

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): **August 4, 2016**

PTC THERAPEUTICS, INC.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35969
(Commission
File Number)

04-3416587
(IRS Employer
Identification No.)

100 Corporate Court
South Plainfield, NJ
(Address of Principal Executive Offices)

07080
(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 2.02. Results of Operations and Financial Condition.

On August 4, 2016, PTC Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2016. 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.

The information in this Item 2.02 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated August 4, 2016

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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: August 4, 2016

By: /s/ Shane Kovacs

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 4, 2016



**PTC THERAPEUTICS REPORTS SECOND QUARTER 2016 FINANCIAL RESULTS
AND PROVIDES CORPORATE UPDATE**

- *Translarna™ net sales of \$15.4M representing 150% year-over-year growth* —
- *Full-year Translarna net sales on-track to meet guidance of \$65M to \$85M* —
- *NHS England and NICE agreement completed allowing reimbursed access* —
- *EMA review of European marketing authorization for Translarna continues* —
- *FDA appeal process initiated in the U.S.* —

SOUTH PLAINFIELD, NJ — August 4, 2016 — PTC Therapeutics, Inc. (NASDAQ: PTCT) today announced a corporate update and reported financial results for the second quarter ending June 30, 2016.

“Making Translarna available to all Duchenne muscular dystrophy patients globally who may benefit continues to be our top priority,” said Stuart W. Peltz, Ph.D., Chief Executive Officer, PTC Therapeutics, Inc. “Global sales are on a strong growth trajectory as we continue to expand access outside of the U.S. We are excited patients in England can now access reimbursed Translarna and have received our first commercial order in England following NICE’s final guidance recommending Translarna. On the regulatory front, we are optimistic that our interactions with the EMA will support the renewal of Translarna’s marketing authorization coupled with an obligation to conduct an agreed upon clinical trial, and we look forward to our next steps in the appeal process of the FDA’s Refuse to File letter.”

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Key Second Quarter and Other Corporate Highlights:

- **Translarna revenue of \$15.4M in second quarter represents 150% year-over-year growth.** PTC continues to grow its global commercial footprint and expand access to Translarna. In addition to Europe, PTC is now providing Translarna to patients on a commercial basis in the Middle East and Latin America.
- **NICE issues final guidance recommending Translarna for patients in England.** The National Institute for Health and Care Excellence (NICE) issued final guidance recommending Translarna for the treatment of ambulatory patients aged five years and older with nmDMD in England in connection with a Managed Access Agreement (MAA) with National Health Services (NHS) England. As part of the MAA, NHS England is waiving the typical three-month implementation period under local regulation, making Translarna immediately available to patients in England.
- **EMA review of European marketing authorization for Translarna continues.** Over the last several months, PTC has been engaged in constructive discussions with the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) regarding the renewal of Translarna’s marketing authorization. The company has been informed that the renewal assessment procedure cannot be completed by mid-year 2016. The CHMP has agreed to the proposal by PTC to submit a draft clinical trial protocol for further discussion, which includes seeking scientific advice from the EMA. The company is optimistic that these interactions will support the renewal of the marketing authorization of Translarna coupled with an obligation to conduct an agreed upon clinical trial.
- **PTC has submitted an appeal to the FDA via the formal dispute resolution process.** PTC has appealed the Refuse to File (RTF) letter issued on February 22, 2016 with respect to the company’s New Drug Application (NDA) for Translarna for the treatment of nmDMD. This process elevates the discussion to the next level of FDA management and exists to encourage open, prompt discussion of scientific and procedural disputes that arise during the drug development process between FDA and companies.

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- **ACT CF Phase 3 clinical trial remains on track while EMA review of cystic fibrosis filing for Translarna is ongoing.** PTC’s confirmatory Phase 3 ACT CF trial is currently ongoing with the results from this trial expected in early 2017. The EMA is currently reviewing the company’s variation submission to Translarna’s marketing authorization, which requests EMA approval for the treatment of nonsense mutation cystic fibrosis (nmCF). Based on recent interactions with the CHMP, PTC no longer anticipates that the CHMP will issue its opinion regarding this submission in 2016 and believes that ACT CF results may be required prior to any approval in this indication.
- **Phase 2 Clinical Trial of Translarna for nmDMD in pediatric patients initiated.** PTC has initiated a Phase 2 clinical trial of Translarna for the treatment of nmDMD in patients between the ages of two and five years of age. This open-label, multiple-dose study will evaluate the safety and pharmacokinetics of Translarna in pediatric patients and will support the potential expansion of Translarna’s label to younger patients.

Second Quarter Financial Highlights:

- Translarna net product sales were \$15.4 million for the second quarter of 2016, representing a 150% increase versus \$6.2 million in the second quarter of 2015. The increase in sales is a result from the continued global commercial expansion and access to Translarna. Translarna net product

sales decreased sequentially from \$18.9 million reported in the first quarter of 2016. In the first quarter, Translarna net product sales were positively impacted by a significant order from Brazil, where purchasing is often fulfilled in national bulk orders. The effect of larger but less frequent orders from Brazil may result in fluctuations in quarterly sales reporting during the course of the year.

- Total revenues for the second quarter of 2016 were \$15.6 million compared to \$6.8 million in the same period of 2015. The change in total revenue was a result of the expanded commercial launch of Translarna, partially offset by lower grant revenue.
- GAAP R&D expenses were relatively flat at \$28.8 million for the second quarter of 2016 compared to \$28.2 million for the same period in 2015. Non-GAAP R&D expenses were \$24.7 million for the second quarter of 2016, excluding \$4.1 million in non-cash, stock-

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based compensation expense, compared to \$24.2 million for the same period in 2015, excluding \$4.0 million in non-cash, stock-based compensation expense.

- GAAP SG&A expenses were \$23.4 million for the second quarter of 2016 compared to \$17.2 million for the same period in 2015. Non-GAAP SG&A expenses were \$18.7 million for the second quarter of 2016, excluding \$4.6 million in non-cash, stock-based compensation expense, compared to \$12.8 million for the same period in 2015, excluding \$4.4 million in non-cash, stock-based compensation expense. The increase in SG&A expense for the second quarter 2016 as compared to the prior year period primarily resulted from additional costs associated with commercial activities in support of Translarna across Europe and other regions.
- Net interest expense for the second quarter of 2016 was \$2.1 million compared to net interest income of \$0.5 million in the same period in 2015. The increase in interest expense is primarily a result of the \$150 million convertible debt offering completed during the third quarter 2015. The debt was recorded on PTC's balance sheet at a discount, which will be amortized over the life of the bond.
- Net loss for the second quarter of 2016 was \$38.9 million compared to a net loss of \$38.4 million for the same period in 2015.
- During the first quarter of 2016, PTC announced a workforce reduction of approximately 18% of its employees and contractors, which resulted in a one-time charge of approximately \$2.5 million. PTC incurred \$0.6 million of this charge in the second quarter.
- Cash, cash equivalents, and marketable securities totaled approximately \$273 million at June 30, 2016 compared to approximately \$339 million at December 31, 2015.
- Shares issued and outstanding as of June 30, 2016 were 34.3 million, which includes 0.2 million shares of unvested restricted stock.

2016 Guidance:

- Total ex-U.S. Translarna nmDMD revenues for 2016 are anticipated to be between \$65 and \$85 million. This guidance assumes current exchange rates and the continued commercial expansion for Translarna in nmDMD outside of the U.S.

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- Operating expenses for the full year 2016 are anticipated to be between \$185 million and \$195 million, excluding expected non-cash stock-based compensation expense of approximately \$40 million, for total operating expenses of approximately \$225 million to \$235 million. These expenses will be primarily in support of our ongoing clinical trials for Translarna in nmDMD and nmCF, commercial launch activities for Translarna outside of the US, and the continued research and clinical development of other product pipeline candidates.
- PTC expects to end 2016 with cash and cash equivalents over \$200 million.

Non-GAAP Financial Measures

- In this press release, PTC's financial results and financial guidance are provided in accordance with accounting principles generally accepted in the United States (GAAP) and using certain non-GAAP financial measures. In particular, non-GAAP financial results exclude stock-based compensation expense. These results are provided as a complement to results reported in GAAP, because management uses these non-GAAP financial measures when assessing and identifying operational trends. In management's opinion, these non-GAAP measures are useful to investors and other users of our financial statements by providing greater transparency into the operating performance at PTC and the company's future outlook.

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PTC Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Net product revenue	\$ 15,437	\$ 6,161	\$ 34,314	\$ 11,230
Collaboration and grant revenue	196	613	214	3,026

Total revenues	15,633	6,774	34,528	14,256
Operating expenses:				
Research and development (1)	28,827	28,190	60,226	56,128
Selling, general and administrative (2)	23,366	17,210	49,304	34,825
Total operating expenses	52,193	45,400	109,530	90,953
Loss from operations	(36,560)	(38,626)	(75,002)	(76,697)
Interest (expense) income, net	(2,060)	498	(4,016)	1,022
Other (expense) income, net	(387)	(88)	(1,107)	(456)
Loss before income tax expense	(39,007)	(38,216)	(80,125)	(76,131)
Income tax benefit (expense)	93	(145)	(22)	(145)
Net loss	<u>\$ (38,914)</u>	<u>\$ (38,361)</u>	<u>\$ (80,147)</u>	<u>\$ (76,276)</u>
Weighted-average shares outstanding (in shares):				
Basic and diluted	34,000,333	33,600,653	33,959,751	33,335,674
Net loss per share - basic and diluted (in dollars per share)	<u>\$ (1.14)</u>	<u>\$ (1.14)</u>	<u>\$ (2.36)</u>	<u>\$ (2.29)</u>

(1) Research and development reconciliation

GAAP research and development	\$ 28,827	\$ 28,190	\$ 60,226	\$ 56,128
Less stock-based compensation expense	4,087	3,957	8,415	8,624
Non-GAAP research and development	<u>\$ 24,740</u>	<u>\$ 24,233</u>	<u>\$ 51,811</u>	<u>\$ 47,504</u>

(2) Selling, general and administrative reconciliation

GAAP selling, general and administrative	\$ 23,366	\$ 17,210	\$ 49,304	\$ 34,825
Less stock-based compensation expense	4,649	4,371	9,236	9,452
Non-GAAP selling, general and administrative	<u>\$ 18,717</u>	<u>\$ 12,839</u>	<u>\$ 40,068</u>	<u>\$ 25,373</u>

PTC Therapeutics, Inc.
Summary Consolidated Balance Sheet
(In thousands, except share amounts)

	June 30, 2016	December 31, 2015
Cash, cash equivalents and marketable securities	\$ 272,893	\$ 338,925
Total assets	<u>\$ 305,563</u>	<u>\$ 365,281</u>
Total debt	\$ 94,936	\$ 91,848
Total deferred revenue	726	139
Total liabilities	<u>\$ 139,939</u>	<u>\$ 139,280</u>
Total stockholders' equity (34,083,319 and 33,916,559 common shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively)	165,624	226,001
Total liabilities and stockholders' equity	<u>\$ 305,563</u>	<u>\$ 365,281</u>

Upcoming Events:

PTC will participate in the following upcoming conference:

- 2016 Webbush PacGrow Healthcare Conference, August 17th at 1:20 p.m. in New York, NY

The presentation will be webcast live on the Events and Presentations page under the investor relations section of PTC's website at www.ptcbio.com and will be archived for two weeks following the presentation. PTC's current investor presentation is available at the same website location.

Today's Conference Call and Webcast Reminder

Today's call will take place at 4:30 p.m. (ET) and can be accessed by dialing (877) 303-9216 (domestic) or (973) 935-8152 (international) five minutes prior to the start of the call and providing the passcode 49796148. The webcast will be available on the investor relations section of the PTC website at www.ptcbio.com. A webcast replay of the call will be available approximately two hours after completion of the call and will be archived on the company's website for two weeks.

About PTC Therapeutics, Inc.

PTC is a global biopharmaceutical company focused on the discovery, development and commercialization of orally administered, proprietary small molecule drugs targeting an area of RNA biology we refer to as post-transcriptional control. Post-transcriptional control processes are the regulatory events that occur in cells during and after a messenger RNA, or mRNA, molecule is copied from DNA through the transcription process. PTC's internally discovered pipeline addresses multiple therapeutic areas, including rare disorders and oncology. PTC has discovered all of its compounds currently under development using its proprietary technologies. PTC plans to continue to develop these compounds both on its own and through selective collaboration arrangements with leading pharmaceutical and biotechnology companies. For more information on the company, please visit our website www.ptcbio.com

About Translarna™

Translarna, discovered and developed by PTC Therapeutics, Inc., is a protein restoration therapy designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation. A nonsense mutation is an alteration in the genetic code that prematurely halts the synthesis of an essential protein. The resulting disorder is determined by which protein cannot be expressed in its entirety and is no longer functional, such as dystrophin in Duchenne muscular dystrophy. Translarna is licensed in the European Economic Area for the treatment of nonsense mutation Duchenne muscular dystrophy in ambulatory patients aged five years and older. Translarna is an investigational new drug in the United States. The development of Translarna has been supported by grants from Cystic Fibrosis Foundation Therapeutics Inc. (the nonprofit affiliate of the Cystic Fibrosis Foundation); Muscular Dystrophy Association; FDA's Office of Orphan Products Development; National Center for Research Resources; National Heart, Lung, and Blood Institute; and Parent Project Muscular Dystrophy.

FOR MORE INFORMATION PLEASE CONTACT:

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FORWARD LOOKING STATEMENTS:

All statements, other than those of historical fact, contained in this press release, are forward-looking statements, including the information provided under the heading "2016 Guidance" and statements regarding the future expectations, plans and prospects for PTC; the timing and outcome of PTC's regulatory strategy and process, including (i) when the EMA's CHMP will

issue an opinion with respect to the renewal of the marketing authorization for Translarna for the treatment of nmDMD and, when issued, whether such opinion will be positive, (ii) the nature of any conditions or restrictions that may be placed on any renewal of the marketing authorization by the European Commission, (iii) PTC's ability to design an acceptable new clinical trial in nmDMD with input from the EMA, (iv) PTC's ability to resolve the matters set forth in the Refuse to File letter with the FDA or otherwise advance Translarna for the treatment of nmDMD in the United States, whether pursuant to the formal dispute resolution process, an accelerated approval process, or otherwise, and (v) whether PTC's Phase 2 study of Translarna for nmDMD in pediatric patients may support expansion of Translarna's label to younger patients; the clinical utility and potential advantages of Translarna; the timing and scope of PTC's commercial and early access program launches; the rate and degree of market acceptance of Translarna; PTC's estimates regarding the potential market opportunity for Translarna, including the size of eligible patient populations and PTC's ability to identify such patients; the timing, results and conduct of PTC's clinical trials and studies of Translarna for the treatment of nmCF and other indications, as well as its studies under its SMA collaboration with Roche and the SMA Foundation, and its Phase 1 study under its cancer stem cell program, including statements regarding the timing of initiation, evaluation, enrollment and completion of the trials and studies and the period during which the results of the trials and studies will become available; PTC's ability to continue to supply Translarna to patients across Europe and in other territories; PTC'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 "guidance," "optimistic," "plan," "target," "anticipate," "believe," "estimate," "expect," "intend," "may," "potential," "project," "possible," "potential," "will," "would," "could," "should," "continue," and similar expressions.

PTC'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: PTC's ability to maintain its marketing authorization of Translarna for the treatment of nmDMD in the European Economic Area (EEA), including whether the EMA determines that the benefit-risk balance of Translarna supports renewal of our marketing authorization in the EEA; the nature and scope of any new nmDMD trial that PTC

may design with the input of the EMA and PTC's ability to enroll, fund and conduct such trial; the outcome of future interactions PTC has with the FDA with respect to Translarna for the treatment of nmDMD, including whether PTC is required to perform additional clinical and non-clinical trials at significant cost and whether such trials, if successful, may enable FDA review of a NDA submission; the EMA's determinations with respect to PTC's variation submission which seeks to add Translarna for the treatment of nonsense mutation cystic fibrosis to PTC's marketing authorization in the EEA; the scope of regulatory approvals or authorizations for Translarna (if any), including labeling and other matters that could affect the availability or commercial potential of Translarna; the outcome of ongoing or future clinical trials or studies, including ACT CF and the Phase 2 study of Translarna for nmDMD in pediatric patients; the eligible patient base and commercial potential of Translarna and PTC's other product candidates; PTC's ability to commercialize and commercially manufacture Translarna in general and specifically as a treatment for nmDMD, including its ability to establish and maintain arrangements with manufacturers, suppliers, distributors and production and collaboration partners on favorable terms; the outcome of pricing and reimbursement negotiations in those territories in which PTC is authorized to sell Translarna; whether patients and healthcare professionals may be able to access Translarna through alternative means if pricing and reimbursement negotiations in the applicable territory do not have a positive outcome; expectations for regulatory approvals,

including PTC's ability to make regulatory submissions in a timely manner (or at all), the period during which the outcome of regulatory reviews will become available, adverse decisions by regulatory authorities, other delay or deceleration of the regulatory process, and PTC's ability to meet existing or future regulatory standards with respect to Translarna; PTC's ability to fulfill any additional obligations, including with respect to further trials or studies relating to cost-effectiveness, obtaining licenses or satisfying requirements for labor and business practices, in the territories in which it may obtain regulatory approval, including the United States, EEA and other territories; the initiation, conduct and availability of data from clinical trials and studies; PTC's scientific approach and general development progress; the sufficiency of PTC's cash resources and PTC's ability to obtain adequate financing in the future for PTC's foreseeable and unforeseeable operating expenses and capital expenditures; and the factors discussed in the "Risk Factors" section of PTC's most recent

Quarterly Report on Form 10-Q as well as any updates to these risk factors filed from time to time in PTC's other filings with the SEC. You are urged to carefully consider all such factors.

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 Translarna will receive full regulatory approval in any territory or maintain its current marketing authorization in the EEA, or prove to be commercially successful in general, or specifically with respect to the treatment of nmDMD.

The forward-looking statements contained herein represent PTC's views only as of the date of this press release and PTC 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 press release except as required by law.