

PTC THERAPEUTICS, INC.
Form 8-K
March 02, 2017

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 2, 2017

PTC THERAPEUTICS, INC.
(Exact Name of Company as Specified in Charter)

| | | |
|---|-----------------------------|--------------------------------------|
| Delaware | 001-35969 | 04-3416587 |
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer 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))

Item 7.01. Regulation FD Disclosure.

On March 2, 2017, PTC Therapeutics, Inc. (“PTC” or the “Company”) issued a press release announcing the results from ACT CF, its Phase 3, double-blind, placebo-controlled, 48-week clinical trial to evaluate the efficacy and safety of ataluren (brand name: Translarna™) in patients with cystic fibrosis caused by nonsense mutations, or nmCF. PTC will host a conference call Thursday, March 2, 2017, at 9:00 a.m. ET to discuss the results of ACT CF.

The full text of the press release announcing the results of ACT CF as well as information on how to access the conference call is attached as Exhibit 99.1 hereto and is incorporated by reference into this Item 7.01.

The information set forth in or incorporated by reference into this Item 7.01 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 8.01. Other Events.

On March 2, 2017, the Company announced that the primary and secondary endpoints were not achieved in ACT CF.

In the intent-to-treat population, the primary endpoint of lung function as measured by absolute change in percent-predicted FEV1 (forced expiratory volume in one second), over 48 weeks from baseline, there was a 0.6% difference in favor of ataluren versus placebo (-1.4% change on ataluren versus -2.0% change on placebo; p=0.534). For the secondary endpoint of rate of pulmonary exacerbations, there was a trend in favor of ataluren, with the rate in the ataluren group being 14% lower than the placebo group (p=0.401). The results were not statistically significant.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated March 2, 2017

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.

PTC THERAPEUTICS,
INC.

Date: March 2, 2017 By: /s/ Shane Kovacs
Shane Kovacs
Chief Financial Officer

EXHIBIT INDEX

| Exhibit No. | Description |
|-------------|-----------------------------------|
| 99.1 | Press Release dated March 2, 2017 |