

Cynapsus Therapeutics Reports Financial Results for the Fourth Quarter and Year Ended 2015

Focus on Advancement of Pivotal Phase 3 Clinical Program in 2016

TORONTO, March 09, 2016 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH), a specialty central nervous system pharmaceutical company developing and preparing to commercialize a fast-acting, easy-to-use, sublingual thin film for the on-demand management of debilitating OFF episodes associated with Parkinson's disease ("PD"), today reported financial results for the fourth quarter and year ended December 31, 2015 and provided an update on its product candidate and corporate activities. Unless specified otherwise, all amounts are in Canadian dollars.

"Following the successful completion of an \$89.3 million (USD\$72.5 million) initial public offering in the United States and listing on NASDAQ in June, we have been focused on the commencement and management of our pivotal Phase 3 clinical program for APL-130277," stated Anthony Giovinazzo, President and CEO. "2016 is a critical year for Cynapsus as we also intend to file our NDA with the U.S. FDA near the end of 2016 or in early 2017. We will also be working with European regulatory authorities to map out our clinical strategy and commence clinical activities in Europe."

Upcoming Milestones

United States

- **CTH-300 Phase 3 Efficacy Study:** Top-line data expected in the second or third quarter of 2016.
- **CTH-301 Phase 3 Safety Study:** Top-line data expected in the fourth quarter of 2016 or the first quarter of 2017.
- **CTH-201 Phase 2 Thorough QT Study:** Subject to FDA review and agreement, if required, this study is planned to begin in the second half of 2016. If commenced, the trial is expected to be completed in the fourth quarter of 2016 or the first quarter of 2017.
- **New Drug Application(NDA)submission:** An NDA is expected to be submitted near the end of 2016 or in early 2017.

European Union

- **European Medicines Agency (EMA) Meeting:** A pre-submission meeting is expected to occur with the EMA in the second quarter of 2016.
- **CTH-302 European Registration Study:** An active comparator study is expected to commence in the second half of 2016.

Recent Business Highlights

- **CTH-200 Bioavailability and Pharmacokinetic Study.** In December 2015, Cynapsus announced the successful completion of bridging study comparing product candidate APL-130277 to subcutaneous apomorphine.
- **XXI World Congress on Parkinson's Disease (IAPRD):** In December 2015, Cynapsus attended the IAPRD and presented in five poster presentations updated clinical data from the Phase 2 trial of APL-130277. Results showed that APL-130277 significantly improved PD symptoms (as measured by MDS-UPDRS Part III), rapidly turning patients from the OFF to ON state, and was generally safe and well tolerated.
- **MJFF Collaboration on Wearable Device:** In January 2016, Cynapsus and The Michael J. Fox Foundation for Parkinson's Research announced that they will work together to incorporate wearable device technology and "big data" approaches into Cynapsus' pivotal Phase 3 clinical study of APL-130277. This is a pilot effort to understand how clinical studies can harness data science approaches to objectively measure disease progression with the goal of speeding progress toward breakthroughs in drug development. The project builds on MJFF's ongoing data science partnership with Intel Corporation, launched in August 2014, to develop platforms for the storage of large volumes of patient-generated data and algorithms to glean insights from this data.

Full Year 2015 Financial Results

- **Cash and Investments.** Cash as of December 31, 2015 totaled \$104.9 million as compared to \$17.5 million as of December 31, 2014. Cash used in operating activities for the 12 months ended December 31, 2015 was \$32.2 million versus \$10.0 million for the 12 months ended December 31, 2014. Cynapsus expects its cash as of December 31, 2015 to be sufficient to fund the Company into 2017.
- **R&D Expense.** Research and development expenses were \$27.4 million for the year ended December 31, 2015, compared to \$5.7 million for the year ended December 31, 2014, an increase of \$21.7 million. The increase in research and development expenses was primarily due to higher headcount and increases in consulting fees, clinical research, packaging development, patent protection, analytics, scientific communications and educational initiatives, and scale-up CMC work for APL-130277.
- **OG&A Expense.** Operations, general and administrative expenses were \$11.4 million for the year ended December 31, 2015, compared to \$5.8 million for the year ended December 31, 2014, an increase of \$5.6 million. The increase in general and administrative expenses was primarily related to increases in investor and public relations activities, professional and consulting fees, and pre-approval commercialization activities.
- **Net Loss.** For the year ended December 31, 2015, net loss attributed to common shareholders was \$27.5 million, or \$2.97 per share, as compared to a net loss of \$10.8 million, or \$2.56 per share, for the year ended December 31, 2014.
- **Reported common shares outstanding** as of December 31, 2015 were 12,278,133 as compared to December 31, 2014 common shares of 5,020,869, as adjusted for the 16:1 share consolidation completed on May 15, 2015.

Cynapsus Therapeutics, Inc.
Consolidated Statements of Loss and Comprehensive Loss
(unaudited)
(in thousands, except per share data)
(in Canadian dollars)

	Three months ended December 31,		Year ended December 31,	
	2015	2014	2015	2014
Expenses				
Research and development	\$ 8,639	\$ 3,094	\$ 27,402	\$ 5,703
Operating, general and administrative	3,675	2,365	11,376	5,761
Acquisition milestone share-based payment	-	-	1,500	-
Loss on Impairment of intangible assets	-	94	-	94
Unrealized foreign exchange gain	(3,782)	(437)	(12,789)	(691)
Other interest income and related charges	(2)	(16)	(19)	(48)
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Loss and comprehensive loss	<u>\$ 8,530</u>	<u>\$ 5,100</u>	<u>\$ 27,470</u>	<u>\$ 10,819</u>
Loss per share – basic and diluted	<u>\$ 0.70</u>	<u>\$ 1.03</u>	<u>\$ 2.97</u>	<u>\$ 2.56</u>
Weighted Average number of shares outstanding - basic and diluted	12,160	4,966	9,246	4,232

Cynapsus Therapeutics, Inc.
Consolidated Statements of Financial Position
(unaudited)
(in thousands)
(in Canadian dollars)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash	\$ 104,911	\$ 17,448
Prepaid expenses and other current assets	870	270
Total current assets	<u>105,781</u>	<u>17,718</u>
Property and equipment, net	567	258
Intangible assets, net	527	575
Total assets	<u>\$ 106,875</u>	<u>\$ 18,551</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	<u>5,240</u>	<u>3,081</u>
Total liabilities	5,240	3,081

Shareholders' equity:		
Share capital	142,581	31,741
Warrants	11,486	13,452
Share-based payments	7,548	2,788
Deficit	(59,981)	(32,511)
Total shareholders' equity	<u>101,634</u>	<u>15,470</u>
Total liabilities and shareholders' equity	<u>\$ 106,875</u>	<u>\$ 18,551</u>

About Cynapsus

Cynapsus is a specialty central nervous system pharmaceutical company developing and preparing to commercialize a fast-acting, easy-to-use, sublingual thin film for the on-demand management of debilitating OFF episodes associated with PD. The Company has successfully completed a Phase 2 clinical trial for its product candidate, APL-130277, a sublingual formulation of apomorphine hydrochloride, or apomorphine. Apomorphine is the only molecule approved for acute, intermittent treatment of OFF episodes for advanced PD patients, but is currently only approved as a subcutaneous injection in the United States. APL-130277 is a "turning ON" medication designed to rapidly, safely and reliably convert a PD patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine. It is designed to convert all types of OFF episodes, including morning OFF episodes, often considered the most difficult to treat. Cynapsus has initiated its Phase 3 clinical program for APL-130277, relying on the abbreviated Section 505(b)(2) regulatory pathway in the United States, and the Company intends to submit an NDA near the end of 2016 or in early 2017.

Forward-Looking Statements

This announcement contains "forward-looking statements" within the meaning of applicable securities laws, including, without limitation, the Company's expectation for filing an NDA near the end of 2016 or in early 2017; expectations regarding the Company's clinical and regulatory activities, including without limitation, the anticipated timing and completion of clinical studies; and expectations regarding the sufficiency of the Company's cash. These forward-looking statements include information about possible or assumed future results of the Company's business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. These forward-looking statements are based on the Company's current expectations and beliefs and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ from those anticipated in such forward-looking statements as a result of risks and uncertainties, and include, but are not limited to, those factors identified under the caption "Risk Factors" in the Company's Form 10-K filed with the United States Securities and Exchange Commission (the "SEC") on March 9, 2016 and its other filings and reports in the United States with the SEC available on the SEC's web site at www.sec.gov, and in Canada with the various Canadian securities regulators, which are available online at www.sedar.com. Furthermore, unless otherwise

stated, the forward-looking statements contained in this press release are made as of the date of this press release, and the Company has no intention and undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, changes or otherwise, except as required by law.

Neither the NASDAQ nor the TSX has approved or disapproved of the contents of this press release.

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