Conatus Pharmaceuticals Inc.
Form 8-K
January 05, 2016

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): January 5, 2016

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

92127

San Diego, CA
(Address of Principal Executive Offices) **(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))

Item 8.01 Other Events.

On January 5, 2016, Conatus Pharmaceuticals Inc. (the "Company") announced that the three-month, double-blind, placebo-controlled stage of the Company's multicenter Phase 2 Liver Cirrhosis clinical trial showed a statistically significant reduction in caspase-cleaved cytokeratin 18 ("cCK18") vs. placebo (p=0.04) in the overall patient population when adjusted for differences between treatment and placebo groups in baseline Model for End-stage Liver Disease ("MELD") score and disease etiology as specified in the trial statistical analysis plan. cCK18 is a mechanism-specific biomarker of caspase-driven cell death. Multiple additional liver disease biomarkers achieved statistically significant reductions vs. placebo in the overall patient population after three months of treatment, while others achieved positive trends. The Company believes that the consistent pattern of improvement across these biomarkers in the overall patient population provides strong evidence of a favorable treatment effect with emricasan, the Company's first-in-class, orally-active pan-caspase inhibitor.

Overall Patient Population	**Placebo (N=42)**		**Emricasan (N=44)**		
	Baseline	**Change at Month 3†**	**Baseline**	**Change at Month 3†**	**p-value***
cCK18 (U/L)	296	+9.3%	289	-4.6%	0.04
Caspase 3/7 (RLU)	2503	+8.8%	2656	-45.5%	<0.0001
flCK18 (U/L)	582	-3%	714	-18%	0.005
ALT (U/L)	25.5	-1.0	27.5	-3.0	0.03
AST (U/L)	41.5	-1.5	50.0	-5.0	0.08

*p-values for treatment effect at Month 3, adjusting for baseline, MELD, etiology; not adjusted for multiple testing.

†Based on last observation carried forward. Data presented are geometric mean for baseline cCK18, caspase 3/7, flCK18, and median change for ALT and AST.

Collectively, two key secondary endpoints and clinically relevant measures of liver function, MELD score and Child-Pugh-Turcotte ("Child-Pugh") score, along with other key liver function parameters, demonstrated favorable trends vs. placebo in the overall patient population after three months of treatment.

Overall Patient Population	**Placebo (N=42)**		**Emricasan (N=44)**		
	Baseline	**Change at Month 3†**	**Baseline**	**Change at Month 3†**	**p-value***
MELD score	12.9	+0.1	12.8	–0.1	0.50
Child-Pugh score	6.9	+0.1	6.9	–0.2	0.10
Total bilirubin (mg/dL)	2.59	+0.07	2.25	–0.05	0.19
INR	1.31	+0.02	1.33	–0.02	0.12
Albumin (g/dL)	3.48	+0.06	3.46	+0.02	0.38

*p-values for treatment effect at Month 3, adjusting for baseline, MELD, etiology; not adjusted for multiple testing.

†Based on last observation carried forward.

The trends in the overall patient population were driven by statistically significant improvements in a subgroup of patients with baseline MELD scores ≥15.

Baseline MELD Score ≥15 Patient Population	**Placebo (N=10)**		**Emricasan (N=9)**		**p-value***
	Baseline	**Change at Month 3†**	**Baseline**	**Change at Month 3†**	
MELD score	16.3	+0.6	16.0	–1.6	0.003
Child-Pugh score	8.2	+0.6	7.8	–0.6	0.003
Total bilirubin (mg/dL)	4.30	–0.06	3.17	–0.55	0.03
INR	1.45	+0.06	1.54	–0.14	0.0004
Albumin (g/dL)	3.19	+0.05	3.41	+0.07	0.78

*p-values for treatment effect at Month 3, adjusting for baseline, MELD, etiology; not adjusted for multiple testing.

†Based on last observation carried forward.

Additional analyses of the three-month data showed the following treatment effects in this subgroup:

- 1.6 reduction in mean MELD score with emricasan vs. 0.6 increase with placebo (p=0.003)
  - Patients achieving at least 2-point reductions in MELD score
    - 6 of 9 with emricasan vs. 2 of 10 with placebo
  - Patients achieving reductions in MELD score to ≤14
    - 4 of 9 with emricasan vs. 1 of 10 with placebo
- 0.6 reduction in mean Child-Pugh score with emricasan vs. 0.6 increase with placebo (p=0.003)
  - Patients achieving at least 1-point changes in Child-Pugh score
    - 4 of 9 had decreases with emricasan vs. 2 of 10 with placebo
    - 0 of 9 had increases with emricasan vs. 4 of 10 with placebo

Consistent with the Company's previous 15 clinical trials, emricasan was generally well-tolerated in the placebo-controlled stage of the Liver Cirrhosis clinical trial, and the overall safety profile was similar in the emricasan and placebo groups with regard to both serious and other adverse events. The Company plans to use the forthcoming six-month data from this clinical trial to understand whether longer dosing may also demonstrate a treatment effect as measured by MELD and Child Pugh in patients with lower baseline MELD scores and the overall patient population. The Company expects that the upcoming six-month Liver Cirrhosis clinical trial data will allow the Company to determine, with the continued engagement of the regulatory authorities, whether the ENCORE-LF clinical trial, originally planned as a Phase 2 clinical trial, may be redesigned to qualify as Phase 3. The Company is advancing with its plans to initiate the ENCORE clinical trials on a staggered basis over the next year.

The double-blind, placebo-controlled Phase 2 Liver Cirrhosis clinical trial was conducted at 26 U.S. sites and enrolled 86 patients with liver cirrhosis due to different etiologies, mild to moderate liver impairment and baseline MELD scores of 11 to 18. In the double-blind and placebo-controlled stage, patients were randomized 1:1 to receive either 25 mg of emricasan or placebo orally twice daily for three months. The primary endpoint was change from baseline in cCK18. Secondary endpoints included changes from baseline in MELD and Child-Pugh scores, which include laboratory parameters associated with liver synthetic and excretory function, such as serum albumin levels, international normalized ratio ("INR") and total bilirubin levels. In the open-label stage, all patients either on emricasan or placebo receive emricasan for an additional three months. Six-month data from patients who continued treatment and three-month data from placebo patients who crossed over to emricasan treatment are expected in the second quarter of 2016.

Among the 86 subjects enrolled and dosed, liver cirrhosis etiologies included alcohol (38%), hepatitis C virus (29%), non-alcoholic steatohepatitis (23%), and other causes (9%). Baseline MELD scores were ≤14 in 78% of enrolled subjects and ≥15 in 22% of enrolled subjects. Baseline Child-Pugh status was A (Child-Pugh score of 5-6) in 43% of subjects and B (Child-Pugh score of 7-9) in 56% of subjects.

* * *

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: improvements in biomarkers as evidence of a favorable treatment effect with emricasan; the use of the six-month data from the Liver Cirrhosis trial to determine whether longer dosing with emricasan may lead to improvements in patients with lower baseline MELD scores and the overall patient population; the ability of the six-month Liver Cirrhosis trial data to allow the Company, with continued engagement of the regulatory authorities, to determine whether the ENCORE-LF clinical trial may be redesigned as a Phase 3 trial; the planned initiation of the ENCORE trials over the next year; the expected results of the six-month data from patients who continued treatment and the three-month data from placebo patients who crossed over to emricasan treatment in the Liver Cirrhosis trial in the second quarter of 2016. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "c "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of th 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: the Company's ability to initiate and successfully complete current and future clinical trials; the potential that further analysis of the data

described herein or additional data may yield different results; the Company's ability to evaluate emricasan's potential medium-term and longer-term effects on liver function and liver structure in its other two ongoing clinical trials; the Company's ability to develop and implement a registration strategy and pathway for emricasan; the U.S. Food and Drug Administration's ("FDA") and other regulatory agencies' interactions and guidance relating to the development of emricasan; the Company's dependence on its ability to obtain regulatory approval for, and then successfully commercialize emricasan, which is the Company's only drug candidate; the Company's reliance on third parties to conduct its clinical trials, enroll subjects, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of emricasan, if approved; the potential that earlier clinical trials may not be predictive of future results; 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; the potential for competing products to limit the clinical trial enrollment opportunities for emricasan in certain indications; the uncertainty of the FDA's and other regulatory agencies' approval processes and other regulatory requirements; the Company's ability to fully comply with numerous federal, state and local laws and regulatory requirements applicable to it; the Company's limited operating history and its ability to operate successfully as a public company; the Company's ability to obtain additional financing in order to complete the development and commercialization 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: January 5, 2016 CONATUS PHARMACEUTICALS INC.

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