

# CONATUS PHARMACEUTICALS INC.

## **FORM 8-K** (Current report filing)

Filed 03/15/17 for the Period Ending 03/15/17

Address	16745 WEST BERNARDO DRIVE Suite 200 San Diego, CA 92127
Telephone	(858) 376-2600
CIK	0001383701
Symbol	CNAT
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

---

---

**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): March 15, 2017

**CONATUS PHARMACEUTICALS INC.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation)

**001-36003**  
(Commission File Number)

**20-3183915**  
(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 2.02. Results of Operations and Financial Condition.**

On March 15, 2017, Conatus Pharmaceuticals Inc. issued a press release announcing its financial results for the quarter and full year ended December 31, 2016. 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 2.02, 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.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

**Exhibit No.    Description**

[99.1](#)            Press release issued on March 15, 2017

---

**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: March 15, 2017

By: /s/ Steven J. Mento  
Steven J. Mento  
President and Chief Executive Officer

## Conatus Pharmaceuticals Reports 2016 Financial Results and Program Updates

SAN DIEGO, March 15, 2017 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced financial results for the fourth quarter and full year ended December 31, 2016, and provided updates on its clinical development programs. Conatus is developing emricasan, its first-in-class, orally active pan-caspase inhibitor, for the treatment of patients with chronic liver disease, with an initial focus on cirrhosis driven by nonalcoholic steatohepatitis (NASH). The company is conducting a parallel set of Emricasa N, a Caspase inhibitor OR, for Evaluation (ENCORE) clinical trials in various patient populations. In December 2016, Conatus entered into an exclusive option, collaboration and license agreement with Novartis for the global development and commercialization of emricasan.

### Financial Results

Total revenues were \$0.8 million for the fourth quarter and full year 2016 compared with \$0.0 million for the fourth quarter and full year 2015. Total revenues for the fourth quarter and full year 2016 consisted of collaboration revenue related to the Novartis agreement.

Research and development expenses were \$6.5 million for the fourth quarter of 2016 compared with \$4.2 million for the fourth quarter of 2015. Research and development expenses were \$20.3 million for the full year 2016 compared with \$16.3 million for the full year 2015. The full year increase in research and development expenses was primarily due to an increase in external costs related to emricasan and higher personnel costs.

General and administrative expenses were \$3.5 million for the fourth quarter of 2016 compared with \$1.8 million for the fourth quarter of 2015. General and administrative expenses were \$10.3 million for the full year 2016 compared with \$7.8 million for the full year 2015. The full year increase in general and administrative expenses was primarily due to higher consulting and legal fees and higher personnel costs.

The net loss for the fourth quarter of 2016 was \$9.1 million compared with \$6.0 million for the fourth quarter of 2015. The net loss for the full year 2016 was \$29.7 million compared with \$24.1 million for the full year 2015.

In December 2016, Conatus received an upfront payment of \$50.0 million under the Novartis agreement. In January 2017, Conatus voluntarily prepaid a \$1.0 million note to Pfizer Inc. which was scheduled to mature in 2020. In February 2017, Conatus issued a \$15.0 million convertible promissory note to Novartis.

Cash, cash equivalents and marketable securities were \$77.0 million at December 31, 2016, compared with \$36.5 million at December 31, 2015, and a projected year-end 2017 balance of between \$45 million and \$55 million. The company believes that current financial resources, together with the anticipated license option exercise milestone payment and expense reimbursements related to the Novartis agreement, are sufficient to maintain operations and ongoing clinical development activities through the end of 2019.

### Program Updates

During 2016, the company announced:

- positive results from the three-month, double-blind, placebo-controlled first stage and six-month open-label second stage of its Phase 2 Liver Cirrhosis clinical trial;
- the initiation of its Phase 2b ENCORE-NF ( NASH Fibrosis) clinical trial;
- U.S. Food and Drug Administration (FDA) Fast Track designation for the development of emricasan in patients with liver cirrhosis caused by NASH;
- the initiation of its Phase 2b ENCORE-PH ( Portal Hypertension) clinical trial; and
- the option, collaboration and license agreement for emricasan with Novartis.

### Novartis Agreement

Under the terms of the agreement with Novartis, Conatus is eligible to receive \$7.0 million following the exercise of the license option, and to receive significant additional payments if certain development, regulatory and commercial milestones are met. Furthermore, Conatus is eligible to receive tiered double digit royalties on emricasan single agent sales and tiered single to double digit royalties on sales of combination products containing emricasan. Conatus has the option to co-commercialize emricasan in the United States, including combination therapies, on a cost-sharing and revenue-sharing basis in lieu of U.S. royalties and with reduced ex-U.S. royalties. Conatus retains limited rights to develop other pan-caspase inhibitors.

In addition, Novartis will reimburse 50% of Conatus' Phase 2b emricasan development expenses after the option exercise, and 100% of certain expenses for required registration-supportive nonclinical activities. Novartis will assume full responsibility for emricasan's Phase 3 development and all combination product development.

Conatus has three ongoing emricasan Phase 2b clinical trials:

- **ENCORE-PH** : A randomized, double-blind, placebo-controlled Phase 2b clinical trial initiated in November 2016 evaluating dosing, efficacy and safety of emricasan in approximately 240 patients with compensated or early decompensated liver cirrhosis caused by nonalcoholic steatohepatitis (NASH), and severe portal hypertension confirmed by hepatic venous pressure gradient (HVPG) of  $\geq 12$  mmHg at baseline. Results after 24 weeks of twice-daily treatment with emricasan or placebo are expected in 2018.
- **ENCORE-NF** : A randomized, double-blind, placebo-controlled Phase 2b clinical trial initiated in January 2016 evaluating potential improvements in fibrosis and steatohepatitis in approximately 330 patients with NASH fibrosis. Results after 18 months of twice-daily treatment or placebo are expected in 2018.
- **POLT-HCV-SVR** : A randomized, double-blind, placebo-controlled Phase 2b clinical trial initiated in May 2014 evaluating potential improvements in Ishak Fibrosis Score in approximately 60 post-orthotopic liver transplant (POLT) recipients with liver fibrosis or cirrhosis post-transplant as a result of

recurrent hepatitis C virus (HCV) infection who have successfully achieved a sustained viral response (SVR) following HCV antiviral therapy. Results after two years of twice-daily treatment or placebo are expected in the first half of 2018.

Conatus plans to initiate an additional emricasan Phase 2b clinical trial in the second quarter of 2017:

- **ENCORE-LF** : A planned randomized, double-blind, placebo-controlled Phase 2b clinical trial to assess a composite clinical endpoint, related serum biomarkers and laboratory parameters associated with liver function, and chronic administration safety information in patients with decompensated NASH cirrhosis and baseline Model for End-stage Liver Disease (MELD) scores of  $\geq 15$ . Initiation of the ENCORE-LF (Liver Function) clinical trial is a trigger for Novartis to exercise its license option.

Conatus also plans to roll out pipeline development opportunities beyond emricasan later in 2017.

#### Conference Call and Audio Webcast

Conatus will host a conference call and audio webcast at 4:30 p.m. Eastern Time today to discuss the financial results and provide a corporate update. To access the conference call, please dial 877-312-5857 (domestic) or 970-315-0455 (international) at least five minutes prior to the start time and refer to conference ID 75917141. A live and archived audio webcast of the call will also be available in the Investors section of the Conatus website at [www.conatuspharma.com](http://www.conatuspharma.com).

#### About Conatus Pharmaceuticals

Conatus is a biotechnology company focused on the development and commercialization of novel medicines to treat liver disease. Conatus is developing its lead compound, emricasan, for the treatment of patients with chronic liver disease. Emricasan is designed to reduce the activity of enzymes that mediate inflammation and apoptosis. Conatus believes that by reducing the activity of these enzymes, emricasan has the potential to interrupt the disease progression across the spectrum of liver disease. For additional information, please visit [www.conatuspharma.com](http://www.conatuspharma.com).

#### Forward-Looking Statements

This press release 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, including statements regarding: projected year-end cash balance; the sufficiency of current financial resources to maintain operations and ongoing clinical development activities through 2019; payments and events contingent on Novartis' exercise of the option; the exercisability of Novartis' option; eligibility to receive payments related to development, regulatory and commercial milestones and royalties; the timelines to announce results from the POLT-HCV-SVR, the ENCORE-NF, and the ENCORE-PH trials; the plan and details to initiate the ENCORE-LF trial in the second quarter of 2017; plans to announce pipeline development opportunities in 2017; and emricasan's potential to interrupt the disease progression across the spectrum of liver disease. 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," "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 press release 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' prior press releases and in the periodic reports it files with the Securities and Exchange Commission. 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.

### Conatus Pharmaceuticals Inc. Selected Condensed Financial Information (Unaudited)

Statements of Operations	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Revenues:				
Collaboration revenue	\$ 799,046	\$ -	\$ 799,046	\$ -
Operating expenses:				
Research and development	6,523,261	4,240,620	20,293,632	16,297,617
General and administrative	3,453,474	1,799,346	10,337,182	7,833,085
Total operating expenses	9,976,735	6,039,966	30,630,814	24,130,702
Loss from operations	(9,177,689)	(6,039,966)	(29,831,768)	(24,130,702)
Other income (expense)	54,187	(4,196)	98,327	(17,924)
Net loss	\$(9,123,502)	\$(6,044,162)	\$(29,733,441)	\$(24,148,626)
Net loss per share, basic and diluted	\$ (0.35)	\$ (0.30)	\$ (1.31)	\$ (1.30)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	25,994,155	19,834,477	22,649,911	18,617,537

**Balance Sheets**

	<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Assets</b>		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 77,015,124	\$ 36,508,109
Other receivables	2,500,000	-
Prepaid and other current assets	937,436	1,982,031
Total current assets	80,452,560	38,490,140
Property and equipment, net	261,446	344,734
Other assets	1,609,834	892,394
Total assets	<u>\$ 82,323,840</u>	<u>\$ 39,727,268</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and other accrued expenses	\$ 7,662,796	\$ 3,982,698
Current portion of deferred revenue	30,897,192	-
Note payable	1,000,000	-
Total current liabilities	39,559,988	3,982,698
Deferred revenue, less current portion	20,803,762	-
Note payable	-	1,000,000
Deferred rent	171,544	204,224
Stockholders' equity	21,788,546	34,540,346
Total liabilities and stockholders' equity	<u>\$ 82,323,840</u>	<u>\$ 39,727,268</u>

CONTACT: Alan Engbring  
Conatus Pharmaceuticals Inc.  
(858) 376-2637  
aengbring@conatuspharma.com