PTC THERAPEUTICS, INC.
Form 8-K
August 02, 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): August 1, 2018
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 1.01. Entry into a Material Definitive Agreement.

On August 1, 2018 (the "Effective Date"), PTC Therapeutics International Limited ("PTC"), a subsidiary of PTC Therapeutics, Inc. (the "Company"), entered into a Collaboration and License Agreement (the "Agreement") with Akcea Therapeutics, Inc. ("Akcea"), for the commercialization by PTC of TEGSEDI™ (inotersen), WAYLIVRA™ (volanesorsen) and products containing those compounds (collectively, the "Products") in countries in Latin America and the Caribbean (the "PTC Territory"). TEGSEDI is an antisense oligonucleotide inhibitor of human transthyretin production, or TTR protein, for the treatment of patients with hereditary transthyretin amyloidosis (hATTR amyloidosis), a severe, rare and fatal genetic disease. WAYLIVRA is an antisense drug candidate in development for two rare metabolic disorders: familial chylomicronemia syndrome (FCS) and familial partial lipodystrophy (FPL). Neither TEGSEDI nor WAYLIVRA is currently approved for marketing in the PTC Territory. In addition, Akcea has granted to PTC a right of first negotiation ("ROFN") to commercialize AKCEA-TTR-Lrx, a follow-on product candidate to inotersen, on an exclusive basis in the PTC Territory.

Under the terms of the Agreement, Akcea has granted to PTC an exclusive right and license, with the right to grant certain sublicenses, under Akcea's product-specific intellectual property to develop, manufacture and commercialize the Products in the PTC Territory. In addition, Akcea has granted to PTC a non-exclusive right and license, with the right to grant certain sublicenses, under Akcea's core intellectual property and manufacturing intellectual property to develop, manufacture and commercialize the Products in the PTC Territory and to manufacture the Products worldwide in accordance with a supply agreement with Akcea. Akcea has in-licensed certain of the Akcea intellectual property from its affiliate, Ionis Pharmaceuticals, Inc. ("Ionis"). Each party has agreed not to, independently or with any third party, commercialize any competing oligonucleotide product in the PTC Territory for the same gene target as inotersen.

Within 30 days after the effective date, Akcea has agreed to assign and transfer to PTC the ownership and sponsorship of applicable regulatory approvals in countries in the PTC Territory, after which PTC has agreed to prepare, file and maintain regulatory filings and approvals for the applicable Products in such countries. After the Effective Date, PTC is responsible for all meetings, communications and other interactions with regulatory authorities in the PTC Territory.

PTC has agreed to pay to Akcea an upfront licensing fee of $18 million, consisting of a payment of $12 million within ten business days after the Effective Date, and $6 million within 30 days after receipt of regulatory approval of WAYLIVRA from the United States Food and Drug Administration or the European Medicines Agency, whichever occurs earlier. In addition, Akcea is eligible to receive milestone payments, on a Product-by-Product basis, of $4 million upon receipt of regulatory approval for a Product from ANVISA, the Brazilian Health Regulatory Authority, subject to a maximum aggregate amount of $8 million for all such Products. Akcea is also entitled to receive royalty payments in the mid-twenty percent range of net sales on a country-by-country and Product-by-Product basis, commencing on the earlier to occur of (1) 12 months after the first commercial sale of such Product in Brazil or (2) the date when PTC, its affiliates or sublicensees have recognized revenue of $10 million or more in cumulative net sales for such Product in the PTC Territory. The royalty payments are subject to reduction in certain circumstances as set forth in the Agreement.

Akcea has granted to PTC a ROFN to commercialize AKCEA-TTR-Lrx in the PTC Territory, subject to negotiation of the terms of a definitive agreement and certain other terms and conditions. Such a definitive agreement would provide for a royalty rate to be paid by PTC for AKCEA-TTR-Lrx equal to the royalty rate PTC has agreed to pay for TEGSEDI under the Agreement, or in the mid-twenty percent range of net sales, and the term of such royalty payments would be the same as the term of the TEGSEDI royalty payments. During a specified period in the Agreement, neither Akcea nor Ionis may enter into an agreement or grant any license to AKCEA-TTR-Lrx that is inconsistent with PTC's ROFN.

The activities of the parties pursuant to the Agreement will be overseen by a Joint Steering Committee, to be composed of an equal number of representatives appointed by each of PTC and Akcea.

The Agreement continues until the expiration of the last to expire royalty term with respect to all Products in all countries in the PTC Territory. Either party may terminate the Agreement on written notice to the other party if such other party is in material breach of its obligations thereunder and has not cured such breach within 30 days after notice in the case of a payment breach or 60 days after notice in the case of any other breach.

The foregoing description of the Agreement is a summary only and is qualified in its entirety by reference to the terms of the Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018.

Item 7.01. Regulation FD Disclosure.

On August 2, 2018, the Company issued a press release in which it announced that it entered into the Agreement. A copy of the press release is attached to 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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 2, 2018, issued by PTC Therapeutics, Inc.

Cautionary Statement Concerning Forward Looking Statements

This Report contains forward-looking statements addressing the Collaboration and Licensing Agreement and any 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 Collaboration and Licensing Agreement; the potential financial impact and benefits to the Company of the Collaboration and Licensing Agreement, including with respect to the timing of regulatory approval of TEGSEDI and WAYLIVRA in countries in the PTC Territory, the commercialization of TEGSEDI and WAYLIVRA, and the Company's expectations with respect to contingent payments to Akcea based on net sales and the potential achievement of regulatory milestones; 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 sim
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 the factors discussed in the "Risk Factors" section of the Company's most recent Quarterly Report on Form 10-Q or 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 candidate will receive or maintain regulatory approval in any territory, or prove to be commercially successful, including TEGSEDI or WAYLIVRA, or any other product candidates. 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. All website addresses given in this Report or incorporated herein by reference are for information only and are not intended to be an active link or to incorporate any website information into this Report.

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: August 2, 2018 By: /s/ Mark E. Boulding
Name: Mark E. Boulding
Title: Executive Vice President and Chief Legal Officer