMAF, in particular as related to the timing of enrollment, completion and evaluation of the Phase 2 clinical studies of RG7916 in SMA patients and the period during which the results of the studies will become available; the clinical utility and potential advantages of RG7916, including its potential to impact every aspect of the disease. 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 initiation, enrollment, conduct and availability of data from either the SUNFISH or FIREFISH studies and the outcome of such studies; 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

| Exhibit No. | Description |
|-------------|--|
| 99.1 | <u>Press Release, dated January 27, 2018</u> |
| 99.2 | <u>Presentation at the International Scientific Congress on Spinal Muscular Atrophy by Dr. Giovanni Baranello from the Fondazione Istituto Neurologico Carlo Besta in Milan, Italy</u> |
| 99.3 | <u>SUNFISH poster presented at the International Scientific Congress on Spinal Muscular Atrophy, authored by Dr. Eugenio Mercuri from the Paediatric Neurology and Nemo Center at Catholic University and Policlinico Gemelli in Rome, Italy</u> |
| 99.4 | <u>JEWELFISH poster presented at the International Scientific Congress on Spinal Muscular Atrophy, authored by Dr. Claudia A. Chiriboga from the Department of Neurology at Columbia University Medical Center in New York, NY</u> |
| 99.5 | <u>SMN protein poster presented at the International Scientific Congress on Spinal Muscular Atrophy, authored by Dr. Agnes Poirier from the Roche Innovation Center in Basel, Switzerland</u> |

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 29, 2018 By: /s/ Mark E. Boulding
Name: Mark E. Boulding
Title: Executive Vice President and Chief Legal Officer