May 12, 2015

Cyclacel Pharmaceuticals Reports First Quarter 2015 Financial Results

-- Approximately 20% of prespecified events remaining in SEAMLESS before study unblinding --
-- Received FDA clearance for the first-in-human Phase 1 study of CYC065 CDK inhibitor --
-- Conference Call Scheduled May 12, 2015 at 4:30 p.m. Eastern Time --

BERKELEY HEIGHTS, N.J., May 12, 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 first quarter ended March 31, 2015.

The Company's net loss applicable to common shareholders for the first quarter ended March 31, 2015 was $5.0 million, or $0.19 per basic and diluted share, compared to net loss applicable to common shareholders of $4.9 million, or $0.25 per basic and diluted share, for the first quarter ended March 31, 2014. As of March 31, 2015, cash and cash equivalents totaled $29.4 million.

"Approximately 20% of the prespecified events remain to be observed before we unblind SEAMLESS, our pivotal, Phase 3 study of sapacitabine in patients aged 70 years or older with acute myeloid leukemia (AML) who are unfit or have refused intensive chemotherapy," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We expect this to occur between the second half of 2015 and the first half of 2016. As we continue study follow-up, we have begun preparations for submission of a Pediatric Investigation Plan (PIP) to the European Medicines Agency. In parallel with sapacitabine activities, we are progressing development of CYC065, our novel, second-generation cyclin dependent kinase (CDK) 2/9 inhibitor. Following submission of our Investigational New Drug (IND) application, we have received clearance from the U.S. Food and Drug Administration (FDA) to begin a first-in-human, Phase 1 clinical trial of CYC065, which will commence following institutional review board approval. We have cash resources for the next two years which are sufficient to advance these programs and deliver on our key milestones."

Business Highlights

Sapacitabine

- Continued follow-up of elderly patients with AML enrolled in the SEAMLESS Phase 3 study. The study is powered at 90% to detect a 27.5% reduction in the risk of death (event) between the experimental and control arms. Approximately 20% of the prespecified events remain to be observed before mature data become available for analysis.
- Continued follow-up of an expanded cohort of older patients with myelodysplastic syndromes (MDS) following front-line treatment failure enrolled in a Phase 2 study.
- Continued follow-up of patients with advanced solid tumors enrolled in a Phase 1 combination study of sapacitabine and seliciclib (Cyclacel's first generation CDK inhibitor).
- Planning an expanded cohort of the Phase 1 study of the sapacitabine and seliciclib combination regimen in an enriched population of gBRCA positive, breast cancer patients.

CYC065 (2nd generation CDK inhibitor)

- Submitted an IND application to the FDA for CYC065, the Company's second-generation, CDK2/9 inhibitor.
- Received FDA clearance to initiate a Phase 1 clinical trial with CYC065. We plan to commence this first-in-human trial following institutional review board approval.
- Presented preclinical data at the American Association of Cancer Research (AACR) 2015 annual meeting demonstrating the therapeutic potential of CYC065 by showing that it inhibits key cancer and leukemia survival mechanisms and causes death by apoptosis in cancer cells. We believe that CYC065 is effective against AML, and in particular, AML with genetic abnormalities, such as MLL rearrangements (MLL-r), which confer a poor prognosis. CYC065 was also shown to be effective against uterine cancer cells including those resistant to chemotherapy and was especially potent in uterine

cancer cells in which cyclin E, the partner protein of CDK2, was amplified or overexpressed. In each case CYC065 showed synergy with available anticancer agents.

Other

- Completed a public offering of shares of common stock for proceeds, net of certain fees and expenses, of approximately $9.2 million.

First Quarter 2015 Financial Results

Grant Revenue

Revenue for the three months ended March 31, 2015 was $0.5 million compared to $0.4 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 complete IND-directed preclinical development of CYC140, a Polo-Like Kinase 1 (PLK 1) inhibitor.

Research and Development Expenses

Research and development expenses were $4.3 million for each of the three months ended March 31, 2015 and March 31, 2014. Research and development expenses related to SEAMLESS were $0.4 million lower during the three months ended March 31, 2015 compared to the same period in the previous year due to certain SEAMLESS site startup costs not being required in this quarter, which costs were partially offset by increases in spending primarily related to grant funded research and development programs.

General and Administrative Expenses

General and administrative expenses for each of the three months ended March 31, 2015 and March 31, 2014 were $1.5 million.

Based on current plans the Company estimates that it has capital resources to reach beyond the availability of mature data for final analysis of SEAMLESS and continue existing programs through late 2017.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on May 12, 2015 at 4:30 p.m. Eastern Time to review the first quarter 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 38615845

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 CDK2/9 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 March 31,	
	2014	**2015**
	(Unaudited)	
Revenues:		
Grant revenue	$ 396	$ 512
Total revenues	396	512
Operating expenses:		
Research and development	4,344	4,342
General and administrative	1,462	1,468
Total operating expenses	5,806	5,810
Operating loss	(5,410)	(5,298)
Other income (expense):		
Change in valuation of financial instruments associated with stock purchase agreement	(47)	(20)
Foreign exchange gains (losses)	10	(378)
Interest income	1	1
Other income, net	—	20
Total other expense, net	(36)	(377)
Loss from continuing operations before taxes	(5,446)	(5,675)
Income tax benefit	569	763
Net loss from continuing operations	(4,877)	(4,912)
Discontinued operations:		
Income from discontinued operations	13	—
Income tax on discontinued operations	(5)	—
Net income from discontinued operations	8	—
Net loss	(4,869)	(4,912)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (4,919)	$ (4,962)
Basic and diluted earnings per common share:		
Net loss per share, continuing operations?-?basic and diluted	$ (0.25)	$ (0.19)

Net income per share, discontinued operations?-?basic and diluted	$ 0.00	$ 0.00
Net loss per share?-?basic and diluted	$ (0.25)	$ (0.19)
Weighted average common shares outstanding	19,530,322	26,067,078

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

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

	December 31, 2014	March 31, 2015
		(Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,189	$ 29,363
Prepaid expenses and other current assets	4,640	5,514
Current assets of discontinued operations	171	147
Total current assets	29,000	35,024
Property, plant and equipment (net)	387	333
Total assets	$ 29,387	$ 35,357
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,792	$ 4,007
Accrued and other current liabilities	4,626	4,054
Current liabilities of discontinued operations	75	75
Total current liabilities	7,493	8,136
Other liabilities	206	192
Total liabilities	7,699	8,328
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2014 and March 31, 2015; 335,273 shares issued and outstanding at December 31, 2014 and March 31, 2015. Aggregate preference in liquidation of? $3,989,749 at December 31, 2014 and March 31, 2015	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2014 and March 31, 2015; 23,199,469 and 34,388,485 shares issued and outstanding at December 31, 2014 and March 31, 2015, respectively	23	34
Additional paid-in capital	330,962	341,415
Accumulated other comprehensive loss	(480)	(691)
Accumulated deficit	(308,817)	(313,729)
Total stockholders' equity	21,688	27,029
Total liabilities and stockholders' equity	$ 29,387	$ 35,357

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