

Neos Therapeutics, Inc.
Form 8-K
March 10, 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 Act of 1934

Date of Report (Date of earliest event reported): **March 6, 2017**

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:

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oWritten communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

oSoliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

oPre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

oPre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13d-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On March 6, 2017, Neos Therapeutics, Inc. (the Company) entered into a license agreement (the License Agreement) with Shire LLC (Shire), pursuant to which Shire granted to the Company a non-exclusive license to certain patents owned by Shire (the Shire Patents) for certain activities with respect to NT-0201, the Company s amphetamine extended release oral suspension product candidate for the treatment of attention deficit hyperactivity disorder.

In connection with its filing of a New Drug Application (an NDA) with the United States Food and Drug Administration (the FDA) for NT-0201, the Company had previously provided notice under Paragraph IV of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, to Shire as the owner of the Shire Patents, asserting that the Shire Patents would not be infringed by NT-0201, are invalid and/or are unenforceable. Under the Hatch-Waxman Act, Shire then had 45 days from the receipt of the paragraph IV certification to commence a patent infringement lawsuit against the Company that would automatically stay, or bar, the FDA from approving the Company s NDA for NT-0201 for 30 months or until a district court decision that is adverse to the asserted patents, whichever was earlier.

The License Agreement contains a covenant from Shire not to file a patent infringement suit against the Company alleging that NT-0201 would infringe the Shire Patents. Additionally, under the terms of the License Agreement, the Company is required to pay a lump sum, non-refundable license fee of an amount less than \$1.0 million due no later than thirty days after receiving regulatory approval by the FDA of the Company s NDA for NT-0201. The Company will also pay a single digit royalty on net sales of the NT-0201 during the life of the Shire Patents.

The foregoing description of the material terms of the License Agreement does not purport to be complete and is subject to, and is qualified in its entirety by, reference to the License Agreement, which will be filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ending March 31, 2017.

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 hereunto duly authorized.

NEOS THERAPEUTICS, INC.

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|--------|---------------------------------------|
| Date: | March 10, 2017 |
| By: | /s/ Vipin Garg |
| Title: | President and Chief Executive Officer |