November 12, 2015

Cyclacel Pharmaceuticals Reports Third Quarter 2015 Financial Results

Conference Call Scheduled November 12, 2015 at 4:30 p.m. EST

BERKELEY HEIGHTS, N.J., Nov. 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 third quarter ended September 30, 2015.

The Company's net loss applicable to common shareholders for the third quarter ended September 30, 2015 was $2.8 million, or $0.08 per basic and diluted share, compared to a net loss applicable to common shareholders of $5.0 million, or $0.22 per basic and diluted share for the third quarter ended September 30, 2014. As of September 30, 2015, cash and cash equivalents totaled $22.7 million.

"SEAMLESS continues to progress towards final data read-out," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "There are now approximately 8% of events remaining to occur and we anticipate reporting top-line data during the first half of 2016. Following unblinding and analysis of the data, we will review the results to determine their suitability for submission to regulators. Our CDK2/9 programs made significant progress over the quarter. The CYC065 Phase 1 trial in solid tumor and lymphoma patients has started and the mechanistic rationale for CDK2/9 inhibition in targeted solid tumors and hematological malignancies is supported by multiple presentations at scientific conferences. Seliciclib was administered to the first patients with Cushing's disease in an investigator-sponsored trial. We and our investigators are excited about the prospects of CDK2/9 inhibitors and we look forward to keeping you apprised as to our progress."

Business Highlights

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

- Continued follow-up with 8% of events remaining before analyzing mature 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.

Cyclin Dependent Kinase (CDK) Inhibitor Programs

- Presented the molecular rationale for clinical development of CYC065 for the treatment of solid tumors at the AACR-NCI-EORTC International Conference: Molecular Targets and Cancer Therapeutics
- Dosed the first patient in a first-in-human, Phase 1 trial of CYC065, the Company's second-generation CDK2/9 inhibitor, in solid tumor and lymphoma patients to evaluate the safety, tolerability and pharmacokinetic profile of CYC065
- Presented the molecular rationale for clinical development of CYC065 for the treatment of leukemias and lymphomas at the Society of Hematologic Oncology (SOHO) 2015 Annual Meeting
- Dosed the first patient in a Phase 2 investigator-sponsored trial (IST) evaluating seliciclib as a potential treatment for Cushing's disease.
- CYC065 data to be presented at the upcoming 2015 San Antonio Breast Cancer Symposium in Texas and at the 4th Neuroblastoma Symposium in Newcastle Upon Tyne, United Kingdom

Third Quarter 2015 Financial Results

Revenue

Revenue was $0.7 million for both the three months ended September 30, 2014 and 2015. Revenue is mainly related to grants from the European Union and the Biomedical Catalyst of the United Kingdom government. The Company recognized $0.3 million from its license and supply agreement with ManRos during the three months ended September 30, 2015.

Research and Development Expenses

Research and development expenses were $2.9 million for the three months ended September 30, 2015, compared to $5.0 million for the same period in the previous year. The decrease was primarily a result of reduced expenditures in study and site startup costs associated with 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 September 30, 2015 were $1.2 million compared to $1.4 million for the same period in 2014. The decrease was primarily the result of lower patent-related and stock-based compensation costs.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on November 12, 2015 at 4:30 p.m. Eastern Time to review the third 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 63652219

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	**Nine months Ended**

	September 30,		September 30,	
	2014	2015	2014	2015
Revenues:				
Grant revenue	$ 735	$ 462	$ 1,487	$ 1,270
Collaboration and research and development revenue	—	253	—	253
Total revenues	735	715	1,487	1,523
Operating expenses:				
Research and development	4,972	2,904	13,861	9,826
General and administrative	1,433	1,205	4,281	4,006
Total operating expenses	6,405	4,109	18,142	13,832
Operating loss	(5,670)	(3,394)	(16,655)	(12,309)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(4)	(27)	(115)	(51)
Change in valuation of liabilities measured at fair value	—	—	20	—
Foreign exchange gains (losses)	10	219	(23)	(354)
Interest income	3	2	5	5
Other income, net	—	13	26	95
Total other income (expense)	9	207	(87)	(305)
Loss from continuing operations before taxes	(5,661)	(3,187)	(16,742)	(12,614)
Income tax benefit	750	478	2,135	1,646
Net loss from continuing operations	(4,911)	(2,709)	(14,607)	(10,968)
Discontinued operations:				
Income from discontinued operations	6	—	29	—
Income tax on discontinued operations	(2)	—	(10)	—
Net income from discontinued operations	4	—	19	—
Net loss	(4,907)	(2,709)	(14,588)	(10,968)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(150)	(150)
Net loss applicable to common shareholders	$ (4,957)	$ (2,759)	$ (14,738)	$ (11,118)
Basic and diluted earnings per common share:				
Net loss per share, continuing operations?—?basic and diluted	$ (0.22)	$ (0.08)	$ (0.68)	$ (0.35)
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)	$ (0.08)	$ (0.68)	$ (0.35)
Weighted average common shares outstanding	22,676,475	34,675,569	21,607,888	31,741,910

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In $000s, except share, per share, and liquidation preference amounts)

	December 31, 2014	September 30, 2015 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,189	$ 22,728
Prepaid expenses and other current assets	4,640	3,966
Current assets of discontinued operations	171	100
Total current assets	29,000	26,794
Property, plant and equipment (net)	387	255
Total assets	$ 29,387	$ 27,049
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 2,792	$ 1,616
Accrued and other current liabilities	4,626	3,572
Current liabilities of discontinued operations	75	75
Total current liabilities	7,493	5,263
Other liabilities	206	186
Total liabilities	7,699	5,449
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2014 and September 30, 2015; 335,273 shares issued and outstanding at December 31, 2014 and September 30, 2015. Aggregate preference in liquidation of $3,989,749 at December 31, 2014 and September 30, 2015.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2014 and September 30, 2015; 23,199,469 and 34,702,910 shares issued and outstanding at December 31, 2014 and September 30, 2015, respectively.	23	34
Additional paid-in capital	330,962	341,891
Accumulated other comprehensive loss	(480)	(540)
Accumulated deficit	(308,817)	(319,785)
Total stockholders' equity	21,688	21,600
Total liabilities and stockholders' equity	$ 29,387	$ 27,049

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