Neos Therapeutics, Inc. Form 8-K January 29, 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 Act of 1934

Date of Report (Date of earliest event reported): January 29, 2016

NEOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

001-37508 (Commission File Number)

27-0395455 (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:

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 240.13d-4(c))

Item 2.02 Results of Operations and Financial Condition.

As disclosed in the Company s Registration Statement on Form S-1, filed with the Securities and Exchange Commission on January 29, 2016 (the Registration Statement), Neos Therapeutics, Inc. (the Company) announces that cash and cash equivalents and available-for-sale investments is expected to be approximately \$90.8 million at December 31, 2015, as compared to \$13.3 million at December 31, 2014. This financial data as of December 31, 2015 is preliminary and is based on information available to management as of the date of this current report on Form 8-K and is subject to completion by management of the Company s financial statements as of and for the year ended December 31, 2015. The Company s independent registered public accountants have not audited, reviewed or performed any procedures with respect to such preliminary financial data and accordingly do not express an opinion or any other form of assurance with respect thereto. These results could change as a result of further review. Results for the year ended December 31, 2015 will be announced during the Company s year-end financial results earnings conference call and included in the Company s Annual Report on Form 10-K for the year ended December 31, 2015.

Pursuant to General Instruction B.2. to Form 8-K, the information set forth in this Item 2.02 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended (the Securities Act), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

As disclosed in the Registration Statement, the Company expects to resubmit a new drug application, or NDA, with the United States Food and Drug Administration, or FDA, for its product candidate Cotempla XR-ODT in the fourth quarter of 2016, following the completion of the bioequivalence bridging study to demonstrate bioequivalence between the clinical trial material and the to-be-marketed drug product, including an assessment of food effect, and to provide process validation and three months of stability data. In addition, the Company plans to submit an NDA for NT-0201, the Company s amphetamine XR liquid suspension product candidate, in the fourth quarter of 2016.

Special Note Regarding Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements concerning our expected cash and cash equivalents and available-for-sale investments as of December 31, 2015, resubmission of the NDA for its product candidate Cotempla XR-ODT and submission of the NDA for the product candidate NT-0201. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as may, will, should, expects, plans, anticipates, could, intends, target, projects, contemplates, believes. estimates, predicts, potential or continue or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. These forward-looking statements reflect our current views about our expectations, strategy, plans, prospects or intentions, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, our

ability to successfully complete the bioequivalence bridging study and other risks set forth under the caption Risk Factors in our most recently filed Quarterly Report on Form 10-Q as updated by our subsequently filed other SEC filings. We assume no obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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: January 29, 2016 By: /s/ Vipin Garg

Title: President and Chief Executive Officer

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