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Conatus Pharmaceuticals Reports Third Quarter 2017 Financial Results and Program Updates

SAN DIEGO, Nov. 01, 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 nine months ended September 30, 2017, and provided updates on its development programs.

Program Updates
In collaboration with Novartis under terms of the company's Option, Collaboration and License Agreement with Novartis, which was executed in December 2016, 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:

- 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 hepatitis C virus (HCV) infection who have successfully achieved a sustained viral response (SVR) following HCV antiviral therapy, with top-line results expected in the second quarter of 2018;

- 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 the second half of 2018 followed by an integrated treatment extension period for clinical outcomes;

- 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; and

- 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 the second half of 2019.

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

Pipeline Expansion Plans

In October 2017, the European Medicines Agency (EMA) granted Orphan Drug Designation in the European Union to the company's pan-caspase inhibitor IDN-7314 for the treatment of primary sclerosing cholangitis (PSC), a disease affecting bile ducts in the liver, which can lead to cirrhosis and liver failure. In June 2017, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation in the United States to IDN-7314 for the treatment of PSC.

These orphan drug designations were based on previously reported data with IDN-7314 demonstrating reduction of relevant biomarkers in two preclinical models of PSC. New results, showing that IDN-7314 markedly diminished inflammasome activation and reduced liver injury in a preclinical model of PSC, were presented in October 2017 at The Liver Meeting®, the annual meeting of the American Association for the Study of Liver Diseases (AASLD). In a separate study, IDN-7314 reduced biochemical markers in a new acute preclinical model of PSC.

Conatus believes the orphan drug designations, along with the growing body of preclinical data, warrant further evaluation of IDN-7314 as a potential product candidate in PSC as a component of its initial pipeline expansion plans. The company's ongoing pipeline expansion activities also include:

- internal development of new preclinical product candidates leveraging its expertise with the caspase inhibition technology platform, and

- evaluation for potential in-licensing or acquisition of external clinical-stage product candidates consistent with its product development and regulatory expertise.

Conatus may pursue the development of product candidates in liver disease and in other related disease areas.

Financial Results
The net loss for the third quarter of 2017 was $4.0 million compared with $6.9 million for the third quarter of 2016. The net loss for the first nine months of 2017 was $13.0 million compared with $20.6 million for the first nine months of 2016.

Total revenues were $9.6 million for the third quarter of 2017 and $26.6 million for the first nine 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 Option, Collaboration and License Agreement with Novartis.

Research and development expenses were $11.2 million for the third quarter of 2017 compared with $4.8 million for the third quarter of 2016. Research and development expenses were $32.3 million for the first nine months of 2017 compared with $13.8 million for the first nine months of 2016. The increases in research and development expenses were primarily due to the ramp up of our ENCORE-NF, ENCORE-PH and ENCORE-LF clinical trials.

General and administrative expenses were $2.4 million for the third quarter of 2017 compared with $2.1 million for the third quarter of 2016. General and administrative expenses were $7.4 million for the first nine months of 2017 compared with $6.9 million for the first nine months of 2016. The increases in general and administrative expenses were primarily due to higher personnel costs and professional fees.

Cash, cash equivalents and marketable securities were $85.2 million at September 30, 2017, compared with $77.0 million at December 31, 2016. Based primarily on lower than expected spending on in-licensing and internal pipeline development, the company is now projecting a year-end 2017 balance of between $70 million and $75 million. The company believes its current and forecasted financial resources 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.

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 99505370. 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 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 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; 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.

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

Conatus Pharmaceuticals Inc.
Selected Condensed Financial Information
(Unaudited)

Statements of Operations	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
	2017	**2016**	**2017**	**2016**
Revenues:				
Collaboration revenue	$ 9,565,890	$ -	$ 26,572,397	$ -
Operating expenses:				
Research and development	11,165,150	4,825,421	32,308,786	13,770,371
General and administrative	2,449,382	2,069,447	7,406,591	6,883,708
Total operating expenses	13,614,532	6,894,868	39,715,377	20,654,079
Loss from operations	(4,048,642)	(6,894,868)	(13,142,980)	(20,654,079)
Other income/expense	48,264	27,958	102,970	44,140
Net loss	$ (4,000,378)	$ (6,866,910)	$ (13,040,010)	$ (20,609,939)
Net loss per share, basic and diluted	$ (0.13)	$ (0.31)	$ (0.46)	$ (0.96)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	30,004,037	22,410,702	28,104,199	21,527,993

Balance Sheets	**September 30, 2017**	**December 31, 2016**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 85,183,887	$ 77,015,124
Other receivables	-	2,500,000
Prepaid and other current assets	1,339,208	937,436
Total current assets	86,523,095	80,452,560
Property and equipment, net	204,914	261,446
Other assets	2,538,211	1,609,834
Total assets	$ 89,266,220	$ 82,323,840
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and other accrued expenses	$ 12,748,770	$ 7,662,796
Current portion of deferred revenue	19,454,795	30,897,192
Note payable	-	1,000,000
Total current liabilities	32,203,565	39,559,988
Deferred revenue, less current portion	12,673,762	20,803,762
Convertible note payable	12,968,493	-
Deferred rent	139,392	171,544
Stockholders' equity	31,281,008	21,788,546
Total liabilities and stockholders' equity	$ 89,266,220	$ 82,323,840