Neos Therapeutics, Inc.
Form 8-K
July 28, 2016

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): **July 25, 2016**

NEOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37508**	**27-0395455**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

2940 N. Highway 360, Grand Prairie, TX	**75050**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(972) 408-1300**

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:

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))

Item 8.01. Other Events.

Cotempla XR-ODT Bioequivalence Bridging Study

On July 28, 2016, Neos Therapeutics, Inc. (Neos) issued a press release (the Press Release) announcing the successful completion of a bioequivalence bridging study for its late stage product candidate, Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablet). A copy of the Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Adzenys XR-ODT Paragraph IV Certification

On July 25, 2016, Neos received a paragraph IV certification from Actavis Laboratories FL, Inc. (Actavis) advising Neos that Actavis has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (the FDA) for a generic version of Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablet for the treatment of ADHD).

The certification notice alleges that the four U.S. patents listed in the FDA s Orange Book for Adzenys XR-ODT, one with an expiration date in April 2026 and three with expiration dates in June 2032, will not be infringed by Actavis 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 Adzenys XR-ODT.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	**Description**
99.1	Press release dated July 28, 2016

* * *

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 Adzenys 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: July 28, 2016

NEOS THERAPEUTICS, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated July 28, 2016