March 24, 2016

Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2015 Financial Results

-- Conference Call Scheduled March 24, 2016 at 4:30 p.m. EDT --

BERKELEY HEIGHTS, N.J., March 24, 2016 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ:CYCC) (NASDAQ:CYCCP); "Cyclacel" or the "Company"), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, today reported its financial results and business highlights for the fourth quarter and full year ended December 31, 2015.

The Company's net loss applicable to common shareholders for the fourth quarter ended December 31, 2015 was $3.4 million, or $0.10 per basic and diluted share, compared to net loss applicable to common shareholders of $4.8 million, or $0.21 per basic and diluted share for the fourth quarter ended December 31, 2014. As of December 31, 2015, cash and cash equivalents totaled $20.4 million.

"In SEAMLESS, our Phase 3 pivotal study in acute myeloid leukemia (AML), approximately 4% of required events remain to be observed before mature data become available, expected around the first half of 2016 or approximately 18 months after completion of enrollment," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The primary endpoint of the study is overall survival. After top-line data readout, the mature data will be evaluated for submissibility to regulatory authorities. In parallel, we have been progressing our CDK inhibitor programs. We have reported encouraging interim data from the ongoing Phase 1/2 combination trial of seliciclib and sapacitabine in solid tumor patients, including durable partial responses and stable disease in patients with BRCA positive breast, ovarian and pancreatic cancers. In particular, two ongoing patients with BRCA positive breast cancer have achieved over 1 and 4.5 years of treatment, respectively. In light of these data and investigator interest, we have started an extension cohort in a BRCA-enriched population of breast cancer patients. Last fall we initiated a first-in-human, Phase 1 study of CYC065, our second-generation CDK2/9 inhibitor, in patients with solid tumors and lymphomas following extensive preclinical data in the literature suggesting broad activity of CYC065 in both liquid and solid tumor models. The Cyclacel team continues to pursue the vision of our founders, as appreciation of the importance of CDK inhibitors is increasing among the medical community."

Recent Business Highlights

SEAMLESS Study

- Continued follow up of patients enrolled in SEAMLESS, a Phase 3 study of orally-administered sapacitabine alternating with intravenous decitabine compared to decitabine alone, as first-line treatment in patients aged 70 years or older with AML.
- Approximately 4% of the pre-specified events remain to be observed until mature data become available for analysis.
- Submitted to the European Medicines Agency (EMA) a Paediatric Investigation Plan application for sapacitabine.

Cyclin Dependent Kinase 2/9 (CDK2/9) Inhibitor Programs

- Dosed first patients in an extension cohort of the Phase 1/2 combination study of seliciclib and sapacitabine in a population of BRCA-positive breast cancer patients. In the first part of the study, several patients with BRCA positive breast, ovarian and pancreatic cancers achieved durable partial responses and stable disease.
- Continued patient recruitment in the first-in-human trial of CYC065, a second-generation CDK2/9 inhibitor, to evaluate the safety, tolerability and pharmacokinetic profile of CYC065 in patients with solid tumors and lymphomas.
- Presented preclinical data on the molecular rationale and therapeutic potential in both hematologic and solid tumors of CYC065 at several medical conferences during the fourth quarter, including the Society of Hematologic Oncology (SOHO) 2015 Annual Meeting, the AACR-NCI-EORTC International Conference, the San Antonio Breast Cancer Symposium (SABCS) and the Neuroblastoma UK Annual Meeting.

Cyclacel's Key Milestones for 2016

Sapacitabine in SEAMLESS

- Continue follow-up of patients until the requisite number of events occur, which is anticipated around the end of the first half of 2016.
- Report top-line results.
- Determine submissibility to regulatory authorities for marketing approval following analysis of the mature data set.
- Progress a Paediatric Investigation Plan for sapacitabine with the EMA.

Sapacitabine in myelodysplastic syndromes (MDS):

- Initiate a Phase 1/2 trial of sapacitabine in combination with other agents to determine safety and tolerability.
- Plan a Phase 2 randomized controlled trial (RCT) of sapacitabine in combination with other agents following review of all relevant clinical data with mature follow-up.

CDK Inhibitor Programs

- Progress the seliciclib and sapacitabine Phase 1/2 study in an extension cohort of breast cancer patients enriched for BRCA mutations.
- Report updated Phase 1 seliciclib and sapacitabine combination data in approximately 60 patients with advanced solid tumors.
- Report top-line results of the CYC065 Phase 1 trial in patients with solid tumors and lymphomas.
- Present additional preclinical data on CYC065 at the upcoming AACR conference in April.
- Report data when available from on-going investigator sponsored trials (ISTs) evaluating seliciclib in patients with Cushing's disease and rheumatoid arthritis. Seliciclib is also being evaluated in cystic fibrosis through a license and supply agreement with ManRos Therapeutics.

Fourth Quarter 2015 Financial Results

Grant Revenue

Revenue for the three months ended December 31, 2015 was $0.4 million compared to $0.2 million for the same period of the previous year. The revenue is related to previously awarded grants from the UK government being recognized over the period to progress CYC065 to IND and complete IND-directed preclinical development of CYC140, a novel, orally available, Polo-Like Kinase 1 (PLK 1) inhibitor.

Research and Development Expenses

Research and development expenses decreased to $2.6 million for the three months ended December 31, 2015 compared to $4.4 million for the same period in the previous year. The decrease was primarily due to reduced study and clinical supply costs associated with the SEAMLESS Phase 3 trial, which completed enrollment in December 2014, offset by increased expenditures primarily related to the first-in-human, Phase 1 study of CYC065 and grant supported research and development.

General and Administrative Expenses

General and administrative expenses for the three months ended December 31, 2015 increased to $1.7 million, compared to $1.6 million for the same period in 2014.

Based on current plans, the Company estimates that it has capital resources to reach beyond the final analysis of SEAMLESS and continue existing programs through the end of 2017.

Conference call and Webcast Information

Cyclacel will conduct a conference call on March 24, 2016 at 4:30 p.m. EDT to review the fourth quarter and full year 2015 results. Conference call and webcast details are as follows:

Conference call information:
US/Canada call: (877) 493-9121/ international call: (973) 582-2750
US/Canada archive: (800) 585-8367 / international archive: (404) 537-3406
Code for live and archived conference call is 72403768

For the live and archived webcast, please visit the Corporate Presentations and Events page on the Cyclacel website at www.cyclacel.com. The webcast will be archived for 90 days and the audio replay for 7 days.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. Sapacitabine, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial, which has completed enrollment and is being conducted under an SPA with the U.S. Food and Drug Administration (FDA) as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other indications, including myelodysplastic syndromes (MDS). Cyclacel's pipeline includes an oral regimen of seliciclib in combination with sapacitabine in a Phase 1 study of patients with solid tumors, including BRCA positive cancers, and CYC065, a novel CDK2/9 inhibitor, in a Phase 1 study of patients with solid tumors and lymphomas with potential utility in

both hematological malignancies and solid tumors. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a development pipeline of novel drug candidates. Please visit www.cyclacel.com for more information.

Forward-looking Statements

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and intended utilization of Cyclacel's product candidates, the conduct and results of future clinical trials, plans regarding regulatory filings, future research and clinical trials and plans regarding partnering activities. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, trials may have difficulty enrolling, Cyclacel may not obtain approval to market its product candidates, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with reliance on collaborative partners for further clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties the Company faces, please refer to our most recent Annual Report on Form 10-K and other periodic and other filings we file with the Securities and Exchange Commission and are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In $000s, except share and per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2014	2015	2014	2015
	(Unaudited)			(Unaudited)
Revenues:				
Grant revenue	$ 247	$ 424	$ 1,734	$ 1,694
Collaboration and research and development revenue	—	—	—	250
Total revenues	247	424	1,734	1,944
Operating expenses:				
Research and development	4,416	2,559	18,277	12,382
General and administrative	1,613	1,726	5,894	5,732
Total operating expenses	6,029	4,285	24,171	18,114
Operating loss	(5,782)	(3,861)	(22,437)	(16,170)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(227)	—	(342)	(51)
Change in valuation of liabilities measured at fair value	—	—	20	—
Foreign exchange gains	13	(14)	(10)	(368)
Interest income	1	4	6	9
Other income, net	88	(1)	114	94
Total other income (expense), net	(125)	(11)	(212)	(316)
Loss from continuing operations before taxes	(5,907)	(3,872)	(22,649)	(16,486)
Income tax benefit	1,108	498	3,243	2,144
Net loss from continuing operations	(4,799)	(3,374)	(19,406)	(14,342)
Discontinued operations:				
Income from discontinued operations	—	—	29	—
Income tax on discontinued operations	—	—	(10)	—
Net income from discontinued operations	—	—	19	—
Net loss	(4,799)	(3,374)	(19,387)	(14,342)
Deemed dividend on convertible exchangeable preferred shares	—	—	—	—
Dividend on convertible exchangeable preferred shares	(50)	(51)	(200)	(201)

Net loss applicable to common shareholders	$ (4,849)	$ (3,425)	$ (19,587)	$ (14,543)
Net loss per share, continuing operations — basic and diluted	$ (0.21)	$ (0.10)	$ (0.89)	$ (0.45)
Net (loss) income per share, discontinued operations — basic and diluted	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Net loss per share — basic and diluted	$ (0.21)	$ (0.10)	$ (0.89)	$ (0.45)
Weighted average common shares outstanding	22,986,528	34,976,268	21,955,381	32,557,146

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

(In $000s, except share, per share, and liquidation preference amounts)

	December 31,	
	2014	**2015**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,189	$ 20,440
Prepaid expenses and other current assets	4,640	4,050
Current assets of discontinued operations	171	76
Total current assets	29,000	24,566
Property, plant and equipment (net)	387	198
Total assets	$ 29,387	$ 24,764
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,792	$ 1,940
Accrued and other current liabilities	4,626	3,738
Current liabilities of discontinued operations	75	75
Total current liabilities	7,493	5,753
Other liabilities	206	176
Total liabilities	7,699	5,929
Stockholders' equity	21,688	18,835
Total liabilities and stockholders' equity	$ 29,387	$ 24,764

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