November 11, 2014

Cyclacel Pharmaceuticals Reports Third Quarter 2014 Financial Results

Conference Call Scheduled November 11, 2014 at 4:30 p.m. EST

BERKELEY HEIGHTS, N.J., Nov. 11, 2014 (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 third quarter ended September 30, 2014.

The Company's net loss applicable to common shareholders for the third quarter ended September 30, 2014 was $5.0 million, or $0.22 per basic and diluted share, compared to net loss applicable to common shareholders of $5.7 million, or $0.32 per basic and diluted share for the third quarter ended September 30, 2013. As of September 30, 2014, cash and cash equivalents totaled $26.7 million.

"We are pleased to report that enrollment in our SEAMLESS, registration-directed, Phase 3 study has reached approximately 90%," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "As we approach completion of enrollment, we are looking forward to three key SEAMLESS milestones that are expected to occur around the end of 2014 or early 2015. These are the Data Safety Monitoring Board's (DSMB) interim analysis for futility, the DSMB's review of data from 400 patients enrolled and completion of enrollment. As we approach these milestones, we expect that our capital resources are sufficient to fund operations beyond announcement of SEAMLESS top-line data during the second half of 2015 or first half of 2016. In parallel to SEAMLESS, we are preparing for the start of the MDS randomized trial next year, continuing clinical investigation of our sapacitabine-seliciclib combination regimen in patients with solid tumors and filing an IND for our novel CYC065 Cyclin Dependent Kinase (CDK) inhibitor."

Business Highlights

Sapacitabine in SEAMLESS, pivotal, Phase 3 study for first-line treatment in elderly patients with acute myeloid leukemia (AML):

- Study enrollment reached approximately 90% of the required patients with the majority from US sites
- Over 100 sites open in the US and Europe
- The study's DSMB conducted the fourth planned safety review of 317 randomized patients with at least 60 days of follow-up and recommended that the study should continue as planned without modifications

Sapacitabine in Phase 2b randomized, controlled trial (RCT) for patients with myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents

- Disclosed proposed study design for eligible patients aged 60 years or older with intermediate-2 or high-risk MDS who have failed prior hypomethylating agent therapy
- Approximately 250 patients will be enrolled in a Phase 2b RCT with a lead-in stage
- Feasibility assessment is in progress
- Clinical trial anticipated to begin in 2015

CYC065

- Presented preclinical data demonstrating therapeutic potential of CYC065, Cyclacel's second-generation cyclin dependent kinase (CDK) inhibitor, to treat acute leukemias, and in particular those with rearrangements in the mixed lineage leukemia (MLL) gene
  - Data showed that, *in vitro,* all tested human AML and acute lymphocytic leukemia (ALL) cell lines with MLL rearrangements (MLLr) were sensitive to CYC065 and that the drug inhibited MLL-driven gene expression
  - Potent anticancer activity of CYC065 was demonstrated *in vivo* in AML xenograft models resulting in over 90% inhibition of tumor growth
  - Data were presented at the 2014 Society of Hematologic Oncology (SOHO) meeting

Third Quarter 2014 Financial Results

Grant Revenue

Revenue for the three months ended September 30, 2014 was $0.7 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 $5.0 million for the three months ended September 30, 2014 compared to $4.6 million for the same period in the previous year. The increase was primarily due to increased expenditures related to grant funded research and development, partially offset by the absence of drug manufacturing costs related to the SEAMLESS study that were incurred during the three months ended September 30, 2013.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2014 decreased to $1.4 million compared to $1.5 million for the same period in 2013. The decrease was primarily due to lower legal and professional fees during the three months ended September 30, 2014.

Cyclacel's Key Milestones for 2014/2015

- Sapacitabine in SEAMLESS:
  - DSMB safety review of approximately 400 patients enrolled with approximately 60-day follow-up
  - DSMB review of SEAMLESS data for futility once approximately 212 events have been observed
  - Completion of SEAMLESS enrollment
- Sapacitabine in MDS:
  - Complete feasibility assessment of proposed RCT
- Sapacitabine in solid tumors:
  - Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors including those carrying gBRCA mutations
- Advance early pipeline

Conference call and Webcast Information:

Cyclacel will conduct a conference call on November 11, 2014 at 4:30 p.m. Eastern Time to review the third quarter 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 23317872

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 being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other studies for myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer and in particular those carrying gBRCA mutations. 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 additional 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended September 30,	
	2013	**2014**
Revenues:		
Grant revenue	$ 309	$ 735
Total revenues	309	735
Operating expenses:		
Research and development	4,575	4,972
General and administrative	1,529	1,433
Total operating expenses	6,104	6,405
Operating loss	(5,795)	(5,670)
Other income (expense):		
Change in valuation of financial instruments associated with stock purchase agreement	—	(4)
Change in valuation of Economic Rights	—	—
Change in valuation of liabilities measured at fair value	—	—
Foreign exchange gains	25	10
Interest income	8	3
Other income, net	16	—
Total other income (expense)	49	9
Loss from continuing operations before taxes	(5,746)	(5,661)
Income tax benefit	730	750
Net loss from continuing operations	(5,016)	(4,911)
Discontinued operations:		
Income from discontinued operations	20	6
Income tax on discontinued operations	(8)	(2)
Net income from discontinued operations	12	4
Net loss	(5,004)	(4,907)
Deemed dividend on convertible exchangeable preferred shares	(661)	—
Dividend on convertible exchangeable preferred shares	(63)	(50)
Net loss applicable to common shareholders	$ (5,728)	$ (4,957)
Basic and diluted earnings per common share:		
Net loss per share, continuing operations	$ (0.32)	$ (0.22)

Net income per share, discontinued operations	$ 0.00	$ 0.00
Net loss per share applicable to common shareholders	$ (0.32)	$ (0.22)
Weighted average shares of common stock outstanding	17,788,568	22,676,475

CYCLACEL PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	December 31, 2013	September 30, 2014 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,146	$ 26,707
Prepaid expenses and other current assets	3,388	4,202
Current assets of discontinued operations	639	267
Total current assets	35,173	31,176
Property and equipment (net)	275	454
Long-term assets of discontinued operations	72	—
Total assets	$ 35,520	$ 31,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,545	$ 2,201
Accrued and other current liabilities	4,431	4,490
Other liabilities measured at fair value	20	—
Current liabilities of discontinued operations	260	75
Total current liabilities	7,256	6,766
Other liabilities	241	221
Total liabilities	7,497	6,987
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2013 and September 30, 2014; 335,273 shares issued and outstanding at December 31, 2013 and September 30, 2014. Aggregate preference in liquidation of $3,989,749 at December 31, 2013 and September 30, 2014.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2013 and September 30, 2014; 19,369,332 and 22,676,475 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively.	19	23
Additional paid-in capital	317,543	328,943
Accumulated other comprehensive loss	(109)	(305)
Accumulated deficit	(289,430)	(304,018)
Total stockholders' equity	28,023	24,643
Total liabilities and stockholders' equity	$ 35,520	$ 31,630

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