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PTC THERAPEUTICS, INC.

Form 8-K

August 28, 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 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 8.01. Other Events.

On August 27, 2018, Akcea Therapeutics, Inc. (“Akcea”), an affiliate of Ionis Pharmaceuticals, Inc. (“Ionis”), and Ionis issued a press release stating that Akcea and Ionis received a Complete Response Letter from the Division of Metabolism and Endocrinology Products of the U.S. Food and Drug Administration regarding the New Drug Application for WAYLIVRA™ (volanesorsen) for the treatment of people with familial chylomicronemia syndrome (“FCS”). WAYLIVRA is also under regulatory review in the E.U. and Canada for the treatment of people with FCS. As previously disclosed, WAYLIVRA, an antisense drug candidate in development for two rare metabolic disorders, FCS and familial partial lipodystrophy (FPL), is subject to a collaboration and license agreement by and between Akcea and PTC Therapeutics International Limited (“PTC”), a subsidiary of PTC Therapeutics, Inc., pursuant to which, among other things, Akcea granted PTC an exclusive right and license to develop, manufacture and commercialize WAYLIVRA in countries in Latin America and the Caribbean.

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 28, 2018 By: /s/ Mark E. Boulding

Name: Mark E. Boulding

Title: Executive Vice President and Chief Legal Officer