PTC THERAPEUTICS, INC.
Form 8-K
April 20, 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): April 20, 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):

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 2.01. Completion of Acquisition or Disposition of Assets.

On April 20, 2017, PTC Therapeutics, Inc. (the "Company"), completed the previously announced acquisition of all rights to Emflaza™ (deflazacort) (the "Transaction"). The Transaction was completed pursuant to an asset purchase agreement, dated March 15, 2017, as amended on April 20, 2017 to amend certain post-closing obligations (as amended, the "Asset Purchase Agreement") by and between the Company and Marathon Pharmaceuticals, LLC ("Marathon").

The assets (the "Assets") acquired by the Company in the Transaction include intellectual property rights related to Emflaza, inventories of Emflaza, certain contractual rights related to Emflaza, including the contractual rights described herein, among others, and certain other assets related to Emflaza.

The Company assumed certain liabilities and obligations in the Transaction, including the contractual obligations described herein and various other liabilities and obligations arising out of, or relating to, the Assets.

Upon the closing of the Transaction, the Company paid to Marathon total upfront consideration of approximately $140 million. The total upfront consideration was comprised of $75 million in cash, funded through cash on hand, and 6,683,598 shares of the Company's common stock. The number of shares of common stock issued at closing was determined by dividing $65 million by the volume weighted average price per share of the Company's common stock on the Nasdaq Stock Market for the 15 trading day period ending on the third trading day immediately preceding the closing. As previously disclosed, Marathon will be entitled to receive contingent payments from the Company based on annual net sales of Emflaza beginning in 2018, up to a specified aggregate maximum amount for such payments, and a single $50 million sales-based milestone, in each case subject to the terms and conditions of the Asset Purchase Agreement. The Company expects that the contingent payments will, on a blended average basis, range in percentages of net sales between the low to mid-twenties.

The above description of the Asset Purchase Agreement is a summary only and is qualified in its entirety by reference to the terms of the Asset Purchase Agreement. A copy of the Asset Purchase Agreement was previously filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed on March 16, 2017. A copy of the amendment to the Asset Purchase Agreement is attached hereto as Exhibit 2.1.

Faes Agreement. Upon the closing of the Transaction, Marathon assigned to the Company all rights, and the Company assumed all obligations, under the Exclusive License and Supply Agreement, dated as of May 12, 2015 and amended as of November 1, 2015, between Marathon and Faes Farma, S.A. ("Faes") (the "Faes Agreement").

Pursuant to the assignment and assumption of the Faes Agreement, Faes grants the Company a license in, to and under certain intellectual property, know-how and technology of Faes (as per the definition of "Licensed Assets" in the Faes Agreement) related to the deflazacort oral suspension pharmaceutical product as owned and currently supplied by Faes in certain markets in the world (the "Faes Product", together with the Licensed Assets, the "Faes Assets") to research, develop, obtain regulatory approval for, market, promote, distribute, sell, use, commercialize and, solely as expressly permitted under the Faes Agreement, manufacture the deflazacort oral suspension pharmaceutical products developed by the Company (or developed by Marathon prior to the closing of the Transaction) based upon and utilizing the Faes Assets and approved by the FDA for the treatment in humans of Duchenne muscular dystrophy or other indications in and for the territory of the United States (the "Deflazacort Suspension Product") as set forth in the Faes Agreement. The license is exclusive during the Manufacturing Term and non-exclusive thereafter. The Manufacturing Term is defined as (a) the Initial Manufacturing Term, commencing on the date of the Faes Agreement and ending on the 20th anniversary thereof, together with (b) any Renewed Manufacturing Terms, which are automatic renewals of the Manufacturing Term for 10-year periods, subject to earlier termination by the parties in accordance with the terms of the Faes Agreement.

Subject to the terms and conditions of the Faes Agreement, Faes reserves all rights under the Licensed Assets to research, develop and manufacture the Faes Product for any and all purposes both inside the United States (with the Company's prior written consent, not to be unreasonably withheld) or outside the United States. Faes also retains the right under the Faes Agreement to research, develop, make and have made, use, market, distribute, offer for sale, sell and import the Faes Product for any and all purposes outside of the United States.

Pursuant to the Faes Agreement, the parties agree to work collaboratively to conduct manufacturing research and development work relating to Deflazacort Suspension Products in accordance with the terms of the Faes Agreement.

Pursuant to the terms of the Faes Agreement, during the initial period commencing on the FDA approval date of Emflaza and continuing until the seventh anniversary of such date, Faes shall be the exclusive supplier to the Company of any finished Deflazacort Suspension Product for use in the United States. During the Manufacturing Term, Faes and its affiliates may only supply deflazacort oral suspension products for use in the United States to the Company. The Faes Agreement provides that Faes shall supply finished Deflazacort Suspension Products to the Company at a specified per unit supply price.

Pursuant to the terms of the Faes Agreement, during the initial period commencing on the FDA approval date of Emflaza and continuing until the seventh anniversary of such date, the Company is obligated to pay to Faes royalty payments, on a quarterly basis, based on a percentage (ranging from low to middle-low double digits) of, or a fixed payment with respect to, the Company's annual net sales of Deflazacort Suspension Product in the United States as specified in the Faes Agreement, subject to reduction in accordance with the terms of the agreement. The royalty payments during such initial period are subject to a minimum aggregate annual payment ranging from €0.5 million to €1.5 million per year.

The Faes Agreement may be terminated at any time upon the mutual agreement of the parties or upon a party's material breach of its material obligations under the Faes Agreement, subject to notice and cure periods and other procedures set forth in the Faes Agreement. The Faes Agreement also contains provisions relating to, among other things, representations and warranties of the parties, purchase orders, pricing, payment terms, costs and expenses, regulatory matters, audit and reporting rights, intellectual property matters, limitations on assignment, confidentiality, indemnification and dispute resolution.

Alcami Agreement. Upon the closing of the Transaction, Marathon assigned to the Company all rights, and the Company assumed all obligations, under the Commercial Manufacturing Agreement, dated as of September 18, 2015 and amended as of September 18, 2016 and January 6, 2017, between Marathon and Alcami Corporation, f/k/a AAIPharma Services Corp. ("Alcami") (the "Manufacturing Agreement").

Pursuant to the assignment and assumption of the Manufacturing Agreement, the Company agrees to exclusively purchase from Alcami, and Alcami agrees to exclusively manufacture and supply, all of the Company's requirements for deflazacort tablets as well as secondary packaging of pre-filled deflazacort oral suspension bottles (the "Manufacturing Products") for the commercialization of such Manufacturing Products in the United States, and any other jurisdiction in which the Company may commercialize the Manufacturing Products, pursuant to the terms of the Manufacturing Agreement. The initial term of the Manufacturing Agreement continues for a period of five years commencing on the first date of shipment of commercial product from Alcami's site with respect to each Manufacturing Product, subject to automatic two-year renewal periods with respect to each Manufacturing Product unless terminated by the parties pursuant to the terms of the Manufacturing Agreement. Pursuant to the terms of the Manufacturing Agreement, the Company is required to supply to Alcami the active pharmaceutical ingredient for Manufacturing Products, which shall remain the sole property of the Company.

The Manufacturing Agreement may be terminated as described above or upon a party's material breach of its obligations under the Manufacturing Agreement in addition to other specified events, including with respect to governmental actions, certain circumstances relating to individual products, force majeure or bankruptcy proceedings, in each case subject to notice, cure periods and other conditions set forth in the Manufacturing Agreement. The Manufacturing Agreement also contains provisions relating to, among other things, representations and warranties of the parties, purchase orders, pricing (including price changes), payment terms, costs and expenses, regulatory matters, non-conforming products, recalls, intellectual property matters, limitations on assignment, confidentiality, indemnification and dispute resolution provisions.

Item 3.02. Unregistered Sales of Equity Securities.

The description of the common stock consideration set forth in Item 2.01 above is incorporated herein by reference. In connection with the closing of the Transaction, the Company issued to Marathon the common stock consideration pursuant to an exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and/or Regulation D promulgated thereunder, based in part on Marathon's representations to the Company that it is an "accredited investor" as that term is defined under Rule 501(a) under the Securities Act.

Item 7.01. Regulation FD Disclosure.

On April 20, 2017, the Company issued a press release in which it announced the closing of the Transaction. A copy of the press release is attached to this Current Report on Form 8-K (this "Report") as Exhibit 99.1 and is incorporated by reference into this Item 7.01.

The information set forth in or incorporated by reference into this Item 7.01, 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 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired

The financial statements of the acquired business required by this item have not been filed on this Report but will be filed by amendment not later than 71 calendar days after the date that this Report was required to be filed.

(b) Pro Forma Financial Information

The pro forma financial information required by this item has not been filed on this Report but will be filed by amendment not later than 71 calendar days after the date that this Report was required to be filed.

(d) Exhibits

See Exhibit Index attached hereto.

Cautionary Statement Concerning Forward Looking Statements

This Report contains forward-looking statements addressing the Transaction and the other transactions contemplated in the Asset Purchase Agreement and other statements about future expectations, prospects, estimates and other matters that are dependent upon future events or developments. All statements, other than those of historical fact, contained in this Report are forward-looking statements, including statements related to the Company's expectations with respect to the future commercial availability of, and access to, Emflaza; the Company's expectations with respect to contingent payments to Marathon based on annual net sales; the future expectations, plans and prospects for the Company; the Company's strategy, future operations, future financial position, future revenues or projected costs; and the objectives of management. Other forward-looking statements may be identified by the words "look forward", "plan," "anticipate," "believe," "estimate," "expect," "intend," "may," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions.

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 Company's preparations for a commercial launch of Emflaza; the Company's ability to realize the anticipated benefits of the Transaction, including the possibility that the expected benefits from the Transaction will not be realized or will not be realized within the expected time period; negative effects of the announcement of the Asset Purchase Agreement or the closing of the Transaction on the market price of the Company's common stock; significant transaction costs, unknown liabilities, the risk of litigation and/or regulatory actions related to the Transaction, as well as other business effects, including the effects of industry, market, economic, political or regulatory conditions; changes in tax and other laws, regulations, rates and policies; the eligible patient base and commercial potential of Translarna™ (ataluren) and Emflaza; the sufficiency of the Company's cash resources and its ability to obtain adequate financing in the future for its foreseeable and unforeseeable operating expenses and capital expenditures; and the factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K as well as any updates to these risk factors filed from time to time in the Company's other filings with the SEC. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that any product will receive or maintain regulatory approval in any territory, or prove to be commercially successful, including Translarna or Emflaza. The forward-looking statements contained herein represent the Company's views only as of the date of this Report 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 Report except as required by law.

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: April 20, 2017

By: /s/ Stuart Peltz

Name: Stuart Peltz

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
2.1	Amendment to the Asset Purchase Agreement dated April 20, 2017
99.1	Press Release, dated April 20, 2017, issued by PTC Therapeutics, Inc.