Neos Therapeutics, Inc.
Form 8-K
October 19, 2015

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 Act of 1934

Date of Report (Date of earliest event reported): **October 16, 2015**

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))

Item 8.01. Other Events.

On January 9, 2015, Neos Therapeutics, Inc. (the *Company*) submitted to the U.S. Food and Drug Administration (the *FDA*) a New Drug Application (the *NDA*) under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cotempla XR-ODT (Methylphenidate Extended Release Orally Disintegrating), 10 mg, 20 mg, and 30 mg tablets. On October 19, 2015, the Company issued a press release announcing that on October 16, 2015, the Company received a notification from the FDA (the *Notification*) stating that, as part of its ongoing review of the Company s NDA, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The FDA stated that the Notification does not reflect a final decision on the information under review. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

The Company plans to work with the FDA to understand the nature of the deficiencies once identified and resolve them as quickly as possible. Under the time frames negotiated as a result of the Prescription Drug User Fee Act (*PDUFA*), the FDA had set November 9, 2015 as a target date for a decision on the NDA.

By filing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of the Company s filings with the U.S. Securities and Exchange Commission (the *Commission*) and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Commission, through press releases or through other public disclosure.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements concerning the PDUFA date for Cotempla XR-ODT. Forward-looking statements generally relate to future events or our future financial or operating performance. Any statements contained herein which do not describe historical facts, including but not limited to statements regarding the approval of the NDA, the Company s expectations with regard to discussions with the FDA, plans, and expectations as to the PDUFA date are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, without limitation, any deficiencies the FDA may identify with respect to Cotempla XR-ODT and whether the Company will be able to address the issues that may relate to those deficiencies, the receipt of regulatory approval for Cotempla XR-ODT and the Company s other product candidates for the treatment of attention deficit disorder (*ADHD*), the Company s ability to market and sell its product candidates, the Company s ability to successfully compete in the market for medications indicated for ADHD, the manufacture of Cotempla XR-ODT or its other product candidates, and other risks set forth under the caption Risk Factors in the Company s final prospectus filed on July 24, 2015 pursuant to Rule 424(b) of the Securities Act of 1933, as amended, as updated by its subsequently filed Quarterly Reports on Form 10-Q and its other SEC filings. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated October 19, 2015.

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 thereunto duly authorized.

NEOS THERAPEUTCS, INC.

Date:	October 19, 2015
By:	/s/ Vipin Garg
Title:	President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated October 19, 2015.