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): **April 2, 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 April 2, 2021, Supernus Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the receipt of the final approval from the U.S. Food and Drug Administration (FDA) for SPN-812 (Qelbree) for the treatment of attention-deficit hyperactivity disorder (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 April 2, 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: April 2, 2021

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

Exhibit 99.1

Supernus Announces FDA Approval of Qelbree™ (SPN-812) for the Treatment of ADHD

Qelbree (viloxazine extended-release capsules) represents the first novel non-stimulant treatment for ADHD in a decade

Supernus plans to make Qelbree available in the U.S. in 2Q 2021

ROCKVILLE, MD., April 2, 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 that the U.S. Food and Drug Administration (FDA) approved Qelbree (viloxazine extended-release capsules) for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age.

“Based on the efficacy demonstrated in the clinical program, we believe Qelbree offers a unique new alternative for the treatment of ADHD,” said Jack A. Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “Qelbree provides prescribing physicians and patients living with ADHD a therapy that is not a controlled substance with proven efficacy and a tolerable safety profile. We are grateful to the patients, families and their care givers who participated in and supported our research.”

“ADHD is one of the most common mental health issues in the U.S.,” said Andrew J. Cutler, M.D., Clinical Associate Professor of Psychiatry at SUNY Upstate Medical University, and Chief Medical Officer, Neuroscience Education Institute. “The right treatment is key for children and adolescents, as they grow and navigate school and social relationships. This approval offers a novel once a day sprinkleable non-stimulant that can be a great option for children and adolescents with ADHD.”

The approval of Qelbree is supported by data from an extensive development program consisting of four Phase III clinical trials that studied more than 1000 pediatric patients from the age of 6 to 17 years. In December 2020, the Company announced positive results from a Phase III trial in adult patients with ADHD and plans to submit a supplemental New Drug Application to the FDA for Qelbree in adults in the second half of 2021.

IMPORTANT SAFETY INFORMATION

Qelbree may increase suicidal thoughts and actions in some children with ADHD, especially within the first few months of treatment or when the dose is changed. Pay close attention to any new or sudden changes in mood, behavior, thoughts, and feelings. Call your child’s doctor right away if there are any new or sudden changes, or if there is development of suicidal thoughts or actions. Qelbree should not be taken by patients that also take certain anti-depression medicines, especially those called a monoamine oxidase inhibitor or MAOI, or certain asthma medicines.

Please see full Prescribing Information, including Boxed Warning, for Qelbree.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals 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, attention-deficit hyperactivity disorder (ADHD), hypomobility in Parkinson’s disease, cervical dystonia and chronic sialorrhea. We are developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in Parkinson’s disease, epilepsy, depression, and rare CNS disorders.

For more information, please visit 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. 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 ability to increase the number of prescriptions written for each of its products; the Company's ability to increase its net revenue; the Company's ability to commercialize its products including Qelbree; the Company's ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies; 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 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 and 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.

CONTACT:

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Or

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