March 24, 2015

Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2014 Financial Results

Conference Call Scheduled March 24, 2015 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., March 24, 2015 (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, 2014.

The Company's net loss applicable to common shareholders for the fourth quarter ended December 31, 2014 was $4.8 million, or $0.21 per basic and diluted share, compared to net loss applicable to common shareholders of $3.6 million, or $0.20 per basic and diluted share for the fourth quarter ended December 31, 2013. As of December 31, 2014, cash and cash equivalents totaled $24.2 million. Following the Company's public offering of common stock in March, 2015, proforma cash and cash equivalents is approximately $34.6 million.

"2014 was a defining year for Cyclacel as we completed enrollment of our SEAMLESS study, one of the largest Phase 3 trials as front-line treatment of elderly patients with acute myeloid leukemia (AML), and also completed Investigational New Drug (IND)-directed development of CYC065, a cyclin dependent kinase (CDK) inhibitor, the area of research Cyclacel was founded to pursue," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Although the SEAMLESS independent Data Safety Monitoring Board (DSMB) determined in an interim analysis of approximately half of the required events that the futility boundary had been crossed, they saw no reason for the trial to be discontinued and recommended recruited patients should stay on study. We will follow-up patients until the prespecified number of events has been observed, which we expect to occur between the second half of 2015 and the first half of 2016. Subject to the outcome of SEAMLESS, we are preparing for potential regulatory submissions.

CYC065, our novel, second generation CDK2/9 inhibitor, has demonstrated therapeutic potential to treat acute leukemias and in particular those with rearrangements in the mixed lineage leukemia (MLL) gene, as well as solid tumors, including certain subtypes of breast cancer. We believe that the pharmaceutical industry has increased interest in CDK inhibitors following the recent first-in-class approval of palbociclib for metastatic breast cancer. CYC065 targets with greater potency and improved properties the same CDK enzymes as our first generation CDK inhibitor, seliciclib, which demonstrated signals of anticancer activity. We expect to file an IND application for CYC065 during the first half of 2015 and begin Phase 1 trials shortly thereafter.

Including net proceeds from a recent financing, we have sufficient cash resources to pursue both our sapacitabine and CYC065 programs for at least the next two years."

Business Highlights

Sapacitabine

- Completed enrollment in the SEAMLESS, pivotal, Phase 3 study for front-line treatment in patients aged 70 years or older with AML, in approximately 110 U.S. and European sites, one of the largest studies in this patient population.
- The SEAMLESS Data Safety Monitoring Board (DSMB) conducted the final planned safety review of 470 randomized patients with at least 60 days of follow-up and found no safety concerns.
- The DSMB determined that the futility boundary had been crossed after 247 events and determined that it would be unlikely for the study to reach statistically significant improvement in survival; however, the DSMB saw no reasons why patients should discontinue treatment on their assigned arm and recommended that recruited patients stay on treatment.
- Approximately 28% of the prespecified events remain to be observed until mature data becomes available for analysis.
- Completed enrollment of patients in an additional part of the ongoing MDS Phase 2 study evaluating better dosing regimens.
- Disclosed proposed myelodysplastic syndromes (MDS) study design for a Phase 2b randomized controlled trial (RCT) in patients aged 60 years or older with intermediate-2 or high-risk MDS who have failed prior hypomethylating agent therapy.
- Conducted feasibility study and determined that the proposed MDS Phase 2b RCT design is feasible.

CYC065 (2nd generation CDK inhibitor)

- Completed IND-directed development. Preparation for IND submission to the U.S. Food and Drug Administration (FDA).
- Presented preclinical data at the 2014 Society of Hematologic Oncology (SOHO) meeting demonstrating therapeutic potential of CYC065 to treat acute leukemias, and in particular AML and acute lymphocytic leukemia (ALL) with rearrangements in the MLL gene.

Other

- Appointed Samuel L. Barker, Ph.D., to the Board of Directors.

Cyclacel's Key Milestones for 2015-16

Sapacitabine

- Continue to follow-up enrolled patients in SEAMLESS until the prespecified number of events is observed, which is expected to occur between the second half of 2015 and the first half of 2016.
- Submit a Pediatric Investigation Plan (PIP) to the European Medicines Agency (EMA).
- Continue follow-up of patients in an additional part of the ongoing Phase 2 MDS study evaluating better dosing regimens.
- Make a decision on Phase 2b RCT in MDS following review of all relevant clinical data with mature follow-up.
- Report updated data from the Phase 1 study of sapacitabine in combination with seliciclib in solid tumor patients, in particular those carrying gBRCA mutations.

CYC065 (2nd generation CDK inhibitor)

- Submit IND to the FDA during the first half of 2015.
- Multiple presentations at the American Association for Cancer Research (AACR) 2015 annual meeting.
- Initiate a Phase 1 clinical trial in patients with advanced solid tumors, subject to IND acceptance.

Seliciclib (1st generation CDK inhibitor)

- Support academic collaborators in investigator sponsored trials (IST) of seliciclib in patients with Cushing's disease and rheumatoid arthritis who have failed prior treatments.

Fourth Quarter 2014 Financial Results

Grant Revenue

Revenue for the three months ended December 31, 2014 was $0.2 million compared to $0.3 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, a CDK inhibitor, to IND and to 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 increased to $4.4 million for the three months ended December 31, 2014 compared to $2.5 million for the same period in the previous year. The increase was primarily due to increased study and product costs associated with the expansion of the SEAMLESS Phase 3 trial into Europe as well as increased expenditures related to grant funded research and development.

General and Administrative Expenses

General and administrative expenses for the three months ended December 31, 2014 decreased to $1.6 million compared to $1.8 million for the same period in 2013. The decrease was primarily due to lower legal and professional fees during the three months ended December 31, 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 2017.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on March 24, 2015 at 4:30 p.m. EDT to review the fourth quarter and full year 2014

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 8143261

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 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 Homologous Recombination (HR) repair-deficient breast, ovarian and pancreatic cancers, including gBRCA positive tumors, and CYC065, a novel CDK 2/9 inhibitor, 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,	
	2013	2014	2013	2014
	(Unaudited)			(Unaudited)
Revenues:				
Grant revenue	$ 299	$ 247	$ 1,084	$ 1,734
Total revenues	299	247	1,084	1,734
Operating expenses:				
Research and development	2,491	4,416	11,277	18,277
General and administrative	1,782	1,613	7,781	5,894
Total operating expenses	4,273	6,029	19,058	24,171

Operating loss	(3,974)	(5,782)	(17,974)	(22,437)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(98)	(227)	(98)	(342)
Change in valuation of Economic Rights	—	—	570	—
Change in valuation of liabilities measured at fair value	—	—	—	20
Foreign exchange gains	18	13	62	(10)
Interest income	1	1	13	6
Other income, net	27	88	5,547	114
Total other income (expense), net	(52)	(125)	6,094	(212)
Loss from continuing operations before taxes	(4,026)	(5,907)	(11,880)	(22,649)
Income tax benefit	452	1,108	1,670	3,243
Net loss from continuing operations	(3,574)	(4,799)	(10,210)	(19,406)
Discontinued operations:				
Income from discontinued operations	21	—	91	29
Income tax on discontinued operations	(6)	—	(34)	(10)
Net income from discontinued operations	15	—	57	19
Net loss	(3,559)	(4,799)	(10,153)	(19,387)
Deemed dividend on convertible exchangeable preferred shares	—	—	(9,027)	—
Dividend on convertible exchangeable preferred shares	(50)	(50)	(298)	(200)
Net loss applicable to common shareholders	$ (3,609)	$ (4,849)	$ (19,478)	$ (19,587)
Net loss per share, continuing operations — basic and diluted	$ (0.20)	$ (0.21)	$ (1.29)	$ (0.89)
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	$ (0.20)	$ (0.21)	$ (1.28)	$ (0.89)
Weighted average common shares outstanding	17,788,568	22,986,528	15,158,225	21,955,381

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2013	**2014**
ASSETS		**(Unaudited)**
Current assets:		
Cash and cash equivalents	$ 31,146	$ 24,189
Prepaid expenses and other current assets	3,388	4,640
Current assets of discontinued operations	639	171
Total current assets	35,173	29,000
Property, plant and equipment (net)	275	387
Long-term assets of discontinued operations	72	—
Total assets	$ 35,520	$ 29,387
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,545	$ 2,792
Accrued and other current liabilities	4,431	4,626
Other liabilities measured at fair value	20	—
Current liabilities of discontinued operations	260	75
Total current liabilities	7,256	7,493
Other liabilities	241	206

Total liabilities	7,497	7,699
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2013 and 2014; 335,273 shares issued and outstanding at December 31, 2013 and 2014. Aggregate preference in liquidation of $3,989,749 at December 31, 2013 and 2014.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2013 and 2014; 19,369,332 and 23,199,469 shares issued and outstanding at December 31, 2013 and 2014, respectively.	19	23
Additional paid-in capital	317,543	330,962
Accumulated other comprehensive income (loss)	(109)	(480)
Deficit accumulated during the development stage	(289,430)	(308,817)
Total stockholders' equity	28,023	21,688
Total liabilities and stockholders' equity	$ 35,520	$ 29,387

CONTACT: Contacts for Cyclacel Pharmaceuticals, Inc.

Company:

Paul McBarron,

(908) 517-7330,

pmcbarron@cyclacel.com

Investor Relations:

Russo Partners LLC,

Robert Flamm,

(212) 845-4226,

robert.flamm@russopartnersllc.com