
**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): **October 17, 2024**

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	SUPN	The Nasdaq Stock Market LLC

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

On October 17 2024, Supernus Pharmaceuticals, Inc. (“Supernus” or the “Company”) issued a press release announcing data from its exploratory open-label Phase 2a clinical study of SPN-820 in adults with major depressive disorder. The Company will host a webcast and conference call at 4:30 p.m. Eastern Time on Thursday, October 17, 2024, to review the data. A live webcast with presentation slides will be available at www.supernus.com. The webcast and presentation slides will be archived on the Company’s website for 60 days following the live call.

A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 7.01 (including Exhibit 99.1) is being “furnished” and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, whether made before or after the date of this report, except as shall be expressly set forth by specific reference in such 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 other than 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 Supernus’ ongoing obligations to disclose material information under the federal securities laws, Supernus 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 Supernus competes, the forward-looking statements of Supernus contained in this Current Report on Form 8-K are also subject to various risks and uncertainties, including those set forth in Item 1A, “Risk Factors,” in Supernus’ Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 — [Press Release Dated October 17, 2024](#) furnished as an Exhibit pursuant to Item 7.01

hereof.

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: October 17, 2024

By: /s/ Timothy C. Dec

Timothy C. Dec

Senior Vice President and Chief Financial Officer



Supernus Announces Promising Data from Open-Label Phase 2a Study of SPN-820 in Adults with Major Depressive Disorder

Phase 2a study demonstrated rapid and substantial decrease in depressive symptoms

SPN-820 was well-tolerated with few adverse events

SPN-820 is a novel, first-in-class intracellular modulator of mTORC1 for the treatment of depression

Company to host webcast today at 4:30 p.m. ET to discuss the topline data

Topline results from Phase 2b randomized double-blind placebo-controlled study of SPN-820 in adults with treatment-resistant depression expected first-half 2025

ROCKVILLE, Md., October 17, 2024 – 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 data from its exploratory open-label Phase 2a clinical study of SPN-820 in adults with major depressive disorder. The study examined the safety and tolerability of SPN-820 2400 mg given once every 3 days as an adjunctive treatment to the current baseline antidepressant therapy, as well as assessed the rapid onset of improvement in depressive symptoms. The analysis is based on 40 enrolled subjects, of which 38 completed the 10-day treatment period.

Summary of the Data

- Clinically meaningful improvement of -6.1 at two hours and -9.6 at Day 10 on the Hamilton Depression Rating Scale-6 Items (HAM-D6) total score.
- Clinically meaningful improvement of -16.6 at four hours and -22.9 at Day 10 on the Montgomery Åsberg Depression Rating Scale (MADRS) total score.
- Suicidal ideation decreased by 80% (12.5% with suicidal ideation at baseline decreased to 2.6% with suicidal ideation at Day 10).
- SPN-820 was well-tolerated with few adverse events (AEs) and had acceptable tolerability with a discontinuation rate of 2.5% due to AEs.
- Most common AEs related to the drug included headache, nausea, somnolence, and dizziness. Additional AEs such as cognitive disorder, dry mouth, fatigue, nasal decongestion, and paresthesia oral were observed.

“These Phase 2a data underscore our belief that SPN-820 has the potential as a novel treatment option for patients with depression, with the opportunity to decrease symptoms quickly and without certain burdensome side effects,” said Jack Khattar, President and CEO of Supernus. “We expect to complete enrollment in the Phase 2b randomized double-blind placebo-controlled study of SPN-820 in adults with treatment-resistant depression in November of this year, with topline results expected in the first half of 2025.”

Webcast Details

Supernus will host a conference call and webcast today, October 17, 2024, at 4:30 p.m. ET to discuss these topline results. A live webcast with presentation slides will be available via [this webcast link](#) or in the Events & Presentations section of the Company's Investor Relations website at www.supernus.com/investors. Following management's prepared remarks and discussion of the interim trial results, the call will open for questions.

Participants may also pre-register any time before the call [here](#). Once registration is completed, participants will be provided a dial-in number with a personalized conference code to access the call. Please dial in 15 minutes prior to the start time.

Following the live call, a replay will be available on the Company's Investor Relations website at www.supernus.com/investors. The webcast will be available on the Company's website for 60 days following the live call.

About SPN-820

SPN-820 is a first-in-class, orally active small molecule that increases the brain mechanistic target of rapamycin complex 1 (mTORC1) mediated synaptic function intracellularly. SPN-820 is being developed to provide a rapid-onset antidepressant response via oral administration for adult patients with depression. The compound has a novel mechanism of action that enhances synaptic activity and cellular metabolism in the brain and has demonstrated a rapid onset of action (signal at two hours) in early clinical studies. SPN-820 is expected to provide rapid antidepressant efficacy without potential dissociative side effects. A Phase 2b clinical study of SPN-820 in approximately 227 adult patients with treatment-resistant depression is ongoing.

About the SPN-820 Phase 2a Clinical Study

The study is a Phase 2a open-label study in 40 subjects with major depressive disorder (MDD). The primary objective of the study is to assess efficacy in MDD, as well as onset of efficacy and safety.

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, ADHD, hypomobility in Parkinson's disease (PD), cervical dystonia, chronic sialorrhea, and dyskinesia in PD patients receiving levodopa-based therapy. We are developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in PD, epilepsy, depression, and other 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 reporting on preliminary and exploratory open label clinical study on SPN-820, 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 and the products of its subsidiaries; the Company's ability to increase net revenue; the Company's ability to commercialize its products and the products of its subsidiaries; 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 ability to conduct and progress 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 including SPN-820; the Company's ability to protect its intellectual property and the intellectual property of its subsidiaries 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 including SPN-820; 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 including SPN-820; 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.

CONTACTS:

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