SUPERNUS PHARMACEUTICALS INC
Form 8-K
August 21, 2013
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): August 16, 2013

Supernus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	
(State or other jurisdiction of Incorporation)	
0-50440	20-2590184
(Commission File Number)	(IRS Employer Identification No.)
1550 East Gude Drive, Rockville MD	20850
(Address of principal executive offices)	(Zip Code)

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

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 (see General Instruction A.2. below):

[ ] 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 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement

Effective December 15, 2012, Supernus Pharmaceuticals, Inc. ("Supernus" or the "Company") entered into a Commercial Supply Agreement with Catalent Pharma Solutions, LLC (the "Agreement") that defines each party's responsibilities with respect to the manufacture, formulation, development and supply of commercial-grade quantities of topiramate, the active pharmaceutical ingredient required for the finished drug product, Trokendi XR™ (the "Product"). The Company entered into the Agreement in anticipation of final approval by the U.S. Food and Drug Administration (the "FDA") of the Product, which was received on August 16, 2013, and the commercial launch of the Product, which will occur during the next few weeks.

Under the Agreement, the parties agreed that Catalent Pharma Solutions, LLC will manufacture at its facility, in accordance with mutually agreed upon specifications and current good manufacturing practices, commercial quantities of the Product for the United States. Supernus will be responsible for providing, at no cost to Catalent Pharma Solutions, LLC, the active pharmaceutical ingredient and any other materials required in connection with the manufacture of the Product, and Catalent Pharma Solutions, LLC will be responsible for the manufacture, including processing, packaging and labeling, of the Product in accordance with the specifications.

The foregoing description of this Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

Item 8.01 Other Events

On August 19, 2013, the Company issued a press release to announce the receipt of final approval from the FDA for Trokendi XR,™ a novel once-daily extended release formulation of topiramate for the treatment of epilepsy. The approval letter states that the FDA completed its review of the application and that Trokendi XR is approved effective August 16, 2013 for use as recommended in the agreed-upon labeling. The FDA granted a waiver for certain pediatric study requirements and a deferral for submission of post-marketing pediatric pharmacokinetic assessments that are due in 2019 followed by clinical assessments in 2025.The company expects to launch the product and for it to be available in pharmacies over the next few weeks. 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) Exhibits

The following documents are furnished as an Exhibit pursuant to Item 1.01 hereof:

Exhibit 10.1* – Commercial Supply Agreement, dated December 15, 2012, by and among Catalent Pharma Solutions, LLC and the Company. (Filed herewith)

The following documents are furnished as an Exhibit pursuant to Item 8.01 hereof:

Exhibit 99.1 – Press Release dated August 19, 2013 of the Company announcing the final approval of Trokendi XR.

*Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities and Exchange Act of 1934, as amended.

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.

SUPERNUS PHARMACEUTICALS, INC.

DATED: August 21, 2013 By: /s/ Gregory S. Patrick

Gregory S. Patrick

Vice-President and Chief Financial Officer

EXHIBIT INDEX

Number	Description	
10.1*	Commercial Supply Agreement, dated December 15, 2012, by and among Catalent Pharma Solutions, LLC and the Company. (Filed herewith)	Attached
99.1	Press Release dated August 19, 2013.	Attached

*Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities and Exchange Act of 1934, as amended.