August 11, 2015

Cyclacel Pharmaceuticals Reports Second Quarter 2015 Financial Results

Conference Call Scheduled August 11, 2015 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., Aug. 11, 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 second quarter ended June 30, 2015.

The Company's net loss applicable to common shareholders for the second quarter ended June 30, 2015 was $3.4 million, or $0.10 per basic and diluted share, compared to a net loss income applicable to common shareholders of $4.9 million, or $0.22 per basic and diluted share for the second quarter ended June 30, 2014. As of June 30, 2015, cash and cash equivalents totaled $26.9 million.

"SEAMLESS continues to progress towards final data read-out," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "There are now approximately 13% of events remaining to occur and we expect to report top-line data during the second half of 2015 through the first half of 2016. Following unblinding and analysis of the SEAMLESS data, we will determine their suitability for submission to regulators in the U.S. and Europe. Additionally, in the Phase 1 study of our all-oral combination of sapacitabine with our first-generation CDK2/9 inhibitor, seliciclib, we reported updated data in heavily pretreated cancer patients with BRCA mutations. The data showed a 55% overall response rate with patients achieving durable benefit after multiple cycles of therapy, including a breast cancer patient who has received to date over 60 cycles. These promising data are encouraging us to explore this regimen further. Our next generation CDK2/9 inhibitor, CYC065, received institutional review board approval for a first-in-human, Phase 1 study in advanced solid tumors and we expect to start treating patients shortly. CYC065 has demonstrated increased potency compared to seliciclib. Based on published preclinical efficacy data, we plan to develop CYC065 as a targeted anticancer agent in both hematological and solid cancers. In addition to our focus on SEAMLESS, we have continued to make progress with our other programs, while ensuring we have sufficient resources to deliver on our key milestones and execute on our business strategy."

Business Highlights

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

- Continued to follow-up patients as 13% of events remain to occur before analyzing the data and reporting top-line results. The SEAMLESS study is powered at 90% to detect a 27.5% improvement of survival between the experimental and control arms.

Sapacitabine and seliciclib, all-oral combination in Phase 1 study in patients with advanced solid tumors

- Observed an overall response rate of 55% in breast, ovarian and pancreatic patients with BRCA mutations in updated data from this study of heavily pre-treated patients.

Cyclin Dependent Kinase (CDK) Inhibitor Programs

- Received institutional review board approval to start a first-in-human Phase 1 trial of CYC065, the Company's second generation CDK2/9 inhibitor, in solid tumor patients to evaluate the safety, tolerability and pharmacokinetic profile of CYC065.
- Presented preclinical data demonstrating therapeutic potential of CYC065 as a targeted anticancer agent at the American Association for Cancer Research Annual Meeting 2015. The data show that CYC065 may reverse drug resistance associated with addiction of cancer cells to cyclin E, the partner protein of CDK2. CYC065 may also inhibit CDK9-dependent oncogenic and leukemogenic pathways, including malignancies driven by certain oncogene and MLL rearrangements. MLL gene status and levels of Bcl-2 family proteins correlated with sensitivity of AML cell lines to CYC065. CYC065's anticancer activity presents an opportunity for patient stratification and combinations with anti-leukemic agents. CYC065 was also effective against uterine cancer cells including those resistant to chemotherapy and was especially potent in uterine cancer cells in which cyclin E was amplified or overexpressed.
- Entered into a license and supply agreement with ManRos Therapeutics regarding the development of seliciclib, the

Company's first generation CDK inhibitor, in cystic fibrosis.
- Dosed first patient in Phase 2 investigator sponsored trial (IST) evaluating seliciclib as a potential treatment for Cushing's disease.

Other Events

- Entered into a Controlled Equity Offering[SM] Sales Agreement with Cantor Fitzgerald & Co., as sales agent ("Cantor"), under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to $8.35 million through Cantor.
- Transferred the listing of the Company's common stock from the NASDAQ Global Market to the NASDAQ Capital Market effective at the opening of business on August 6, 2015. The Company's common stock will continue to trade under the symbol "CYCC." The Company currently meets the NASDAQ Capital Market initial listing criteria, except for the bid price requirement. With the transfer to the NASDAQ Capital Market, the Company is being afforded an additional 180-day grace period to regain compliance with NASDAQ's minimum bid price requirement of a stock price of at least $1.00 for at least ten consecutive business days during this grace period ending on February 2, 2016 or be delisted.

Second Quarter 2015 Financial Results

Grant Revenue

Revenue for the three months ended June 30, 2015, was $0.3 million compared to $0.4 million for the same period of the previous year. The revenue is related to grants from the European Union and the Biomedical Catalyst of the United Kingdom government.

Research and Development Expenses

Research and development expenses were $2.6 million for the three months ended June 30, 2015, compared to $4.5 million for the same period in the previous year. The decrease was primarily a result of reduced expenditure in the SEAMLESS Phase 3 study this quarter compared to the same period last year.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2015 remained relatively flat at $1.3 million compared to $1.4 million for the same period in 2014.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on August 11, 2015 at 4:30 p.m. Eastern Time to review the second 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 95466148

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 patients carrying BRCA 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.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2015**	**2014**	**2015**
Revenues:				
Grant revenue	$ 356	$ 296	$ 752	$ 808
Total revenues	356	296	752	808
Operating expenses:				
Research and development	4,545	2,580	8,889	6,922
General and administrative	1,386	1,333	2,848	2,801
Total operating expenses	5,931	3,913	11,737	9,723
Operating loss	(5,575)	(3,617)	(10,985)	(8,915)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(64)	(4)	(111)	(24)
Change in valuation of liabilities measured at fair value	20	—	20	—
Foreign exchange losses	(43)	(195)	(33)	(573)
Interest income	1	2	2	3
Other income, net	26	62	26	82
Total other expense	(60)	(135)	(96)	(512)
Loss from continuing operations before taxes	(5,635)	(3,752)	(11,081)	(9,427)
Income tax benefit	816	405	1,385	1,168
Net loss from continuing operations	(4,819)	(3,347)	(9,696)	(8,259)
Discontinued operations:				
Income from discontinued operations	10	—	23	—
Income tax on discontinued operations	(3)	—	(8)	—
Net income from discontinued operations	7	—	15	—
Net loss	(4,812)	(3,347)	(9,681)	(8,259)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(100)	(100)
Net loss applicable to common shareholders	$ (4,862)	$ (3,397)	$ (9,781)	$ (8,359)

Basic and diluted earnings per common share:				
Net loss per share, continuing operations?-?basic and diluted	$ (0.22)	$ (0.10)	$ (0.47)	$ (0.28)
Net income per share, discontinued operations?-?basic and diluted	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Net loss per share?-?basic and diluted	$ (0.22)	$ (0.10)	$ (0.46)	$ (0.28)
Weighted average common shares outstanding	22,582,283	34,388,486	21,064,739	30,250,769

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

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

	December 31, 2014	June 30, 2015 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,189	$ 26,902
Prepaid expenses and other current assets	4,640	3,453
Current assets of discontinued operations	171	124
Total current assets	29,000	30,479
Property, plant and equipment (net)	387	309
Total assets	$ 29,387	$ 30,788
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,792	$ 2,609
Accrued and other current liabilities	4,626	3,806
Current liabilities of discontinued operations	75	75
Total current liabilities	7,493	6,490
Other liabilities	206	198
Total liabilities	7,699	6,688
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2014 and June 30, 2015; 335,273 shares issued and outstanding at December 31, 2014 and June 30, 2015. Aggregate preference in liquidation of $3,989,749 at December 31, 2014 and June 30, 2015.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2014 and June 30, 2015; 23,199,469 and 34,388,486 shares issued and outstanding at December 31, 2014 and June 30, 2015, respectively.	23	34
Additional paid-in capital	330,962	341,530
Accumulated other comprehensive loss	(480)	(388)
Accumulated deficit	(308,817)	(317,076)
Total stockholders' equity	21,688	24,100
Total liabilities and stockholders' equity	$ 29,387	$ 30,788

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