Conatus Pharmaceuticals Inc.
Form 8-K
April 04, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 4, 2018

CONATUS PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36003**	**20-3183915**

(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
16745 West Bernardo Drive, Suite 200 San Diego, CA (Address of Principal Executive Offices)		**92127 (Zip Code)**

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

(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 (*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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

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 April 4, 2018, Conatus Pharmaceuticals Inc. (the "Company") announced top-line results from the Company's exploratory Phase 2b POLT-HCV-SVR proof-of-concept clinical trial of emricasan, he Company's first-in-class, orally active pan-caspase inhibitor, in liver transplant patients with fibrosis or cirrhosis. The POLT-HCV-SVR trial, initiated in the second quarter of 2014, enrolled post-orthotopic liver transplant ("POLT") recipients whose transplanted livers were damaged by recurrent Hepatitis C virus ("HCV") infection. The patients subsequently achieved a sustained viral response ("SVR") following HCV antiviral therapy, but their transplanted livers had residual fibrosis or cirrhosis (baseline Ishak Fibrosis Score of F2 to F6). Patients were stable transplant recipients who were an average of seven years post-transplant on chronic immunosuppression. HCV, the initial cause of the inflammatory insult to the transplanted liver, was eliminated by antiviral therapies prior to the study. Patients were randomized 2:1 to receive 25 mg of emricasan or placebo, twice daily for two years. Biopsies were taken at baseline, after one year of treatment, and after two years of treatment.

The primary endpoint was defined as the difference in percentage of responders between the treatment and placebo arms at the two-year biopsy compared with the baseline biopsy. A response was defined as improvement or stability in Ishak Fibrosis Score for patients with baseline scores of F2 to F5 or improvement in Ishak Fibrosis Score for patients with baseline scores of F6. The prespecified goal was a difference of 15 percentage points or more in response rates between the treatment and placebo arms. The trial did not meet its primary endpoint in the heterogeneous overall trial population but an emricasan treatment effect was observed in the subgroup of patients with advanced fibrosis and early cirrhosis.

A descriptive summary of the observed response rates, patients with both a baseline and two-year biopsy, after two years of dosing for different stages of fibrosis is provided below. All p values noted are ad hoc, as prospective statistical powering was not feasible in this previously unstudied patient population.

Analyses of Overall Population and Prespecified Subgroups

Ishak Fibrosis Score at Baseline	**Emricasan Response Rate**	**Placebo Response Rate**	**Difference**	**Ad hoc p value**
	% (n/N)	**% (n/N)**		
Overall Population	77.4 (24/31)	75.0 (15/20)	2.4	0.842
F2*	83.3 (5/6)	100 (5/5)	-16.7	1.000
F2, F3, F4	92.0 (23/25)	66.7 (10/15)	25.3	0.081
F3, F4	94.7 (18/19)	50.0 (5/10)	44.7	0.011
F3, F4, F5*	95.0 (19/20)	58.3 (7/12)	36.7	0.019

F2, F3, F4, F5	92.3 (24/26)	70.6 (12/17)	21.7	0.093
F6*	0 (0/5)	100 (3/3)	-100	0.018

*Prespecified subgroups

Emricasan provided evidence of an anti-fibrotic treatment effect in the prespecified subgroup of patients with advanced fibrosis or early cirrhosis (F3-F5 at baseline), with 95.0% of patients (19/20) in the emricasan arm achieving responses in Ishak Fibrosis Score after two years of treatment, compared with 58.3% (7/12) in the placebo arm, a 36.7 percentage point difference in response rate ($p<0.02$). In addition, in patients with the potential to continue worsening, those less than F6 at baseline, only 2 of 26 (7.7%) on emricasan compared with 5 of 17 (29.4%) on placebo showed an increase in fibrosis score at year 2 – a treatment difference of 21.7 percentage points. Inflammatory activity markers (ALT, cCK18, flCK18, Knodell activity index components) were either normal or only slightly elevated at baseline.

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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 press release are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believe “predicts,” “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: reported top-line results are based on preliminary analysis of key data and as a result, such top-line results may change following a more comprehensive review and may not accurately reflect the complete results of the clinical trial; the Company’s ability to successfully enroll patients in and complete its ongoing clinical trials; Novartis continuing development and commercialization of emricasan; the Company’s 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; and those risks described in the Company’s periodic reports it files with the Securities and Exchange Commission. The events and circumstances reflected in the Company’s 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, the Company 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.

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.

Date: April 4, 2018 CONATUS PHARMACEUTICALS INC.

By: /s/ Keith W. Marshall, Ph.D., M.B.A.
Name: Keith W. Marshall, Ph.D., M.B.A.
Title: Executive Vice President, Chief Operating Officer and Chief Financial Officer