
**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): **April 21, 2020**

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 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 1.01 Entry Into a Material Definitive Agreement.

On April 21, 2020, Supernus Pharmaceuticals, Inc. (the “Company”) entered into a Development and Option Agreement (the “Development Agreement”) with Navitor Pharmaceuticals, Inc. (“Navitor”). Under the terms of the Development Agreement, the Company and Navitor will jointly conduct a Phase II clinical program for NV-5138 in treatment-resistant depression pursuant to a mutually agreed to development plan (the “Development Plan”), with the Company providing research and development support activities (“R&D Support Activities”). The Company and Navitor will also create a joint steering committee (the “JSC”) to oversee the overall relationship between the parties and oversee performance of the Development Plan.

Total payments, exclusive of royalty payments on net sales of NV-5138 and development costs under the Development Agreement, have the potential to reach \$410 million to \$475 million, which include an upfront payment of \$25 million (as described below), an additional license or acquisition fee depending on whether Supernus ultimately licenses or acquires NV-5138 (as described below), and subsequent clinical, regulatory and sales milestone payments. The Company will bear all development costs incurred by either the Company or Navitor up to a maximum of \$50 million excluding the costs and expenses for the Company’s R&D Support Activities. The Development Agreement provides Navitor an option to request that the Company pay certain development costs in excess of \$50 million once expenses reach this threshold.

In consideration of the rights granted to the Company under the Development Agreement, the Company will pay to Navitor a one time, non-refundable and non-creditable option issue fee of \$10 million, and, under the terms of the Series D Preferred Stock Purchase Agreement between the Company and Navitor, dated April 21, 2020, the Company will acquire Series D Preferred Shares (the “Series D Preferred Shares”) of Navitor for \$15 million, representing approximately 13% ownership in Navitor. Jack A. Khattar, President and Chief Executive Officer of the Company, will join the Navitor Board of Directors.

Under the Development Agreement, Navitor granted to the Company an exclusive option for the Company to negotiate and (a) enter into a license agreement (the “License Agreement”) with Navitor under which the Company will be granted an exclusive license and the right to sublicense (i) any and all patents that solely cover NV-5138 and products containing NV-5138, and (ii) any and all know-how that is solely useful to exploit NV-5138 or any products containing NV-5138 in the Field or in the Territory (as those terms are defined in the Development Agreement) (such option, the “License Option”), or (b) enter into a purchase agreement (the “Purchase Agreement”) with Navitor on the terms provided in the Development Agreement (the “Purchase Option”). The Company may exercise its License Option or Purchase Option at any time during a period commencing on the effective date of the Development Agreement and expiring on the earlier date of (a) a JSC recommendation to progress or not to progress to a Phase III study of a product containing NV-5138; and (b) the date the Parties enter into the License Agreement or Purchase Agreement, as applicable (the “Option Period”).

The Development Agreement grants the Company a right of first refusal (the “ROFR”) to negotiate for rights to develop and commercialize any composition of matter that has a similar mechanism of action as NV-5138 (excluding NV-5138 and any product containing NV-5138) in the central nervous system for the treatment, prevention or prophylaxis of any condition of the central nervous system (such product, a “Pipeline Product”) in the Territory. Accordingly, prior to Navitor proposing to assign, license or otherwise transfer any rights to a third party to develop and commercialize any Pipeline Product in the Territory, Navitor will provide written notice to the Company and allow the Company a specified period of time to exercise the ROFR. The failure of Navitor and the Company to enter into a definitive agreement with respect to any Pipeline Product will relieve Navitor of its ROFR obligations solely with respect to that particular Pipeline Product.

The Development Agreement will terminate upon the expiration of the Option Period. The Development Agreement may be terminated by either party immediately for the insolvency of the other party or on 30 days' written notice for an uncured material breach of the Development Agreement by the other party. The Company may also terminate the Development Agreement in its entirety on 30 days' written notice to the Company. If the Development and Option Agreement expires without the exercise by the Company of the License Option or Purchase Option, Navitor will pay a percentage of any Future Proceeds (as that term is defined in the Development Agreement) received by Navitor or its affiliates to the Company.

The terms, rights, obligations and preferences of the Preferred Stock are set forth in the Fourth Amended and Restated Certificate of Incorporation of Navitor (the “Restated Certificate”). Under the Restated Certificate, holders of Series D Preferred stock will receive dividends on a *pari passu* basis with Series C Preferred Stock (together with the Series D Preferred Stock, the “Senior Preferred Stock”), but prior and in preference to any dividends on any other class or series of capital stock of Navitor (the “Series D Preferred Dividends”). Holders of Series D Preferred stock will also receive Senior Preferred Dividends if and as declared by the Board of Directors of Navitor. The Series D Preferred stock will be convertible into common stock of Navitor.

Upon the occurrence of certain triggering events such as a liquidation, dissolution or winding up of Navitor, either voluntary or involuntary, the holders of the Series D Preferred Stock are entitled to receive, on a *pari passu* basis, before any payment shall be made to the holders of non-Senior Preferred Stock, an amount per share equal to (a) in the case of Series D Preferred Stock, the greater of (i) the Series D Original Issue Price (as that term is defined in the Restated Certificate), plus any dividends declared but unpaid thereon or such amount per share as would have been payable had all shares of Series D Preferred Stock been converted into Navitor common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (as that term is defined in the Restated Certificate).

Each holder of Series D Preferred Stock has a vote equal to the number of shares of Common Stock into which its Series D Preferred Stock would be convertible as of the record date, and is entitled to elect one director of Navitor (the "Series D Director"), for as long as there are issued and outstanding more than 1,000,000 shares of Series D Preferred Stock. In addition, for so long as the Preferred Stock remains outstanding, Navitor is prohibited from, directly or indirectly, taking certain actions that will adversely affect the rights of the Series D Preferred Stockholders.

The foregoing description of the terms of the Development Agreement is only a summary, does not purport to be complete and is qualified in its entirety by reference to the Development Agreement, which the Company intends to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020. Unless otherwise defined herein, the capitalized terms used above shall have the same meaning ascribed to them in the Development Agreement.

Item 8.01 Other Events.

On April 21, 2020, the Company issued a press release announcing its entry into the Development Agreement. 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 April 21, 2020](#), 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: April 24, 2020

By: /s/ Gregory S. Patrick

Gregory S. Patrick

Senior Vice-President and Chief Financial Officer



Supernus and Navitor Announce Development and Option Agreement for Orally Active mTORC1 Activator NV-5138

- Companies to Collaborate on Phase II Development for NV-5138 in Depression
- NV-5138 is a Novel First-in-Class Activator of mTORC1
- Supernus Receives Exclusive Option to License or Acquire NV-5138 Prior to Initiation of Phase III Clinical Program

ROCKVILLE Md., and CAMBRIDGE, Mass., April 21, 2020 –Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, and Navitor Pharmaceuticals, Inc., a privately-held company leading the discovery and development of mTORC1-targeted therapeutics, announced today a joint development and option agreement for Navitor’s mTORC1 activator, NV-5138.

NV-5138 is a first-in-class, orally active small molecule that directly activates brain mTORC1, the gatekeeper of cellular metabolism and renewal, which is often suppressed in people suffering from depression. Phase I data demonstrated early proof of concept in which a single dose of NV-5138 showed rapid and sustained improvement in core symptoms of depression with favorable safety and tolerability in patients with treatment-resistant depression (TRD).

Under the terms of the agreement, Supernus and Navitor will jointly conduct a Phase II clinical program for NV-5138 in TRD. Supernus will pay the costs of Phase II development up to \$50 million, plus certain costs associated with nonclinical development and formulation. In addition, Navitor has granted Supernus an exclusive option to license or acquire NV-5138 in all world territories, excluding Greater China, prior to initiation of a Phase III clinical program. In exchange for the option to license or acquire NV-5138, Navitor will receive an upfront payment of \$25 million, composed of a \$10 million option fee and a \$15 million equity investment representing approximately 13% ownership in Navitor. Total payments, exclusive of royalty payments on net sales of NV-5138 and development costs under the agreement, have the potential to reach \$410 million to \$475 million, which includes the upfront payment of \$25 million, an additional license or acquisition fee depending on whether Supernus ultimately licenses or acquires NV-5138, and subsequent clinical, regulatory and sales milestone payments. Supernus also will have the first right of refusal for any compound with a similar mechanism of action on mTORC1 as NV-5138 in the central nervous system. In conjunction with the equity investment, Jack Khattar, President and CEO of Supernus, will join the Board of Directors of Navitor.

"We are excited to add NV-5138 to our innovative late-stage portfolio in psychiatry as part of our long-term growth strategy," said Jack Khattar, President & CEO of Supernus. "Navitor is leveraging a novel mechanism of action to address unmet needs in treatment-resistant depression. NV-5138, an oral agent, can have a highly differentiated clinical profile characterized by a potentially rapid onset of action, and favorable tolerability. We are committed to patients suffering from depression and to bringing to them novel alternative treatment options."

"As a pharmaceutical company committed to the commercialization of CNS therapeutics with a proven history of successful CNS drug development and registration and a strong financial position, Supernus is an ideal partner to help advance further development of this potentially game-changing treatment for treatment-resistant depression. We are excited to work with the Supernus team to build on the positive data generated to date for NV-5138," said Thomas E. Hughes, Ph.D., Chief Executive Officer of Navitor. "This transaction also strengthens Navitor’s overall mission to bring forward mTORC-targeted therapies in disease states in which dysregulation of cellular metabolism contributes to pathology, including diseases with substantial unmet need like depression."

About NV-5138

NV-5138 is an orally bioavailable small molecule that directly and transiently activates mTORC1, the master modulator of cellular metabolism, which is suppressed in the brain of patients suffering from depression. NV-5138 binds to and modulates sestrin, which senses amino acid availability in the brain, a potent natural activator of mTORC1. In a Phase 1 study in treatment-resistant patients, a single dose of NV-5138 produced rapid signals of efficacy on measures of the core symptoms of depression. Preclinical models have demonstrated that oral administration of NV-5138 produces rapid upregulation of key

synaptic proteins, synaptic remodeling in the prefrontal cortex and hippocampus, sustained antidepressant behavioral responses, cognitive improvements and compound-specific spectral power changes, as measured by quantitative electroencephalography (qEEG). NV-5138 has potential applications in the treatment of depression, cognitive impairments and other neurological indications. Navitor's strong intellectual property portfolio includes issued composition of matter patent protection for NV-5138 and related compounds.

About mTORC1

Complex 1 of the mechanistic target of rapamycin (mTORC1), activity governs the pace and ability of the cell to synthesize protein and other cellular components. Increased mTORC1 activity contributes to a broad array of diseases of aging by increasing protein misfolding and driving cellular stress, inflammation, and fibrosis. In other disease states such as severe depression, inadequate mTORC1 activity contributes to disease pathology by limiting energy utilization and protein synthesis, leading to impaired function. Multiple preclinical studies have shown that mTORC1 activation is required for the efficacy of many rapid-acting antidepressant compounds, including but not limited to modulators of the N-methyl-D-aspartic-acid (NMDA)-mediated signaling pathway like ketamine.

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 currently markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy. The Company is also developing several product candidates to address large market opportunities in the CNS market.

About Navitor

Navitor Pharmaceuticals, Inc. is the leader in the development of mTORC1-targeted therapeutics designed to help patients live longer and healthier lives. The Company's proprietary platform enables specific modulation of mTORC1, the gatekeeper of cellular metabolism and renewal, with the first-ever absolutely selective mTORC1 inhibition and the unique ability for mTORC1 activation. Navitor's lead clinical-stage candidate, NV-5138, is a small molecule that directly activates mTORC1 that is being developed for treatment-resistant depression, with additional opportunities in cognition and memory. The Company's NAValog program, which provides unprecedented selectivity in mTORC1 inhibition, is initially targeting chronic kidney disease and has broad potential application for age-related diseases..

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, Supernus' ability to successfully complete the development of its product candidates and NV-5138, obtain regulatory approval and commercially market them; its ability to sustain and increase its profitability; its ability to raise sufficient capital to fully implement its corporate strategy; its future financial performance and projected expenditures; its ability to increase its net revenue; its ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies; its product research and development activities, including the timing and progress of its clinical trials, and projected expenditures; its ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize its product candidates and NV-5138; its ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; its expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of its product candidates and NV-5138; the accuracy of its estimates of the size and characteristics of the markets that may be addressed by its product candidates and NV-5138; its ability to increase its manufacturing capabilities for its products, product candidates and NV-5138; its projected markets and growth in markets; its product formulations and patient needs and potential funding sources; its staffing needs; and other risk factors set forth from time to time in its filings with the Securities and Exchange Commission made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. Supernus 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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