Neos Therapeutics, Inc.
Form 8-K
November 01, 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): **October 31, 2017**

NEOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37508**	**27-0395455**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

2940 N. Highway 360

Grand Prairie, TX 75050

(972) 408-1300

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

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:

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 240.13d-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 x

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. x

Item 8.01. **Other Events.**

On October 31, 2017, Neos Therapeutics, Inc. (Neos) received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. (Teva) advising Neos that Teva has submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (the FDA) for a generic version of Cotempla XR-ODT (methylphenidate extended release orally disintegrating tablet for the treatment of ADHD). Neos has new product exclusivity for a three-year period from the date of approval for Cotempla XR-ODT.

The certification notice alleges that the three U.S. patents listed in the FDA s Orange Book for Cotempla XR-ODT, one with an expiration date in April 2026 and two with expiration dates in June 2032, will not be infringed by Teva s proposed product, are invalid and/or are unenforceable. Neos is evaluating the paragraph IV certification and intends to vigorously enforce its intellectual property rights relating to Cotempla XR-ODT.

Neos has 45 days from the receipt of the paragraph IV certification to commence a patent infringement lawsuit against Teva that would automatically stay, or bar, the FDA from approving Teva s ANDA for 30 months or until a district court decision that is adverse to the asserted patents, whichever is earlier.

* * *

Neos cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as may, will, should, expects, plans, anticipates, co intends, target, projects, contemplates, believes, estimates, predicts, potential or continue or the negative of these words or other expressions that concern Neos expectations, strategy, plans, prospects or intentions. Such statements include, without limitation, statements regarding Neos s intention to vigorously enforce its intellectual property rights. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Neos s actual future results may differ materially from its current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Neos s ability to successfully enforce its intellectual property rights, and to defend its patents; the possibility that Neos may be required to file lawsuits to defend the patent rights covering its product or technology, and the substantial costs associated with such lawsuits; the possible introduction of generic competition to Cotempla XR-ODT; the risk that Neos may not be able to raise sufficient capital when needed, or at all; and other risks set forth under the caption Risk Factors in Neos most recent Annual Report on Form 10-K, as updated by Neos other subsequently filed SEC filings. Neos assume no obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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.

Date: November 1, 2017

NEOS THERAPEUTICS, INC.

By: /s/ Vipin Garg
Vipin Garg
President and Chief Executive Officer