

SUPERNUS PHARMACEUTICALS INC
Form 8-K
March 08, 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): **March 6, 2017**

Supernus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
Incorporation)

001-35518
(Commission File Number)

1550 East Gude Drive, Rockville MD
(Address of principal executive offices)

20-2590184
(IRS Employer Identification No.)

20850
(Zip Code)

Registrant's telephone number, including area code: **(301) 838-2500**

Not Applicable

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(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 (see General Instruction A.2. below):

- 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))
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Item 1.01 Entry into a Material Definitive Agreement.

On March 6, 2017, Supernus Pharmaceuticals, Inc. (Supernus or the Company) entered into Settlement and License Agreements (the Agreements) with Zydus Pharmaceutical (USA), Inc. and Cadila Healthcare Limited (collectively, Zydus), to settle ongoing patent litigation regarding Zydus filing of an Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of the Company s Trokendi XR® (extended-release topiramate) capsules. The ANDA included a paragraph IV certification seeking approval to engage in the manufacture, use and sale of the Zydus product prior to the expiration of United States Patent Nos. 8,298,576 (the 576 Patent), 8,298,580 (the 580 Patent), 8,663,683 (the 683 Patent), 8,877,248 (the 248 Patent), 8,889,191 (the 191 Patent), and 8,992,989 (the 989 Patent, and to the 576 Patent, the 580 Patent, the 683 Patent, the 248 Patent, and the 191 Patent, the Patents-in-Suit).

Under the terms of the Agreements, Zydus admits, solely with respect to the Zydus ANDA and the Zydus product, that the claims of the Patents-in-Suit asserted at the time of the execution of the Agreements were infringed by the filing of the Zydus ANDA and, absent a license from the Company, would be infringed by the manufacture, use, sale, offer for sale, or importation of the Zydus product in the United States. Zydus also admits, solely with respect to the Zydus ANDA and the Zydus product, that the Patents-in-Suit, and all the claims contained therein, are valid and enforceable. Under the Agreements, the Company grants to Zydus a non-exclusive license to the Patents-in-Suit to manufacture, have manufactured, import, use and market a generic version of Trokendi XR® in the United States beginning on January 1, 2023, or earlier under certain circumstances, and Zydus will make royalty payments to the Company. The Company retains the right itself or through an affiliate to market an authorized generic product and grant additional licenses under the Patents-in-Suits to third parties.

Item 8.01 Other Events.

On March 6, 2017, the Company issued a press release announcing a settlement with Zydus of ongoing patent litigation regarding Zydus filing of an ANDA seeking approval to market a generic version of the Company s Trokendi XR® (extended-release topiramate) capsules. A copy of this press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

The following document is filed as an Exhibit pursuant to Item 8.01 hereof:

Exhibit 99.1 Press Release Dated March 6, 2017.

SIGNATURES

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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.

SUPERNUS PHARMACEUTICALS, INC.

DATED: March 8, 2017

By: /s/ Gregory S. Patrick
Gregory S. Patrick
Vice-President and Chief Financial Officer

EXHIBIT INDEX

Number	Description	
99.1	Exhibit 99.1 Press Release Dated March 6, 2017.	Attached