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): **December 22, 2020**

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 December 22, 2020, Supernus Pharmaceuticals, Inc. (the "Company") issued a press release announcing positive topline results from its Phase III Study for SPN-812 in adults for the treatment of attention deficit hyperactivity disorder (ADHD). A copy of this press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. A presentation slide show related to the Phase III Study results is furnished as Exhibit 99.2 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 — Press Release Dated December 22, 2020, furnished as an Exhibit pursuant to Item 8.01 hereof.
Exhibit 99.2 — Presentation Slides for SPN-812 Topline Results, 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: December 23, 2020

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

Exhibit 99.1

Supernus Announces Positive Results from Phase III Study for SPN-812 in Adults with ADHD

- **Met primary endpoint with robust statistical significance**
- **Showed efficacy on both hyperactivity/impulsivity and inattention subscales with statistical significance**
- **Showed statistically significant onset of action as early as week 2**
- **Had a good safety and tolerability profile throughout the study**
- **Topline data confirm positive results from prior Phase IIa study in adults and Phase III studies of SPN-812 in children and adolescents**

ROCKVILLE, Md., December 22, 2020 - Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced positive topline results from a Phase III study of SPN-812 in adults (P306) for the treatment of attention deficit hyperactivity disorder (ADHD).

At a daily dose of up to 600mg, the trial met the primary endpoint with robust statistical significance (p=0.0040) compared to placebo in improving the symptoms of ADHD from baseline to end of study as measured by ADHD Investigator Symptom Rating Scale (AISRS). In addition to meeting the primary efficacy endpoint, the Phase III study met the key secondary efficacy endpoint with statistical significance (p=0.0023) in the change from baseline of the Clinical Global Impression – Severity of Illness (CGI-S) Scale at week 6. The active dose was well tolerated.

SPN-812 is under review by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD in pediatric patients 6 to 17 years of age. As announced in November, 2020, the FDA issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for SPN-812 for the treatment of ADHD in pediatric patients to indicate that the review cycle for the application was complete and that the application is not ready for approval in its present form. The Company will be meeting with the FDA in January 2021 to discuss the CRL. Assuming approval for pediatrics, the Company plans to submit a supplemental NDA (sNDA) to the FDA for SPN-812 in adults in the second half of 2021.

“These compelling data in adults will be important for our planned sNDA submission to make this treatment option available, if approved by the FDA, to the adult ADHD patient population, which represents approximately half of the total ADHD market in the U.S.,” stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “We now have positive Phase III data proving the efficacy and safety of SPN-812 in a broad range of ADHD patient populations; children 6-11 years old, adolescents 12-17 years old, and adults.”

About the P306 Study

The study was a randomized, double-blind, placebo controlled, multicenter, parallel group clinical trial in adult patients diagnosed with ADHD. The study had a two-arm flexible dose design where treatment was administered orally once a day over six weeks, including the titration phase up to a total daily dose of 600mg SPN-812 or matched placebo.

A total of 374 adult patients were randomized across placebo and a daily dose of SPN-812 starting with 200mg with flexible dose administration up to 600mg. The primary objective was to assess the effect of SPN-812 in reducing the symptoms of ADHD. The primary outcome measure was the change from baseline to the end of the study in the AISRS. Safety and tolerability of SPN-812 were assessed by the monitoring of adverse events (AEs), clinical laboratory tests, vital signs, ECGs, suicidality and physical examinations. Patients who completed the study were offered the opportunity to continue into an ongoing open-label safety extension study.

Topline Results

At the end of the study, SPN-812 reached statistical significance compared to placebo in the primary endpoint. Patients receiving SPN-812 had a -15.5 point change from baseline in the primary endpoint compared to -11.7 for placebo at week 6 (p=0.0040).

This primary result, based on a Mixed Model Repeated Measures (MMRM) analysis using the Full Analysis Set (FAS) population, was confirmed by sensitivity analysis with a p-value of 0.0085.

The study demonstrated fast onset of action, reaching statistical significance as early as week 2 with a p-value of 0.0397, and maintaining statistical significance through the end of the trial at week 6.

Similar to the previously reported studies in pediatric patients 6 to 17 years of age, at the end of the P306 study, SPN-812 reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the AISRS with p-values of 0.0380 and 0.0015, respectively.

In addition, SPN-812 met the CGI-S secondary endpoint with a p-value of 0.0023 compared to placebo at week 6 and showed significant improvement as early as week 2 with a p-value of 0.0203.

Safety and tolerability

Overall, the trial exhibited a good safety and tolerability profile. Adverse events (AEs) were primarily mild to moderate leading to a low placebo-adjusted discontinuation rate due to AEs in the SPN-812 group of 4.1% (9.0% for SPN-812 compared to 4.9% in the placebo group). Treatment related AEs that reported at more than or equal to 5% for SPN-812 were insomnia, fatigue, decreased appetite, nausea, headache, and dry mouth.

Topline data for the P306 study can be accessed by visiting 'Events & Presentations' in the Investor Relations section of the Company's website at www.supernus.com.

About SPN-812
SPN-812 is a novel non-stimulant for the treatment of ADHD. Based on data generated to date, the Company believes SPN-812 could be a well-differentiated ADHD treatment due to its different pharmacological and pharmacokinetic profile. The active ingredient in SPN-812, viloxazine hydrochloride, has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy; Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy; APOKYN® (apomorphine hydrochloride injection) for the acute treatment of hypomobility in advanced Parkinson's disease (PD); MYOBLOC® (rimabotulinumtoxinB) for the treatment of cervical dystonia and treatment of chronic sialorrhea in adults; and XADAGO® (safinamide) as an adjunctive treatment to levodopa/carbidopa in PD patients with hypomobility. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-812 for the treatment of ADHD; SPN-830 (apomorphine infusion pump) for the continuous treatment of motor fluctuations ("on-off" episodes) in PD; SPN-820 for treatment-resistant depression; and SPN-817 for the treatment of epilepsy.

See full Prescribing Information for our products here: Trokendi XR, Oxtellar XR, APOKYN, MYOBLOC, and XADAGO.

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 future interactions and communications with the FDA, including its expectation to discuss with the FDA the issues raised in the CRL regarding the NDA for SPN-812 for the treatment of ADHD in pediatric patients 6 to 17 years of age and the Company's plans to address them, the Company's future resubmission of the NDA for SPN-812, 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.

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Exhibit 99.2

Supernus Pharmaceuticals

SPN-812

Topline Results – ADHD Phase III Study in Adults (P306)

December 2020

Safe Harbor Statement

This presentation and other matters discussed today or answers that may be given to questions asked include forward-looking statements within the meaning of the federal securities laws. These statements, among other things, relate to Supernus' business strategy, goals and expectations concerning its product candidates, ability to integrate t acquired portfolio into its infrastructure, future operations, prospects, plans and objectiv of management. The words "anticipate", "believe", "could", "estimate", "expect", "intend" "may", "plan", "predict", "project", "will", and similar terms and phrases are used to ident forward-looking statements in this presentation. Supernus' operations involve risks and uncertainties, many of which are outside its control, including the potential impact of COVID-19, and any one of which, or a combination of which, could materially affect its results of operations and whether the forward-looking statements ultimately prove to be correct. Supernus assumes no obligation to update any forward-looking statements exc as required by applicable law.

Supernus has filed with the U.S. Securities and Exchange Commission (SEC) reports a other documents required by Section 13 or 15(d) of the Securities Exchange Act of 193 as amended. Before you purchase any Supernus securities, you should read such repo and other documents to obtain more complete information about the company's operations and business and the risks and uncertainties that it faces in implementing its business plan. You may get these documents for free by visiting EDGAR on the SEC website at http://www.sec.gov.

SPN-812 Phase III Adult Study

	P306 N = 374	Study Design
ADHD Patients	Adults	Randomized, double-blind, two arm placebo-controll study
Daily Doses	200mg to 600mg	Starting dose of 200mg on week 1, 400mg on week followed by flexible dosing between 200mg and 600 per day.
Primary Endpoint	Change from baseline to end of study on ADHD Investigator Symptom Ratin Scale (AISRS) total score compared to placebo.	

SPN-812 Phase III Adult Study: Fast Onset of Action

Efficacy Starting as Early as Week 2 – Primary Endpoint

Primary Endpoint			
Visit	Statistics	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	37.6	38.5
Week 1	p-value		0.2941
Week 2	p-value		0.0397
Week 3	p-value		0.0005
Week 4	p-value		0.0014
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-11.7	-15.5
	p-value		0.0040

Primary Analysis of AISRS. EOS = End of Study

*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

SPN-812 Phase III Adult Study: Fast Onset of Action

Efficacy Starting as Early as Week 2 – Secondary Endpoint

Clinical Global Impression - Severity Score (CGI-S)			
Visit	Statistics	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	4.6	4.6
Week 1	p-value		0.1833
Week 2	p-value		0.0203
Week 3	p-value		<0.0001
Week 4	p-value		0.0004
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-1.0	-1.4
	p-value		0.0023

EOS = End of Study
*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

SPN-812 Phase III Adult Study

Significant Reduction in Inattention Subscale

Inattention Subscale			
Visit	Statistics	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	21.1	21.5
Week 1	p-value		0.1127
Week 2	p-value		0.0113
Week 3	p-value		0.0003
Week 4	p-value		0.0006
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-6.1	-8.5
	p-value		0.0015

EOS = End of Study
*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

SPN-812 Phase III Adult Study

Significant Reduction in Hyperactivity/Impulsivity Subscale

Hyperactivity/Impulsivity Subscale			
Visit	Statistics	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	16.5	17.0
Week 1	p-value		0.9991
Week 2	p-value		0.3478
Week 3	p-value		0.0073
Week 4	p-value		0.0236
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-5.8	-7.2
	p-value		0.0380

EOS = End of Study
*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

SPN-812 Phase III Adult Study

Summary of Treatment Related Adverse Events (Safety Population)

Number (%) of Patients - **Treatment Related AEs with ≥ 5% Incidence**

P306	Placebo (N=183)	SPN-812 (N=189)
Insomnia	9 (4.9)	43 (22.8)
Fatigue	5 (2.7)	22 (11.6)
Decreased appetite	4 (2.2)	19 (10.1)
Nausea	4 (2.2)	19 (10.1)
Headache	9 (4.9)	17 (9.0)
Dry mouth	4 (2.2)	17 (9.0)
Discontinuation due to AEs	9 (4.9)	17 (9.0)

AEs = Adverse Events