CONATUS PHARMACEUTICALS INC.

FORM 8-K
(Current report filing)

Filed 08/02/17 for the Period Ending 08/02/17

Address	16745 WEST BERNARDO DRIVE Suite 200 San Diego, CA 92127
Telephone	(858) 376-2600
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): August 2, 2017

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 2.02 Results of Operations and Financial Condition.

On August 2, 2017, Conatus Pharmaceuticals Inc. issued a press release announcing its financial results for the quarter and six months ended June 30, 2017. 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 August 2, 2017

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: August 2, 2017

CONATUS PHARMACEUTICALS INC.

By: /s/ Steven J. Mento, Ph.D.
Name: Steven J. Mento, Ph.D.
Title: President and Chief Executive Officer

EXHIBIT 99.1

Conatus Pharmaceuticals Reports Second Quarter 2017 Financial Results and Program Updates

SAN DIEGO, Aug. 02, 2017 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT), a biotechnology company focused on the development and commercialization of novel medicines to treat liver disease, today announced financial results for the quarter and six months ended June 30, 2017, and provided updates on its clinical development programs.

Financial Results
The net loss for the second quarter of 2017 was $5.4 million compared with $6.5 million for the second quarter of 2016. The net loss for the first six months of 2017 was $9.0 million compared with $13.7 million for the first six months of 2016.

Total revenues were $10.0 million for the second quarter of 2017 and $17.0 million for the first six months of 2017, compared with $0.0 million for the comparable periods in 2016. Total revenues for both periods in 2017 consisted of collaboration revenue related to the company's Option, Collaboration and License Agreement with Novartis, which was executed in December 2016.

Research and development expenses were $13.2 million for the second quarter of 2017 compared with $4.2 million for the second quarter of 2016. Research and development expenses were $21.1 million for the first six months of 2017 compared with $8.9 million for the first six months of 2016. The increases in research and development expenses for both periods were primarily due to the ramp up of the ENCORE-NF and ENCORE-PH clinical trials, as well as the commencement of the ENCORE-LF clinical trial.

General and administrative expenses were $2.2 million for the second quarter of 2017 compared with $2.2 million for the second quarter of 2016. General and administrative expenses were $5.0 million for the first six months of 2017 compared with $4.8 million for the first six months of 2016.

Conatus completed an underwritten public offering of 5,980,000 shares of its common stock in May 2017 at a price of $5.50 per share, generating net proceeds of approximately $30.7 million, of which approximately $11.2 million was used to repurchase and retire 2,166,836 shares of Conatus' common stock held by funds affiliated with Advent Private Equity.

Cash, cash equivalents and marketable securities were $88.2 million at June 30, 2017, compared with $77.0 million at December 31, 2016, and a projected year-end 2017 balance of between $55 million and $65 million. The company believes its financial resources, including a $7.0 million license option exercise payment received in July 2017 and anticipated expense reimbursements related to the Novartis agreement, are sufficient to maintain operations and ongoing emricasan clinical development activities through the end of 2019, as well as to fund anticipated pipeline expansion activities.

Program Updates
With the receipt of the license option exercise payment in July 2017, Conatus' exclusive license with Novartis for the global development and commercialization of emricasan became effective under terms of the Option, Collaboration and License Agreement. In collaboration with Novartis, Conatus is conducting four randomized, double-blind, placebo-controlled Phase 2b clinical trials designed to evaluate emricasan treatment in various patient populations, including three EmricasaN, a Caspase inhibitOR, for Evaluation (ENCORE) clinical trials in patients with fibrosis or cirrhosis caused by nonalcoholic steatohepatitis (NASH), and a fourth clinical trial in POLT-HCV-SVR patients:

- ENCORE-NF (for NASH Fibrosis), initiated in the first quarter of 2016, in approximately 330 patients with NASH fibrosis, with top-line results expected in the first half of 2019;

- ENCORE-PH (for Portal Hypertension), initiated in the fourth quarter of 2016, in approximately 240 patients with compensated or early decompensated NASH cirrhosis and severe portal hypertension, with top-line results expected in 2018 followed by an integrated treatment extension period for clinical outcomes;

- ENCORE-LF (for Liver Function), initiated in the second quarter of 2017, in approximately 210 patients with decompensated NASH cirrhosis, with top-line results expected in 2019; and

- POLT-HCV-SVR, initiated in the second quarter of 2014, in approximately 60 post-orthotopic liver transplant (POLT) recipients with liver fibrosis or cirrhosis post-transplant as a result of recurrent HCV infection who have successfully achieved a sustained viral response (SVR) following HCV antiviral therapy, with top-line results expected in the first half of 2018.

Results from the four ongoing emricasan clinical trials are expected to support the design of Phase 3 clinical efficacy and safety trials.

In June 2017, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to Conatus' drug candidate IDN-7314 for the treatment of primary sclerosing cholangitis (PSC). Conatus will continue to evaluate IDN-7314 as a potential product candidate, along with other potential product candidates, and intends to announce initial pipeline expansion plans 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 54274394. 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.

About Conatus Pharmaceuticals
Conatus is a biotechnology company focused on the development and commercialization of novel medicines to treat liver disease. In collaboration with Novartis, Conatus is developing its lead compound, emricasan, for the treatment of patients with chronic liver disease. Emricasan is a first-in-class, orally active pan-caspase inhibitor designed to reduce the activity of enzymes that mediate inflammation and apoptosis. Conatus believes that by reducing the activity of these enzymes, caspase inhibitors have the potential to interrupt the progression of a variety of diseases. For additional information, please visit 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: the projected year-end cash balance; the sufficiency of current financial resources to maintain operations and ongoing clinical development activities through 2019, as well as to fund anticipated pipeline expansion activities; the timelines to announce results from the ENCORE-NF, the ENCORE-PH, the ENCORE-LF, and the POLT-HCV-SVR clinical trials; evaluation of IDN-7314 and other potential product candidates; the timeline to announce initial pipeline expansion plans; and caspase inhibitors' potential to interrupt the progression of a variety of diseases. 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; 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 June 30,**		**Six Months Ended June 30,**	
	2017	**2016**	**2017**	**2016**
Revenues:				
Collaboration revenue	$10,008,431	$ -	$17,006,507	$ -
Operating expenses:				
Research and development	13,217,925	4,246,488	21,143,636	8,944,950
General and administrative	2,194,184	2,238,134	4,957,209	4,814,261
Total operating expenses	15,412,109	6,484,622	26,100,845	13,759,211
Loss from operations	(5,403,678)	(6,484,622)	(9,094,338)	(13,759,211)
Other income/expense	(13,209)	13,477	54,706	16,182
Net loss	$ (5,416,887)	$ (6,471,145)	$ (9,039,632)	$(13,743,029)
Net loss per share, basic and diluted	$ (0.19)	$ (0.30)	$ (0.33)	$ (0.65)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	28,103,393	21,542,188	27,138,536	21,085,610

Balance Sheets	**June 30, 2017**	**December 31, 2016**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$88,198,337	$ 77,015,124
Other receivables	7,000,000	2,500,000
Prepaid and other current assets	1,017,603	937,436
Total current assets	96,215,940	80,452,560
Property and equipment, net	228,405	261,446
Other assets	2,538,211	1,609,834

Total assets	$98,982,556	$ 82,323,840
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and other accrued expenses	$10,077,313	$ 7,662,796
Current portion of deferred revenue	24,630,685	30,897,192
Note payable	-	1,000,000
Total current liabilities	34,707,998	39,559,988
Deferred revenue, less current portion	17,063,762	20,803,762
Convertible note payable	12,779,452	-
Deferred rent	151,358	171,544
Stockholders' equity	34,279,986	21,788,546
Total liabilities and stockholders' equity	$98,982,556	$ 82,323,840

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