Conatus Pharmaceuticals Inc.
Form 8-K
December 19, 2016

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 19, 2016

CONATUS PHARMACEUTICALS INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36003**	**20-3183915**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

16745 West Bernardo Drive, Suite 200, San Diego, CA 92127
(Address of Principal Executive Offices) (Zip Code)

(858) 376-2600
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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:

[ ] 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))

Item 1.01. Entry into a Material Definitive Agreement.

Option, Collaboration and License Agreement

On December 19, 2016 (the "Execution Date"), Conatus Pharmaceuticals Inc. ("Conatus") entered into an Option, Collaboration and License Agreement (the "Agreement") with Novartis Pharma AG ("Novartis") for the global development and commercialization of emricasan, Conatus' first-in-class, orally active pan-caspase inhibitor. Under the Agreement, Novartis will make an upfront payment of $50 million to Conatus within five business days of the Execution Date.

Conatus has granted Novartis an exclusive option (the "Option") to collaborate with Conatus to develop products containing emricasan either as a single active ingredient ("Emricasan Only Products") or in combination with other Novartis compounds for liver cirrhosis or liver fibrosis ("Combination Products"), including but not limited to Farnesoid X receptor agonists that Novartis is currently developing for the treatment of chronic liver diseases (collectively "Emricasan Products"), and upon exercise of the Option, Conatus will grant Novartis an exclusive, worldwide license to Conatus' patent rights relating to emricasan to develop and commercialize Emricasan Products for the treatment, diagnosis and prevention of disease in all indications in humans. The Option is exercisable upon, among other things, Conatus providing notice to Novartis of the initiation of its planned Phase 2b clinical trial in decompensated nonalcoholic steatohepatitis ("NASH") liver cirrhosis subjects (the "ENCORE-LF Trial"), which initiation is expected in the second quarter of 2017. The Option expires on October 31, 2017. Following Novartis' exercise of the Option (the "License Effective Date"), Conatus will receive $7 million, subject to certain usual and customary closing conditions, including required anti-trust approvals.

Conatus is eligible to receive up to an aggregate of $650 million in milestone payments over the term of the Agreement, contingent on the achievement of certain development, regulatory and commercial milestones. Novartis will be required to pay to Conatus tiered royalties ranging from the high-teens to the high-twenties as a percentage of net sales of Emricasan Only Products and tiered royalties ranging from the high-single digits to the mid-teens as a percentage of net sales of Combination Products, subject to reduction in certain cases. Conatus may elect, after the initiation of the first Phase 3 clinical trial for an Emricasan Product, to enter into a co-commercialization agreement with Novartis under which it would receive up to 30 percent of the commercial profits less the same percentage of the commercial losses (the "Profit and Loss Share") for Emricasan Products in the United States. In the event Conatus so elects to enter into a co-commercialization agreement with Novartis, the net sales used to determine the amount of commercial milestone payments Conatus is entitled to receive from Novartis will be reduced by the Profit and Loss Share, Conatus will not receive royalties for sales in the United States and the royalties for sales outside of the United States will be reduced to the mid-teens to the low-twenties as a percentage of net sales of Emricasan Only Products and the mid-single digits to the low-teens as a percentage of net sales of Combination Products.

Pursuant to the Agreement, Conatus is responsible for completing its (i) ongoing ENCORE-PH Phase 2b trial in primarily compensated NASH subjects, (ii) ongoing POLT-HCV-SVR Phase 2b trial in subjects with reestablished liver fibrosis, post-orthotopic liver transplant, due to hepatitis C virus who have a sustained viral response, (iii) ongoing ENCORE-NF Phase 2b trial in NASH fibrosis and (iv) planned ENCORE-LF Trial (collectively the "Phase 2b Trials"). In the event the costs of the Phase 2b Trials and related development work between the Execution Date and the License Effective Date differ from the agreed upon budget by the parties, Novartis will reimburse Conatus for any additional costs or Conatus will credit any amount under budget to Novartis' future costs for the Phase 2b Trials. After the License Effective Date, Novartis and Conatus will share the costs of the Phase 2b Trials equally. Conatus expects the upfront and license option exercise payments and the cost-sharing under the Agreement to fund Conatus' ongoing operations through 2019. Novartis will be responsible for Phase 3 development of Emricasan Only Products and all development for Combination Products, and Novartis has agreed to use commercially reasonable efforts to develop and commercialize Emricasan Products.

Upon the License Effective Date, Conatus and Novartis will establish a Joint Steering Committee composed of senior personnel from each of Conatus and Novartis to oversee the collaboration, development and commercialization of the Emricasan Products. In the event of a change of control of Conatus, Novartis has the right to disband the Joint Steering Committee and all decision-making power otherwise assigned to the Joint Steering Committee will be assigned solely to Novartis.

Pursuant to the Agreement, for the period from the Execution Date until the earlier of five years after the first commercial sale of an Emricasan Product in the United States or major European market or ten years from the Execution Date, Conatus has agreed not to develop in any pivotal registration clinical trials or commercialize any pan-caspase inhibitors in liver disease. For the period from the Execution Date until five years after the first commercial sale of an Emricasan Only Product, Novartis has agreed not to develop in any pivotal registration clinical trials or commercialize any pan-caspase inhibitors for the diagnosis, prevention or treatment of disease in all indications in humans.

Under the Agreement, Novartis will have a right of first negotiation prior to any offer by Conatus to any third party for future pan-caspase inhibitors that Conatus may develop or acquire for the treatment of liver diseases or for certain retained pan-caspase inhibitors, provided that any license or collaboration that Conatus enters into or proposes to enter into must be on terms and conditions in the aggregate no more favorable to such third party than those last offered to Novartis.

With Conatus' written consent, Novartis may sublicense the rights granted to it by Conatus in the United States and in any major European market. In the event Novartis sublicenses its rights under the Agreement in the United States or a major European market, Novartis is required to pay Conatus a certain percentage of all amounts paid to Novartis pursuant to the sublicense, with certain exceptions. Novartis may sublicense the rights granted to it by Conatus in all other territories at any time and in its sole discretion, provided that the sublicense complies with the applicable provisions of the Agreement. Novartis is also required to pay all milestone and royalty payments on net sales of Emricasan Products made by sublicensees.

If Novartis has not exercised the Option during the designated option period, the Agreement will expire. If Novartis exercises the Option, unless terminated earlier, the Agreement will remain in effect on a product-by-product and country-by-country basis until Novartis' royalty obligations expire. Both parties have certain termination rights in the circumstances of an uncured material breach or insolvency by the other party. Novartis has certain termination rights in the event of a mandated clinical trial hold for any Emricasan Only Product. Additionally, after the License Effective Date, Novartis has the right to terminate the Agreement without cause upon 180 days prior written notice to Conatus. In such event, the license granted to Novartis will be terminated and revert to Conatus, and Novartis will transfer any ongoing trials for the Emricasan Only Products to Conatus and will cease development of the Emricasan Products. In the event Novartis terminates the Agreement due to Conatus' uncured material breach or insolvency, the license granted to Novartis pursuant to the Agreement will become irrevocable and Novartis will be required to continue to make all milestone and royalty payments otherwise due to Conatus under the Agreement, provided that if Conatus materially breaches the Agreement such that the rights licensed to Novartis or the commercial prospects of the Emricasan Products are seriously impaired, the milestone and royalty payments will be reduced by 50 percent.

Additionally, the Agreement contains customary representations, warranties and covenants by Conatus and Novartis. Each of Conatus and Novartis is required to indemnify the other against all claims arising or resulting from the indemnifying party's negligence or willful misconduct or breach of any covenants, warranties or representations in the Agreement, except to the extent that such claims arise from the breach, negligence or willful misconduct of the party seeking indemnification.

Investment Agreement

Concurrently with the entry into the Agreement, Conatus and Novartis entered into an Investment Agreement (the "Investment Agreement") whereby Conatus agreed to sell and Novartis agreed to purchase, convertible promissory notes (the "Notes") in one or two closings (each a "Closing"), for an aggregate principal amount of up to $15 million. Each Closing will occur at a date and time designated by Conatus, subject to the satisfaction of certain closing conditions, but must occur prior to December 31, 2019.

The maturity date of the Notes will be December 31, 2019. The Notes will bear interest on the unpaid principal amount at a rate of 6 percent per annum from the date of issuance. Conatus may prepay or convert the Notes into shares of Conatus' common stock, at its option, until December 31, 2019. Novartis may convert the Notes into shares of Conatus' common stock upon a change of control of Conatus or termination of the Agreement in its entirety. If converted, the principal and accrued interest under the Notes will convert into Conatus' common stock at a conversion price equal to 120 percent of the 20-day trailing average closing price per share of the common stock immediately prior to the conversion date. Upon the occurrence of certain events of default, the Notes require Conatus to repay the principal amount of the Notes and any unpaid accrued interest.

The foregoing description of the Agreement, the Investment Agreement and the form of Note, and the transactions contemplated thereby, does not purport to be complete and is subject to, and qualified in its entirety by reference to, the complete text of the Agreement, the Investment Agreement and the form of Note, which will be filed with the Securities and Exchange Commission (the "SEC") as exhibits to Conatus' Annual Report on Form 10-K for the year ending December 31, 2016.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On December 19, 2016, Shahzad Malik, M.D. resigned from the Board of Directors (the "Board") of Conatus. Dr. Malik's decision to resign from the Board did not result from any disagreement with Conatus concerning any matter relating to its operations, policies or practices. In connection with this resignation, pursuant to Conatus' bylaws, the Board voted to decrease the size of the Board from seven to six members. The Board appointed James Scopa as the chair of the Audit Committee to replace Dr. Malik as the Audit Committee chair. The Board also determined that Mr. Scopa qualifies as an "audit committee financial expert" as that phrase is defined under the regulations promulgated by the SEC. Further, the Board appointed Daniel L. Kisner, M.D. as a member of the Audit Committee.

Item 7.01. Regulation FD Disclosure.

On December 19, 2016, Conatus issued a press release announcing the Agreement and the Investment Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Current Report on Form 8-K are forward-looking statements, including statements regarding: the timing of the exercisability of the Option; the initiation of the ENCORE-LF trial in the second quarter of 2017; payments and events contingent on Novartis' exercise of the Option, including eligibility to receive payments related to development, regulatory and commercial milestones and royalties; and the sufficiency of financial resources to fund Conatus'

emricasan development through 2019. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "esti "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this Current Report on Form 8-K and are subject to a number of risks, uncertainties and assumptions, including: Conatus' ability to successfully enroll patients in and complete its ongoing and planned clinical trials; the Option being exercised by Novartis and Novartis continuing development and commercialization of emricasan; Conatus' reliance on third parties to conduct its clinical trials, including the enrollment of patients, and manufacture its clinical drug supplies of emricasan; potential adverse side effects or other safety risks associated with emricasan that could delay or preclude its approval; results of future clinical trials of emricasan; Conatus' ability to obtain additional financing in order to co- commercialize emricasan or develop other compounds; and those risks described in Conatus' periodic reports it files with the SEC. The events and circumstances reflected in Conatus' forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, Conatus does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued on December 19, 2016

SIGNATURE

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.

CONATUS PHARMACEUTICALS INC.

Date: December 19, 2016

By: /s/ Charles J. Cashion
Charles J. Cashion
Senior Vice President, Finance, Chief Financial Officer and Secretary