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): **February 8, 2021**

Supernus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35518**	**20-2590184**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)
9715 Key West Ave **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.)

Securities registered pursuant to Section 12(b) of the Exchange Act

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value per share	SUPN	The Nasdaq Global Market

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 8.01 Other Events.

On February 8, 2021, Supernus Pharmaceuticals, Inc. (the "Company") issued a press release announcing it has resubmitted its New Drug Application for SPN-812 for the treatment of ADHD in pediatric patients. 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

Exhibit 99.1 — Press Release Dated February 8, 2021, furnished as an Exhibit pursuant to Item 8.01 hereof.
Exhibit 104 — The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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: February 8, 2021

By: /s/ James P. Kelly
James P. Kelly
Executive Vice-President and Chief Financial Officer

Exhibit 99.1

Supernus Resubmits New Drug Application for SPN-812 for the Treatment of ADHD in Pediatric Patients

ROCKVILLE, Md., February 8, 2021 - Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced it has resubmitted its New Drug Application (NDA) for SPN-812 for the treatment of ADHD in pediatric patients. The U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the NDA in November 2020 indicating that the review cycle for the application was incomplete and that the application was not ready for approval in its present form. Supernus and the FDA held a Type A meeting in January 2021 to discuss the CRL and the requirements for the NDA resubmission.

The primary issue cited in the SPN-812 CRL relates to the Company's in-house laboratory that conducts analytical testing, which recently moved to a new location. In the NDA resubmission Supernus removed reference to its in-house laboratory and addressed other contents of the CRL.

The FDA will classify the NDA resubmission as Class I or Class II upon acceptance of the resubmission. Generally, a Class I review constitutes a two-month review from the date of resubmission and a Class II review constitutes a six-month review from the date of resubmission.

In December 2020, Supernus announced positive results from a Phase III study for SPN-812 in adults with ADHD. The Company plans to submit a supplemental NDA to the FDA for SPN-812 in adults in the second half of 2021, assuming approval for pediatric patients.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases.

Our diverse neuroscience portfolio includes approved treatments for epilepsy, migraine, hypomobility in Parkinson's Disease, cervical dystonia and chronic sialorrhea. We are committed to developing a broad range of novel CNS product candidates to address high unmet medical needs. Our development programs include new potential treatments for attention-deficit hyperactivity disorder, hypomobility in Parkinson's Disease, epilepsy, depression, and rare CNS disorders. For more information, please visit https://www.supernus.com/.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not convey historical information but relate to predicted or potential future events that are based upon management's current expectations. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These forward-looking statements include expectations regarding the Company's recent and future interactions and communications with the FDA, the potential approval of the NDA for SPN-812 following resubmission, the planned submission of an sNDA to the FDA for SPN-812 in adults and the potential benefits and commercialization of SPN-812. In addition to the factors mentioned in this press release, such risks and uncertainties include, but are not limited to, the Company's ability to sustain and increase its profitability; the Company's ability to raise sufficient capital to fully implement its corporate strategy; the implementation of the Company's corporate strategy; the Company's future financial performance and projected expenditures; the Company's product research and development activities, including the timing and progress of the Company's clinical trials, and projected expenditures; the Company's ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its products and product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the Company's product formulations and patient needs; potential funding sources; the Company's staffing needs; and other risk factors set forth from time to time in the Company's filings with the Securities and Exchange Commission made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as

amended. The Company undertakes no obligation to update the information in this press release to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated or unanticipated events.

CONTACTS:

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or

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