Conatus Pharmaceuticals Reports 2018 Financial Results and Program Updates

March 8, 2019

SAN DIEGO, March 08, 2019 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced financial results for the fourth quarter and full year ended December 31, 2018, and provided updates on its development programs.

Program Updates
The company is conducting three double-blind, placebo-controlled 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 liver fibrosis or cirrhosis caused by nonalcoholic steatohepatitis (NASH).

- The ENCORE-NF (for NASH Fibrosis) clinical trial, initiated in the first quarter of 2016, has enrolled approximately 330 patients with baseline NASH Clinical Research Network (CRN) fibrosis scores of F1 (up to 20% of enrolled patients), F2, and F3. The primary endpoint is a biopsy-based one point or greater improvement in NASH CRN fibrosis score compared with placebo at week 72, with no worsening of steatohepatitis. 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 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, has enrolled approximately 210 patients with stable decompensated NASH cirrhosis. The primary endpoint is event-free survival, which is a composite of all-cause mortality, new decompensation events, or ≥4 points progression in Model for End-stage Liver Disease (MELD) score. Enrollment was completed in the first quarter of 2019. Top-line results triggered by reaching a prespecified number of events are expected in mid-2019.

- The ENCORE-PH (for Portal Hypertension) clinical trial, initiated in the fourth quarter of 2016, enrolled 263 patients with compensated or early decompensated NASH cirrhosis and 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. Top-line results were reported in December 2018 showing HVPG trends consistently favoring emricasan compared with placebo in the overall population but not meeting the primary endpoint. Post hoc analyses showed clinically meaningful treatment effects for emricasan compared with placebo and a trend toward clinical benefit in the prespecified subpopulation of compensated patients, with the greatest improvement in compensated patients with baseline HVPG ≥16 mmHg. Patients had the option to continue on their assigned doses of treatment or placebo in a double-blind 24-week extension period to evaluate longer term safety, liver function and clinical outcomes. Results following the extension period are expected in mid-2019.

In its internal development program, the company has assembled a proprietary portfolio of orally active molecules that inhibit the NLRP3 inflammasome pathway and the activation of the potent inflammatory cytokine IL-1b. Inhibition of IL-1b is a clinically validated approach to treating inflammatory diseases, with several injectable biologic products using that mechanism of action already on the market. The NLRP3 inflammasome pathway is dependent upon caspase 1, which activates IL-1b. Caspase 1 occupies a uniquely central position in the inflammasome pathway, and the company has leveraged its scientific expertise in caspase research and development to design potent, selective and orally bioavailable inhibitors of caspase 1. Excess IL-1b has been linked to a variety of diseases including rare genetic inflammatory diseases, cancer, liver and other gastrointestinal diseases, and cardiovascular diseases.

The company is announcing today the selection of its first internally developed product candidate, CTS-2090, based on its preclinical profile, including high selectivity for caspase 1, and drug-like properties. CTS-2090 is currently in preclinical development and IND-enabling studies, with an initial clinical trial expected to begin by the first half of 2020. Additional details will be discussed in the conference call and webcast scheduled for 4:30 p.m. ET today (information below).

Financial Results
The net loss for the fourth quarter of 2018 was $3.9 million compared with $4.4 million for the fourth quarter of 2017. The net loss for the full year 2018 was $18.0 million compared with $17.4 million for the full year 2017.

Total revenues were $7.4 million for the fourth quarter of 2018 compared with $8.8 million for the fourth quarter of 2017, and $33.6 million for the full year 2018 compared with $35.4 million for the full year 2017. Total revenues consisted of collaboration revenues related to the Novartis agreement. The decreases in revenues for both periods were primarily due to lower emricasan-related research and development expenses resulting in corresponding lower revenues related to the Novartis agreement, partially offset by the effects of adopting the ASC 606 revenue recognition standard.

Research and development expenses were $8.9 million for the fourth quarter of 2018 compared with $10.9 million for the fourth quarter of 2017. Research and development expenses were $41.4 million for the full year 2018 compared with $43.2 million for the full year 2017. The decreases in both periods were primarily due to lower costs related to the ENCORE clinical trials, as well as lower costs related to emricasan manufacturing

activities, partially offset by higher costs related to new product candidate development.

General and administrative expenses were $2.5 million for the fourth quarter of 2018 compared with $2.3 million for the fourth quarter of 2017. General and administrative expenses were $10.5 million for the full year 2018 compared with $9.7 million for the full year 2017. The increases in general and administrative expenses for both periods were primarily due to higher personnel costs and recognition of deferred collaboration costs due to adoption of the new revenue recognition standard.

In December 2018, the company, at its option, converted the outstanding principal plus accrued and unpaid interest of the Novartis note into shares of the company's common stock. Cash, cash equivalents and marketable securities were $40.7 million at December 31, 2018, compared with $74.9 million at December 31, 2017, and a projected year-end 2019 balance, without including any potential milestone payments under the Novartis collaboration, of between $10 million and $15 million.

Conference Call and Audio Webcast
Conatus will host a conference call and audio webcast at 4:30 p.m. ET 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 3249458. 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 chronic diseases with significant unmet need. In collaboration with Novartis, Conatus is developing its lead in-licensed compound, emricasan, for the treatment of patients with NASH-driven chronic liver diseases. Conatus is independently developing its lead internally developed compound, CTS-2090, for the treatment of patients with chronic diseases involving inflammasome pathways. 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 expectation and timeline to begin an initial clinical trial of CTS-2090; the projected year-end cash balance; emricasan's potential as a treatment for NASH-driven chronic liver diseases; and CTS-2090's potential as a treatment for chronic diseases involving inflammasome pathways. 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 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 supplies of CTS-2090; potential adverse side effects or other safety risks associated with emricasan or CTS-2090 that could delay or preclude its approval; results of future clinical trials of emricasan or CTS-2090; Conatus' ability to obtain additional financing in order to co-commercialize emricasan or develop CTS-2090 or 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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Collaboration revenue	$ 7,409	$ 8,805	$ 33,586	$ 35,377
Operating expenses:				
Research and development	8,886	10,911	41,368	43,220
General and administrative	2,528	2,301	10,495	9,707
Total operating expenses	11,414	13,212	51,863	52,927
Loss from operations	(4,005)	(4,407)	(18,277)	(17,550)
Other income/expense	99	51	267	154
Net loss	$ (3,906)	$ (4,356)	$ (18,010)	$ (17,396)
Net loss per share, basic and diluted	$ (0.13)	$ (0.15)	$ (0.59)	$ (0.61)
Weighted average shares outstanding used in computing				

net loss per share, basic and diluted	31,118	30,018	30,370	28,587

Balance Sheets	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 40,692	$ 74,853
Collaboration receivables	3,677	3,367
Prepaid and other current assets	3,057	1,004
Total current assets	47,426	79,224
Property and equipment, net	154	179
Other assets	1,223	2,538
Total assets	$ 48,803	$ 81,941
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and other accrued expenses	$ 8,446	$ 13,970
Current portion of deferred revenue	10,075	14,172
Total current liabilities	18,521	28,142
Deferred revenue, less current portion	2,815	12,519
Convertible note payable	-	13,158
Deferred rent	68	126
Stockholders' equity	27,399	27,996
Total liabilities and stockholders' equity	$ 48,803	$ 81,941

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