

SUPERNUS PHARMACEUTICALS INC
Form 8-K
December 10, 2018

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): **December 5, 2018**

Supernus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
Incorporation)

001-35518

(Commission File Number)

20-2590184

(IRS Employer Identification No.)

1550 East Gude Drive, Rockville MD

(Address of principal executive offices)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01

Other Events.

On December 5, 2018, Supernus Pharmaceuticals, Inc. (the Company) issued a press release announcing that the Company will report the results of its two pivotal Phase III studies of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (ADHD) on Thursday, December 6, 2018. A copy of this press releases is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

On December 6, 2018, the Company issued a press release announcing positive topline results from its Phase III studies of SPN-812 in children for the treatment of ADHD. The trial was successful in meeting the primary endpoint, demonstrating that SPN-812 at daily doses of 100mg and 200mg in study P301 and 200mg and 400mg in study P303 achieved a statistically significant improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD Rating Scale-5. All SPN-812 doses tested in the trials were well tolerated. The Company expects to announce topline data from study P302, the first adolescent Phase III trial of SPN-812, by the end of December 2018. Topline data from the second adolescent Phase III trial, P304, are expected by the end of the first quarter of 2019. The Company expects to submit a New Drug Application for SPN-812 in the second half of 2019, and to launch it, pending U.S. Food and Drug Administration approval, in the second half of 2020. A copy of this press release is furnished as Exhibit 99.2 heretoand is incorporated herein by reference.

Item 9.01

Financial Statements and Exhibits.

(d) Exhibit

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

Exhibit 99.1 Press Release Dated December 5, 2018.

Exhibit 99.2 Press Release Dated December 6, 2018.

Exhibit 99.3 Presentation Slides.

EXHIBIT INDEX

Number	Description	
99.1	<u>Press Release Dated December 5, 2018.</u>	Attached
99.2	<u>Press Release Dated December 6, 2018.</u>	Attached
99.3	<u>Presentation Slides.</u>	Attached

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: December 10, 2018

By:

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