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): June 9, 2022

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)

MD

20-2590184

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

9715 Key West Ave

(Address of Principal Executive Offices)

Rockville

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

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. \Box

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

Item 7.01 Regulation FD.

Supernus Pharmaceuticals, Inc. ("Supernus" or the "Company") is presenting at the Jefferies Healthcare Conference today, June 9, 2022. During the conference the Company will present an updated version of its investor presentation. A copy of the presentation 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," "inay," "will," "should," or "anticipate" or similar terminology. All statements of historical facts included in 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, 2021 which 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 — Investor Presentation, Dated June 9, 2022 filed as an Exhibit pursuant to Item 7.01 hereof.

Exhibit 104 — The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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^{*} The information furnished under Item 7.01 and Item 9.01 of this Current Report on Form 8-K, including the exhibits, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange act of 1934, as amended, or otherwise subject to liabilities under that section, nor shall it be deemed incorporated by reference in any registration statement or other filings of the Company under the Securities act of 1933, as amended, except as shall be set forth by specific reference in such filing.

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: June 9, 2022

/s/ Timothy C. Dec Timothy C. Dec Senior Vice President and Chief Financial Officer

Supernus Pharmaceuticals

Jefferies Healthcare Conference

June 2022



Safe Harbor Statement

This presentation and other matters discussed today or answers that may be given questions asked include forward-looking statements within the meaning of the fersecurities laws. These statements, among other things, relate to Supernus' busing strategy, goals and expectations concerning its product candidates, ability to interact acquired portfolio into its infrastructure, future operations, prospects, plans and of management. The words "anticipate", "believe", "could", "estimate", "expect", "may", "plan", "predict", "project", "will", and similar terms and phrases are used forward-looking statements in this presentation. Supernus' operations involve risuncertainties, many of which are outside its control, including the potential impact COVID-19, and any one of which, or a combination of which, could materially af results of operations and whether the forward-looking statements ultimately procorrect. Supernus assumes no obligation to update any forward-looking statements as required by applicable law.

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



Proven Execution in CNS & ADHD

30+ Years of CNS experience including Four Products in ADHD



2005 - Present

















<u>Pipe</u>

SPN

SPN

SPN

SPN

SPN

SPN

SPN

SPN



1997 - 2005







For several years, and prior to becoming independent in 2005, Supernus operated as Shire Laboratories, Inc., a division of Shire. SPN-830, SPN-820, SPN-840, SPN-8443, SPN-446, SPN-448, and SPN-396 are product candidates in various stages of development. All trademarks are the property of their respective owners



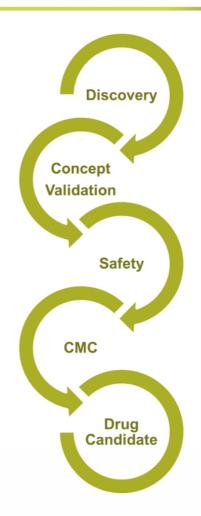
Significant Experience & Capabilities in Drug Develo

Discovery Platform

Design and synthesis of new compounds based on structure, function and disease pathways

Toxicology

Validated drug candidates



In vitro, PK, preclinical proof of concept, and stability studies

In-house CMC/drug delivery expertise & GMP manufacturing



Robust CNS Pipeline to Drive Long-term Growth

<u>Program</u>	<u>Indications</u>	Discovery Preclinical Phase 1 Phase 2 Phase 3 I
Qelbree viloxazine	ADHD- Adult	
SPN-830	PD	
SPN-840	PD	
SPN-820	TRD*	
SPN-817	Epilepsy	
SPN-845	PD	
SPN-443	ADHD	
SPN-446	CNS	
SPN-448	CNS	
SPN-396	CNS	

*TRD = Treatment Resistant Depression PD = Parkinson's Disease







Novel Non-Stimulant ADHD Product

- Launched in May 2021 for patients 6 to 17 years of age
 - Sales force of approximately 195 sales representatives
 - Clinical feedback from the market in line with Phase III clinical data demonstrating a well-differentiated profile
- Launched in May 2022 for adult patients
- IP with expirations from 2029-2033
- ADHD market is significant with 80 million prescriptions.

1 - Source: IQVIA Jan - Dec 2021

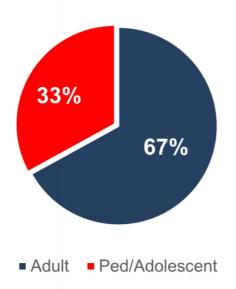
© 2022 Supernus Pharmaceuticals, Inc. All Rights Reserved

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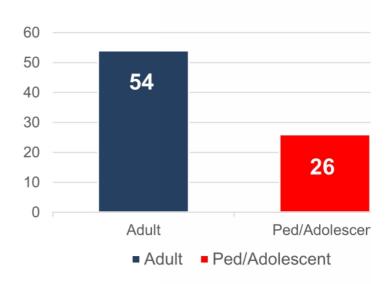
ADHD Adult Opportunity: Significant Market Segme

2021 Total ADHD U.S Market - 80 Million Prescriptions

% of Market



2021 Prescriptions (millions)

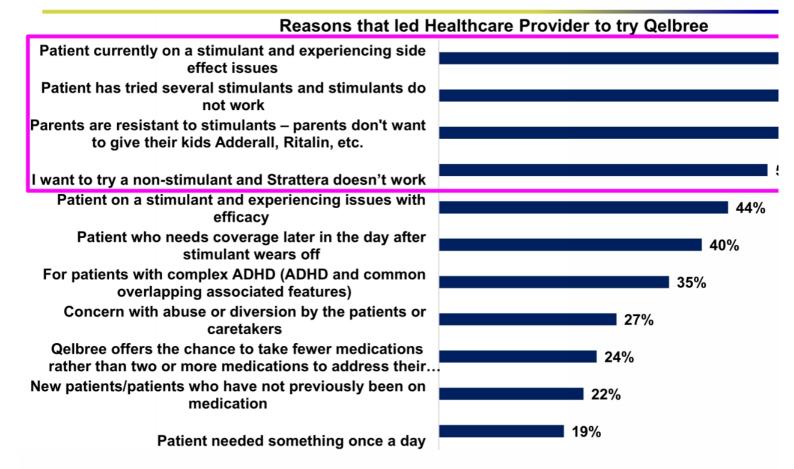


Source: IQVIA



Top Reasons to Try Qelbree®

Patients Having Issues With Stimulants & Looking For a Non-Stimulant That

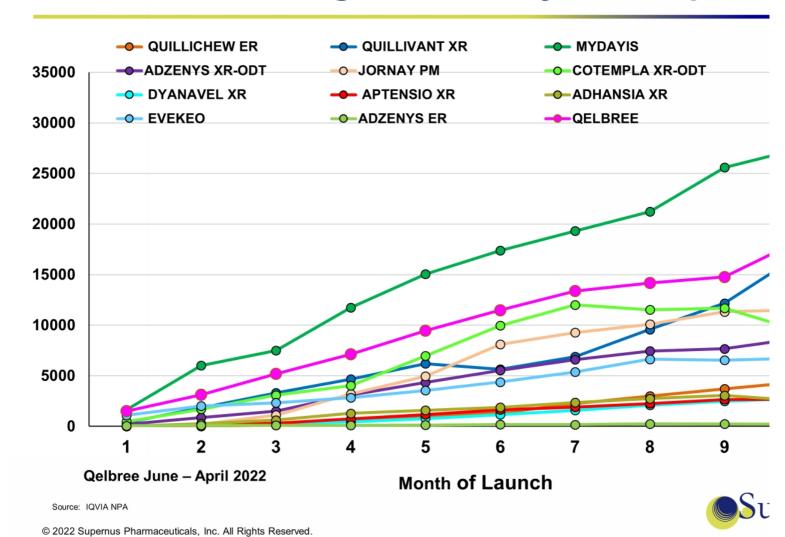


Source: Internal market research among Qelbree prescribers – n=104.

Q28. Thinking about the patients you have put on Qelbree, what medications were they on/what issues were they having that led you to try Qelbree?



ADHD Launch-Aligned Monthly Prescription





Monthly Prescriptions since Launch



Source: IQVIA NPA



Major Presence in Parkinson's Disease (PD)

1 Million U.S. PD Patients - Market Expected to Grow to \$6.2B by 2026 (1)





Significantly Decreased Dyskinesia and OF Thereby Significantly Increasing Good ON

GOCOVRI achieved reductions in dyskinesia & OFF episodes without having to adjust lev

Placebo-adjusted, pooled results from pivotal trials*

Primary endpoint

127%
DECREASE IN DYSKINESIA

10.1-point reduction in UDysRS score

(-17.7 GOCOVRI vs. -7.6 placebo)(1)(2)†

Secondary endpoints

136%
DECREASE IN OFF TIME

1-hour decrease

(-0.6 GOCOVRI vs. 0.4 placebo) (1)(2)†

129
INCREAGOOD C

2.4-hour inc

(3.8 GOCOVRI vs.

- (1) Elmer LW, CNS Drugs. 2018.
- (2) Data on file. Adamas Pharma LLC, Emeryville, CA.

* Pooled results from 2 independent positive, pivotal, Phase 3, randomized, placebo-controlled trials (Study 1 and Study 2) in PD patients on levodopa. Study 1, a 24-week study, was conducted in 121 PD patients with dyskinesia (GOCOVRI [n = 63], placebo [n = 58]). Study 2, a 12-week study, was conducted in 75 PD patients with dyskinesia (GOCOVRI [n = 37], placebo [n = 38]).

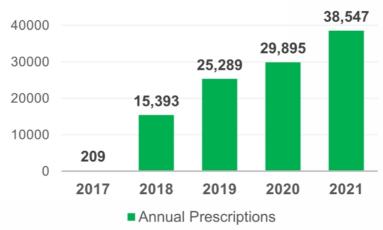
† In Study 1, GOCOVRI reduced the UDysRS total score by 15.9 points (vs 8.0 with placebo) (P = 0.0009), decreased OFF time by 0.6 hours (vs an increase of 0.3 hours with placebo) (P = 0.0171), and increased GOOD ON time by 3.6 hours (vs 0.8 hours with placebo) (P < 0.0001) from baseline. In Study 2, GOCOVRI reduced the UDysRS total score by 20.7 points (vs 6.3 with placebo) (P < 0.0001), decreased OFF time by 0.5 hours (vs an increase of 0.6 hours with placebo)





A Key Growth Driver

- 2021 Net Sales : \$87.6M, 23% growth vs. 2020
 - Supernus recorded \$9.8M in 2021 net sales (acquisition closed on Nov 2)
- For the treatment of dyskinesia in patients with PD receiving levodop therapy, with or without concomitant dopaminergic medications
- Adjunctive treatment to levodopa/carbidopa in patients with PD experion
 "off" episodes



Source: Company Records





Significant Target Patient Pop

Over 50% of people with PD experience OFF episodes, dyskinesia or both within 5 years, and up to 100% after 10 years (1)(2) PD PATIENTS DIAGNOSED IN U.S.

1,000,000

800,000

DIAGNOSED AND TREATED PATIENTS

700,000

LEVODOPA-TREATED PATIENTS

GOCOVRI potential addressable U.S. patient population

400,000 to 500,000 patients(3)

- (1) Kim H-J, et al., Mov Disord, 2020.
- (2) Mizuno Y et al., Journal of Neural Transmission, 2018
- (3) Estimated based on market research.





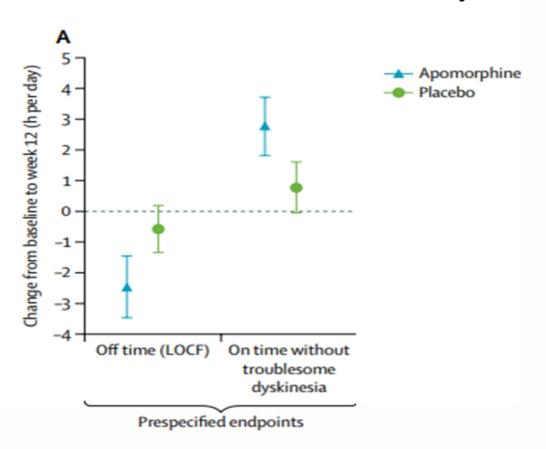
Novel Apomorphine Subcutaneous Injection Device

- Non-invasive dopaminergic stimulation therapy for continuous treatment of ON-OFF episodes in PD
- Potentially first non-surgical continuous dopaminergic stimulat device
- Currently available options
 - Gastro-intestinal surgically implanted levodopa/carbidopa infusior
 - Deep brain stimulation
- Could be eligible for Orphan Drug Designation and 7-year exc
- NDA filing accepted by FDA with early October 2022 PDUFA



Novel Apomorphine Subcutaneous Injection Device

TOLEDO Phase III Study Results



Primary E

SPN-830 den 2.47 hours reduction in compared to pl p= 0.0

Regina Katzenschlager et al, The Lancet Neurology. 2018;Vol 17(9):749-759



Novel MOA for Treatment-Resistant Depression (TRD)

- First-in-class selective brain mTORC1 activator
 - Directly activates mTORC1 enhancing synaptic activity and cellular metabolism in the
- Early efficacy signal on HAMD-6 scale in TRD patients
 - Rapid onset of action (signal at 2 hours)
 - Meaningful effect sizes (>0.4 through 3 days on 1 dose)
- Multiple ascending dose (MAD) study demonstrated:
 - drug penetration and target engagement
 - favorable safety/tolerability profile across broad range of doses
- Initiated Phase II clinical trial in TRD
- Significant market opportunity
 - Major depressive disorder (MDD) affects approximately 17.3M U.S. adults¹
 - ~30% of MDD patients are treatment resistant²

1- National Institute of Mental Health, 2017 National Survey on Drug Use and health

2- Rush AJ Et al.(2006) Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D Report. The American Journal of Psychiatry,163(11), 1905-1917

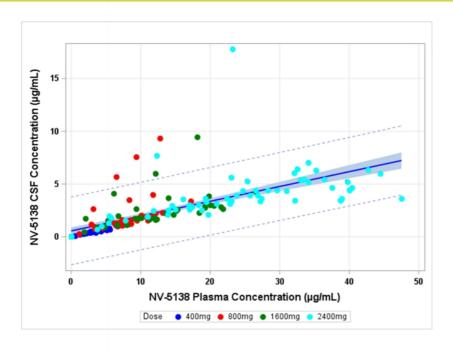


Multiple Ascending Dose Study

- Healthy subjects, placebo-controlled pharmacokinetic study
 - 5 Cohorts: 400 mg, 800 mg, 1600 mg, 2400 mg and 3000 mg
- Plasma & cerebrospinal fluid (CSF) drug concentration
 - 400 mg 2400 mg dose levels
 - Single dose, at Day 1
 - Multiple doses, at Day 7
- Metabolomic biomarkers of mTORC1 activation
 - Concentrations measured in CSF for 400 mg 2400 mg dose level
 - N-acetylmethionine
 - N-formylmethionine
 - Orotic acid



SPN-820 CSF Concentration vs. Plasma Concentrati

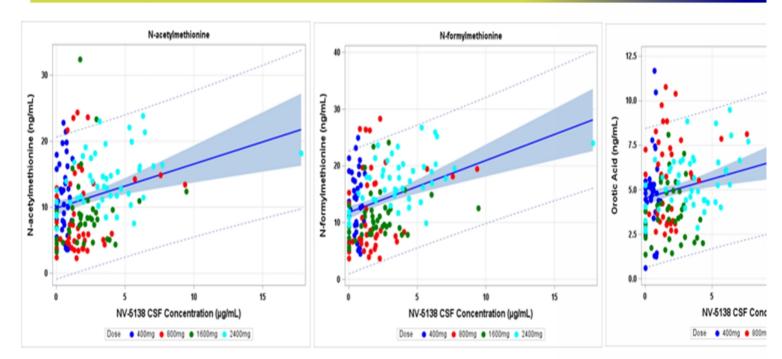


SPN-820/NV-5138 CSF concentrations significantl increase with the increase plasma concentrations (p

Dots represent the observed data, the solid line represent the model predicted curve, the shaded area represent the 95% confidence interval on the predicted curve, and the dotted lines delimit the 95% prediction interval.



Biomarker Concentrations vs. SPN-820 CSF Concer



Dots represent the observed data, the solid line represent the model predicted curve, the shaded area represent the confidence interval on the predicted curve, and the dotted lines delimit the 95% prediction interval.

Biomarker concentrations significantly increase with the increase of SPN-820/NV-5138 CSF concentrations



Financial Summary and Guidance

1Q 2022 Financial Results¹

- Total revenues of \$152.5 million, up 16% over 1Q 2021
- Net earnings and diluted earnings per share (GAAP) of \$25.6 million and \$0 respectively
- Operating income (GAAP) of \$2.0 million; operating income (non-GAAP) of million
- Cash, cash equivalents, and investments at \$437.5 million as of March 31, 2

¹ Reported on May 9, 2022, including reconciliation of GAAP vs Non-GAAP



Financial Summary and Guidance

Full Year 2022 Financial Guidance¹

	(\$ millions)
Total Revenues	\$640 - \$680
Combined R&D and SG&A expenses	\$460 - \$490
Operating Earnings - GAAP	\$20 - \$40
Adjustments:	
Amortization of intangible assets	\$80 - \$85
Share-based compensation	\$20 - \$25
Contingent consideration	\$8 - \$12
Depreciation	\$2 - \$3
Operating Earnings - non-GAAP	\$130 - \$165

¹ Guidance as confirmed on May 9, 2022





Positioned For Long-Term Growth



Diversified CNS Portfolio

Qelbree®, Oxtellar XR®, Trokendi XR®, APOKYN®, GOCOVRI®, XADAGO®, MYOB

Innovative Pipeline in CNS

Qelbree® ADHD (Adult)

 SPN-830
 PD

 SPN-820
 TRD

 SPN-840/845
 PD

SPN-817 Epilepsy

 SPN-443
 ADHD

 SPN-446/448/396
 CNS

