
**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): **May 24, 2021**

Supernus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

001-35518

(Commission File Number)

20-2590184

(I.R.S. Employer Identification No.)

9715 Key West Ave

(Address of Principal Executive Offices)

Rockville

MD

20850

(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 May 24, 2021, Supernus Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the availability of Qelbree™ (viloxazine extended-release capsules) for the treatment of attention-deficit hyperactivity disorder in pediatric patients 6 to 17 years of age. 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 May 24, 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.



Qelbree™ (viloxazine extended-release capsules), a new non-controlled substance, Now Available for the Treatment of ADHD in Pediatric Patients 6-17 Years of Age

Qelbree™ has proven efficacy in ADHD, with improvement in symptoms as early as the first week

ROCKVILLE, MD., May 24, 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 its recent U.S. Food and Drug Administration (FDA) approved treatment Qelbree (viloxazine extended-release capsules) for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age, is now available. For more information on access, ways to save and additional patient support services, visit: <https://www.qelbree.com/>.

“The availability of Qelbree™ has helped to create a shift in the way providers can approach treatment for children and teens with ADHD,” said Ann Childress, M.D, Psychiatrist with a subspecialty in child and adolescent psychiatry, Clinical Researcher, and President of the Center for Psychiatry and Behavioral Medicine in Las Vegas. “Many of my patients and their caregivers seek non-stimulant options as we work together to develop a treatment regimen. Having access to a once-daily capsule – that can even be sprinkled on food – with proven long-acting efficacy, as well as early onset of improvement, is sure to make an impact on children and teens looking for new treatment options to manage their ADHD.”

Supernus has developed a robust patient access program to support those who qualify for treatment. In addition to a co-pay assistance program, the Company has launched a sampling program and full support hub. Supernus is committed to helping patients access Qelbree.

“At Supernus, we continue to be focused on advancing treatments across the CNS landscape, including the treatment of ADHD,” said Jack A. Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “As a non-controlled substance that has a unique profile of proven efficacy, safety, and tolerability, Qelbree provides patients living with ADHD a novel treatment option like no other ADHD medication. We look forward to being able to support the ADHD community as we officially launch Qelbree in the market alongside our patient support programs to improve access to this important treatment option.”

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 third quarter 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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