Conatus Pharmaceuticals Inc.
Form 8-K
December 06, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

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FORM 8-K

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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 5, 2018

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CONATUS PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

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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	**(Zip Code)**
(Address of Principal Executive Offices)	

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

(Former Name or Former Address, if Changed Since Last Report.)

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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 December 5, 2018, Conatus Pharmaceuticals Inc. (the "Company") announced top-line results from the Company's Phase 2b ENCORE-PH clinical trial of emricasan, the Company's first-in-class, orally active pan-caspase inhibitor under development in compensated or early decompensated nonalcoholic steatohepatitis ("NASH") cirrhosis patients with severe portal hypertension. The trial's primary endpoint was change in mean hepatic venous pressure gradient (HVPG) from baseline to Week 24 in any of three emricasan dosing groups compared with placebo. The total patient population was composed of two prespecified subgroups – patients with compensated NASH cirrhosis (201 of 263 patients, or 76%) and patients with early decompensated NASH cirrhosis (62 of 263 patients, or 24%). The trial did not meet its primary endpoint in the overall trial population but clinically meaningful treatment effects were observed in subsets of the compensated patient subgroup.

In patients with compensated NASH cirrhosis, post hoc analyses demonstrated consistent improvements in mean HVPG at week 24 over baseline. The magnitude of the improvement in mean HVPG generally increased as the baseline HVPG levels increased.

Mean HVPG Change from Baseline of Emricasan vs. Placebo*

Overall Compensated and Decompensated Patient Population			
Mean Baseline HVPG	***Emricasan 5 mg BID***	***Emricasan 25 mg BID***	***Emricasan 50 mg BID***
≥12 mmHg	-0.3 (p=0.666)	-0.5 (p=0.416)	-0.6 (p=0.337)
Compensated Patient Subpopulation			
≥12 mmHg	-1.0 (p=0.098)	-1.1 (p=0.087)	-0.7 (p=0.275)
≥13 mmHg	-1.4 (p=0.047)	-1.4 (p=0.040)	-1.5 (p=0.037)
≥14 mmHg	-1.5 (p=0.037)	-1.8 (p=0.015)	-1.6 (p=0.032)
≥15 mmHg	-1.4 (p=0.074)	-1.6 (p=0.035)	-2.0 (p=0.017)
≥16 mmHg	-2.2 (p=0.010)	-2.3 (p=0.006)	-2.0 (p=0.023)
≥17 mmHg	-2.6 (p=0.009)	-2.8 (p=0.005)	-2.5 (p=0.015)

*Post-hoc analyses based on ANOVA model adjusted for baseline HVPG

Mean HVPG Change from Baseline of Emricasan and Placebo*

Overall Compensated and Decompensated Patient Population				
Mean Baseline HVPG	***Emricasan 5 mg BID***	***Emricasan 25 mg BID***	***Emricasan 50 mg BID***	***Placebo BID***
≥12 mmHg	-0.5 (N=61)	-0.7 (N=62)	-0.8 (N=56)	-0.2 (N=64)
Compensated Patient Subpopulation				

≥12 mmHg	-0.8 (n=46)	-0.8 (n=47)	-0.4 (n=42)	+0.2 (n=53)
≥13 mmHg	-0.9 (n=39)	-0.9 (n=46)	-1.0 (n=37)	+0.5 (n=44)
≥14 mmHg	-1.0 (n=35)	-1.3 (n=38)	-1.1 (n=31)	+0.5 (n=39)
≥15 mmHg	-1.2 (n=30)	-1.3 (n=35)	-1.7 (n=25)	+0.3 (n=35)
≥16 mmHg	-1.6 (n=26)	-1.7 (n=30)	-1.5 (n=21)	+0.5 (n=26)
≥17 mmHg	-1.7 (n=23)	-1.9 (n=25)	-1.6 (n=19)	+0.9 (n=20)

*Post-hoc analyses based on ANOVA model adjusted for baseline HVPG

In a post hoc analysis, the high-risk subgroup of compensated patients with HVPG ≥16 mmHg, which is the clinical cutoff to predict decompensation and higher risk of death, at baseline showed a clinically meaningful ≥2-point improvement in mean HVPG compared with placebo in all three emricasan dosing groups. A trend in responses predictive of clinical benefit (≥20% reduction in HVPG from baseline) was also observed in the total ≥12 mmHg compensated patient population with the greatest responses observed in the ≥16 mmHg cohort in the 5 mg BID and 50 mg BID dose groups.

Post Hoc ≥20% Responders (from Baseline) in Compensated NASH Cirrhosis Subgroup*

Baseline HVPG	*Emricasan 5 mg BID*	*Emricasan 25 mg BID*	*Emricasan 50 mg BID*	*Placebo BID*
≥16 mmHg	22% (p=0.023) (7%, 39%) (n=6/27)	13% (p=0.110) (1%, 26%) (n=4/30)	20% (p=0.013) (6%, 42%) (n=5/25)	0% (n=0/26)
≥12 mmHg	15% (p=0.379) (-7%,19%) (n=7/46)	19% (p=0.162) (-4%, 23%) (n=9/47)	19% (p=0.176) (-4%, 24%) (n=8/42)	9% (n=5/53)

*Post-hoc chi-square test for assessing difference in response rates (95% CI of risk difference)

Consistent with safety results from 17 previously completed clinical trials, emricasan was generally well-tolerated in the ENCORE-PH clinical trial, and the overall safety profile was similar in the emricasan and placebo groups. Patients enrolled in the ENCORE-PH clinical trial are continuing treatment or placebo in a six-month extension period to evaluate longer term safety, liver function and clinical outcomes, and results from the extension are expected in mid-2019.

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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 expected results from the six-month extension of the ENCORE-PH clinical trial. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target” “contemplates,” “believes,” “estimates,” “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: December 6, 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