

SUPERNUS PHARMACEUTICALS INC
Form 8-K
September 04, 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): **August 29, 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**

Edgar Filing: SUPERNUS PHARMACEUTICALS INC - Form 8-K

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))

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 7.01 Regulation FD Disclosure.

Supernus Pharmaceuticals, Inc. (the Company) makes the following disclosure:

Enrollment in the Phase III studies has progressed ahead of schedule on SPN-812, and is now complete in the P301, P302 and P303 studies with data expected in 4Q 2018. Enrollment in the P304 study is at approximately 76%. Data are still expected in 1Q 2019. The table below summarizes the studies and their status:

| | P301 | P303 | P302 | P304 |
|------------------|----------------|----------------|----------------|----------------|
| SPN-812 | N = 432 | N = 300 | N = 300 | N = 234 |
| ADHD Patients | 6-11 years | 6-11 years | 12-17 years | 12-17 years |
| Total Daily Dose | 100 - 200mg | 200 - 400mg | 200 - 400mg | 400 - 600mg |
| Enrollment | Complete | Complete | Complete | 76% |
| Data Expected | 4Q 2018 | 4Q 2018 | 4Q 2018 | 1Q 2019 |

Rollover from the Phase III trials to the open label extension remains at approximately 90%.

The Company continues to progress its plans to initiate the pivotal Phase III bipolar program in the second half of 2019. Recently, the Company completed certain activities, including market research and claims database analysis, on the use of oxcarbazepine in bipolar. The Company will be using information generated from these activities to finalize plans for the Phase III program. As a result, the Company deemed the investigator-initiated trial on Oxtellar XR in bipolar as no longer necessary, and has since stopped the study.

The Company is furnishing the foregoing information in this Current Report on Form 8-K to comply with Regulation FD. Such information shall not be deemed to be 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, and shall not be deemed to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended (the Securities Act), or the Exchange Act, whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

This Current Report on Form 8-K contains forward-looking statements that do not convey historical information, but relate to predicted or potential future events, such as statements of our plans, strategies and intentions. These statements can often be identified by the use of forward-looking terminology such as believe, expect, intend, may, will, should, or anticipate or similar terminology. All statements of historical facts included in this Current Report on Form 8-K are forward-looking statements. All forward-looking statements speak only as of the date of this Current Report on Form 8-K. Except for the Company's ongoing obligations to disclose material information under the federal securities laws, the Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In addition to the risks and uncertainties of ordinary business operations and conditions in the general economy and the markets in which the Company competes, the forward-looking statements of the Company contained in this Current Report on Form 8-K are also subject various risks and uncertainties, including those set forth in Item 1A, Risk Factors, in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (as filed on March 1, 2018), and in its subsequent filings made with the Securities and Exchange Commission.

Item 8.01 **Other Events.**

On August 29, 2018, the Company issued a press release announcing that the Company's management will present an overview and update of the Company's business, and host investor meetings, at the 2018 Wells Fargo Healthcare Conference in Boston, MA on September 5, 2018. 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 furnished as an Exhibit pursuant to Item 8.01 hereof:

Exhibit 99.1 Press Release Dated August 29, 2018.

EXHIBIT INDEX

| Number | Description | |
|---------------|---|----------|
| 99.1 | <u>Press Release Dated August 29, 2018.</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: September 4, 2018

By:

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