May 11, 2016

Cynapsus Therapeutics Reports First Quarter 2016 Financial Results and Recent Developments

Focus on Advancement of Pivotal Phase 3 Clinical Program in 2016

TORONTO, May 11, 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 quarter ended March 31, 2016 and provided an update on its product candidate and corporate activities. Unless specified otherwise, all amounts are in United States ("U.S.") dollars.

"2016 is a critical year for Cynapsus as we continue to focus on the management and conclusion of our pivotal Phase 3 clinical program for APL-130277," stated Anthony Giovinazzo, President and CEO. "We expect to announce top-line data from the CTH-300 Phase 3 efficacy trial in the second or third quarter of this year and we intend to file our NDA with the U.S. FDA near the end of 2016 or in early 2017. We are also refining our U.S. commercialization strategy and engaging with European regulatory authorities to finalize our clinical development strategy in Europe."

Change in Functional and Reporting Currency

Effective January 1, 2016, the functional and reporting currency of Cynapsus and our subsidiary changed to the U.S. dollar in order to better reflect our underlying performance. We determined that our expenditures and cash flows are now principally denominated in U.S. dollars, and are expected to remain principally denominated in U.S. dollars in the future. Accordingly, our unaudited condensed interim consolidated financial statements included in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 are expressed in U.S. dollars. The Canadian dollar had previously been the functional and reporting currency of our business and our consolidated financial statements for periods through December 31, 2015 were previously expressed in Canadian dollars.

Upcoming Milestones and Events

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

- **2nd Congress of the European Academy of Neurology Meeting:** Three posters with clinical data will be presented on May 30, 2016, in Copenhagen, Denmark.
- **20th International Congress of Parkinson's Disease and Movement Disorders Meeting:** Seven posters with clinical data will be presented on June 21, 2016, in Berlin, Germany.
- **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

- **MJFF Collaboration on Wearable Device:** On January 7, 2016, Cynapsus and The Michael J. Fox Foundation for Parkinson's Research ("MJFF") announced that they are working 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.
- **MonoSol Rx License Agreement.** On April 1, 2016, subsequent to the end of the first quarter, Cynapsus and MonoSol Rx, LLC ("MonoSol Rx") entered into a license agreement pursuant to which MonoSol Rx granted Cynapsus an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications covering all oral films containing apomorphine for the treatment of OFF episodes in PD patients, as well as two other fields. Under the license agreement, MonoSol Rx has received and will receive, as applicable, up front and contingent milestone payments and mid-single-digit royalty payments on net sales of APL-130277.
- **American Academy of Neurology Annual Meeting (AAN):** In April 2016, Cynapsus attended the AAN and presented in three 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), was generally safe and well tolerated, and rapidly turning patients from the OFF to ON state, regardless of varying disease severity.

Q1 2016 Financial Results

- **Cash.** Cash as of March 31, 2016 totaled $68.6 million as compared to $75.8 million as of December 31, 2015. Cash used in operating activities for the three months ended March 31, 2016 was $7.3 million versus $4.6 million for the three months ended March 31, 2015. Cynapsus expects its cash as of March 31, 2016 to be sufficient to fund the Company into 2017.
- **R&D Expense.** Research and development expenses were $5.2 million for the three months ended March 31, 2016, compared to $2.4 million for the three months ended March 31, 2015, an increase of $2.8 million. The increase in research and development expenses was primarily due to increased activity associated with the APL-130277 program. Expenditures increased as a result of increases in consulting, clinical research, packaging development, patent protection, analytics, scientific communications and educational initiatives, and scale-up chemistry, manufacturing and controls work for APL-130277.
- **OG&A Expense.** Operations, general and administrative expenses were $3.1 million for the three months ended March 31, 2016, compared to $1.5 million for the three months ended March 31, 2015, an increase of $1.6 million. The increase in OG&A expenses was primarily related to increases in investor and public relations activities, professional and consulting fees, activities in preparing for commercialization, and travel costs.
- **Net Loss.** For the three months ended March 31, 2016, net loss was $8.4 million, or $0.68 per share, as compared to a net loss of $4.1 million, or $0.78 per share, for the three months ended March 31, 2015.
- **Reported common shares outstanding** as of March 31, 2016 were 12,309,366 common shares as compared to 12,278,133 common shares as of December 31, 2015.

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

	Three months ended March 31,	
	2016	**2015**
Expenses		
Research and development	$ 5,219	$ 2,353
Operating, general and administrative	3,141	1,504
Acquisition milestone share-based payment	-	1,209
Unrealized foreign exchange gain	(4)	(953)
Other interest income and related charges	-	(7)
Loss for the period	8,356	4,106
Other comprehensive loss		
Foreign currency translation adjustment	-	1,303
Loss and comprehensive loss for the period	$ 8,356	$ 5,409
Loss per share – basic and diluted	$ 0.68	$ 0.78
Weighted Average number of shares outstanding - basic and diluted	12,291,040	5,233,766

Cynapsus Therapeutics Inc.
Consolidated Statements of Financial Position
(unaudited)
(in thousands)
(in U.S. dollars)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash	$ 68,622	$ 75,803
Prepaid expenses and other current assets	500	629
Total current assets	69,122	76,432
Property, plant and equipment	470	409
Intangible assets	372	380
Total assets	$ 69,964	$ 77,221
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	3,659	3,799
Total liabilities	3,659	3,799
Shareholders' equity:		
Share capital	119,891	119,565
Warrants	10,523	10,623
Share-based payments	7,346	6,333
Deficit	(60,789)	(52,433)
Accumulated other comprehensive loss	(10,666)	(10,666)
Total shareholders' equity	66,305	73,422
Total liabilities and shareholders' equity	$ 69,964	$ 77,221

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. For additional company information, please visit our website at www.cynapsus.ca. For more information about the Phase 3 studies, including enrollment criteria, please visit the following website: http://cth300and301trials.cynapsus.ca/

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, as amended by Amendment No. 1 to Form 10-K/A filed with the SEC on March 18, 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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