# 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 4, 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 May 4, 2021, Supernus Pharmaceuticals, Inc. (the "Company") issued a press release announcing that Newron Pharmaceuticals S.p.A. ("Newron") received a Paragraph IV Notice Letter ("Notice Letter") from Aurobindo Pharma Limited, India and its wholly owned subsidiary Aurobindo Pharma USA Inc. (collectively "Aurobindo") , advising Newron of the filing by Aurobindo of an Abbreviated New Drug Application to the U.S. Food and Drug Administration ("FDA") seeking approval for safinamide tablets. The Notice Letter is directed to the three XADAGO patents with U.S. patent numbers 8,076,515, 8,278,485 and 8,283,380, that expire between June 2027 and December 2028 and are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. The Company has a license agreement with Zambon S.p.A., Newron's partner, related to the XADAGO Patents, and as a new chemical entity, XADAGO is under the 5 year FDA exclusivity period that expires on March 21, 2022. The Company is currently reviewing the details of this Notice Letter with its partners to respond as appropriate to protect the intellectual property rights relating to XADAGO. 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 4, 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: May 4, 2021

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

**Exhibit 99.1**

# Supernus Announces Paragraph IV ANDA Filing for XADAGO®

**ROCKVILLE, MD, May 4, 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 Newron Pharmaceuticals S.p.A. ("Newron") received a Paragraph IV Notice Letter ("Notice Letter") from Aurobindo Pharma Limited, India and its wholly owned subsidiary Aurobindo Pharma USA Inc. (collectively "Aurobindo"), advising Newron of the filing by Aurobindo of an Abbreviated New Drug Application to the U.S. Food and Drug Administration ("FDA") seeking approval for safinamide tablets. The Notice Letter is directed to the three XADAGO patents with U.S. patent numbers 8,076,515, 8,278,485 and 8,283,380, that expire between June 2027 and December 2028 and are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. The Company has a license agreement with Zambon S.p.A., Newron's partner, related to the XADAGO Patents, and as a new chemical entity, XADAGO is under the 5 year FDA exclusivity period that expires on March 21, 2022. The Company is currently reviewing the details of this Notice Letter with its partners to respond as appropriate to protect the intellectual property rights relating to XADAGO.

**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; 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:

Jack A. Khattar, President and CEO
Jim Kelly, Executive Vice President and CFO
Supernus Pharmaceuticals, Inc.
Tel: (301) 838-2591

Or

Investor Contact:

Peter Vozzo
Westwicke/ICR
Office: (443) 213-0505
Mobile: (443) 377-4767
Email: peter.vozzo@westwicke.com