Conatus Pharmaceuticals Reports Third Quarter 2018 Financial Results and Program Updates

November 1, 2018

SAN DIEGO, Nov. 01, 2018 (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, 2018, and provided updates on its clinical development programs.

Program Updates
The company is conducting three Phase 2b clinical trials in collaboration with Novartis – the EmricasaN, a Caspase inhibitOR, for Evaluation (ENCORE) trials, designed to evaluate emricasan, a first-in-class pan-caspase inhibitor, in patients with fibrosis or cirrhosis caused by nonalcoholic steatohepatitis (NASH).

- The ENCORE-PH (for Portal Hypertension) clinical trial, initiated in the fourth quarter of 2016, has enrolled approximately 240 patients with compensated or early decompensated NASH cirrhosis and severe portal hypertension. The primary endpoint is the mean change in hepatic venous pressure gradient (HVPG) for each of three treatment groups compared with placebo at week 24. ENCORE-PH remains on track with prior guidance, with top-line results expected in the current quarter followed by an integrated 24-week treatment extension period for clinical outcomes.

- The ENCORE-NF (for NASH Fibrosis) clinical trial, initiated in the first quarter of 2016, has enrolled approximately 330 patients with NASH fibrosis. The primary endpoint is a one point or greater improvement in NASH Clinical Research Network (CRN) fibrosis score compared with placebo at week 72, with no worsening of steatohepatitis. ENCORE-NF enrolled patients with baseline NASH CRN fibrosis scores of F1 (up to 20% of enrolled patients), F2, and F3. The primary endpoint will be evaluated and can be achieved in either of two prospectively defined patient populations – the F1/F2/F3 population or the F2/F3 population. Either of these populations may be used in a future Phase 3 trial. The company believes that the ENCORE-NF analysis plan as described has the potential to facilitate discussions with regulatory authorities regarding its use as a study to support regulatory approval. Top-line results from ENCORE-NF are expected in the first half of 2019.

- The ENCORE-LF (for Liver Function) clinical trial, initiated in the second quarter of 2017, is expected to enroll approximately 210 patients with decompensated NASH cirrhosis. The primary endpoint is event-free survival, with an event-driven stopping point. All subjects will be treated for a minimum of 48 weeks. Guidance for the ENCORE-LF clinical trial has been updated, with top-line results previously expected in the second half of 2019 now expected in mid-2019.

During the third quarter, the company announced the publication of results from preclinical studies of emricasan, demonstrating improvements in portal hypertension and survival in mouse models of secondary biliary cirrhosis. In October, the company announced accepted abstracts for two oral presentations and a poster at The Liver Meeting®, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in San FranciscoNovember 9-13, 2018. In addition, the company will be meeting with institutional investors at the Stifel 2018 Healthcare Conference in New York on Tuesday, November 13, 2018.

Financial Results
The net loss for the third quarter of 2018 was $4.6 million compared with $4.0 million for the third quarter of 2017. The net loss for the first nine months of 2018 was $14.1 million compared with $13.0 million for the first nine months of 2017.

All revenues were related to the company's collaboration with Novartis. Total revenues were $7.7 million for the third quarter of 2018 compared with $9.6 million for the third quarter of 2017. Total revenues were $26.2 million for the first nine months of 2018 compared with $26.6 million for the first nine months of 2017. The decreases in revenues for both periods were primarily due to lower emricasan-related research and development expenses resulting in corresponding lower revenues from Novartis, partially offset by the effects of adopting the ASC 606 revenue recognition standard.

Research and development expenses were $9.7 million for the third quarter of 2018 compared with $11.2 million for the third quarter of 2017. The decrease in research and development expenses was primarily due to lower spending related to the ENCORE-NF and ENCORE-PH clinical trials and manufacturing activities, partially offset by higher spending related to the ENCORE-LF clinical trial. Research and development expenses were $32.5 million for the first nine months of 2018 compared with $32.3 million for the first nine months of 2017. The increase in research and development expenses was primarily due to higher spending related to the ENCORE-LF and ENCORE-PH clinical trials and new product candidate development, partially offset by lower spending related to the ENCORE-NF clinical trial and manufacturing activities.

General and administrative expenses were $2.7 million for the third quarter of 2018 compared with $2.4 million for the third quarter of 2017. General and administrative expenses were $8.0 million for the first nine months of 2018 compared with $7.4 million for the first nine months of 2017. The increases in general and administrative expenses for both periods were primarily due to higher personnel costs.

Cash, cash equivalents and marketable securities were $49.6 million at September 30, 2018, compared with $74.9 million at December 31, 2017, and a projected year-end 2018 balance of between $35 million and $40 million. The company believes that current financial resources, together with the anticipated reimbursements for 50% of the costs for the ongoing clinical trials, without including any potential milestone payments under the Novartis collaboration, are sufficient to maintain operations through the end of 2019, as well as to fund initial 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 5773926. 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 clinical trials; the potential for the ENCORE-NF clinical trial to serve as a study to support regulatory approval; 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.

Conatus Pharmaceuticals Inc.
Selected Condensed Financial Information
(In thousands, except per share data)
(Unaudited)

Statements of Operations	**Three Months Ended September 30, 2018**	**2017**	**Nine Months Ended September 30, 2018**	**2017**
Revenues:				
Collaboration revenue	$ 7,666	$ 9,566	$ 26,177	$ 26,572
Operating expenses:				
Research and development	9,664	11,165	32,482	32,309
General and administrative	2,660	2,449	7,967	7,406
Total operating expenses	12,324	13,614	40,449	39,715
Loss from operations	(4,658)	(4,048)	(14,272)	(13,143)
Other income/expense	69	48	168	103
Net loss	$ (4,589)	$ (4,000)	$ (14,104)	$ (13,040)
Net loss per share, basic and diluted	$ (0.15)	$ (0.13)	$ (0.47)	$ (0.46)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	30,190	30,004	30,118	28,104

Balance Sheets	**September 30, 2018**	**December 31, 2017**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 49,620	$ 74,853
Collaboration receivables	4,109	3,367
Prepaid and other current assets	3,170	1,004
Total current assets	56,899	79,224
Property and equipment, net	124	179
Other assets	1,119	2,538

Total assets	$ 58,142	$ 81,941
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and other accrued expenses	$ 11,099	$ 13,970
Current portion of deferred revenue	12,661	14,172
Total current liabilities	23,760	28,142
Deferred revenue, less current portion	3,962	12,519
Convertible note payable	13,718	13,158
Deferred rent	84	126
Stockholders' equity	16,618	27,996
Total liabilities and stockholders' equity	$ 58,142	$ 81,941

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