August 12, 2014

Cyclacel Pharmaceuticals Reports Second Quarter 2014 Financial Results

Conference Call Scheduled August 12, 2014 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., Aug. 12, 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 second quarter ended June 30, 2014.

The Company's net loss applicable to common shareholders for the second quarter ended June 30, 2014 was $4.9 million, or $0.22 per basic and diluted share, compared to net income applicable to common shareholders of $1.4 million, or $0.10 per basic and diluted share, which included a non-routine income item of $5.5 million, for the second quarter ended June 30, 2013. As of June 30, 2014, cash and cash equivalents totaled $33.5 million.

"We are pleased to report that we have enrolled over 70% of the required number of patients in our Phase 3 SEAMLESS trial in front-line AML. At present we have approximately 90 study centers open for enrollment in the US and Europe with additional sites to be added," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We expect to complete SEAMLESS enrollment around the end of 2014 with data readout in the second half of 2015. Having surpassed enrollment of 300 patients, we expect the study's Data Safety Monitoring Board (DSMB) to perform the fourth periodic safety review once 60 days of follow-up have been observed. The next DSMB review will be an interim analysis for futility and will occur after 212 events have been observed. As indicated previously, SEAMLESS is funded to completion. Following Phase 2 data for sapacitabine reported at ASH 2013, demonstrating a near doubling of expected median survival of older patients with MDS after treatment failure of hypomethylating agents, we disclosed during ASCO 2014 our proposed randomized, controlled trial design in this underserved patient population. We are currently conducting assessment of feasibility for this study and will provide further information once the findings become available."

Business Highlights

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

- Study enrollment is over 70% of the required patients from mostly US clinical sites
- Approximately 90 sites open in the US and Europe; with additional sites to be activated
- Surpassing 300 patients enrolled triggers fourth safety review by the DSMB

Sapacitabine 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 randomized, controlled trial (RCT) with a lead-in stage
- Feasibility assessment is in progress

Other Events

- Closed an underwritten offering for net proceeds for approximately $9.3 million after deduction of offering expenses

Second Quarter 2014 Financial Results

Grant Revenue

Revenue for the three months ended June 30, 2014, was $0.4 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 Cyclin Dependent Kinase 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 $4.5 million for the three months ended June 30, 2014, compared to $2.6 million for the same period in the previous year. The increase was primarily due to study and site startup costs associated with the expansion of the SEAMLESS registration study into Europe.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2014 decreased to $1.4 million compared to $1.8 million for the same period in 2013. The decrease was primarily due to higher legal and professional fees during the three months ended June 30, 2013.

Cyclacel's Key Milestones for 2014

- Sapacitabine in SEAMLESS:
  - DSMB safety review of approximately 300 patients enrolled with 60-day follow-up
  - DSMB review of SEAMLESS data for futility once 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 August 12, 2014 at 4:30 p.m. Eastern Time to review the second 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 77500832

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 June 30,	
	2013	**2014**
Revenues:		
Grant revenue	$ 264	$ 356
Total revenues	264	356
Operating expenses:		
Research and development	2,631	4,545
General and administrative	1,787	1,386
Total operating expenses	4,418	5,931
Operating loss	(4,154)	(5,575)
Other income (expense):		
Change in valuation of financial instruments associated with stock purchase agreement	—	(64)
Change in valuation of liabilities measured at fair value	—	20
Foreign exchange losses	(101)	(43)
Interest income	3	1
Other income, net	5,500	26
Total other income (expense)	5,402	(60)
Income (loss) from continuing operations before taxes	1,248	(5,635)
Income tax benefit	230	816
Net income (loss) from continuing operations	1,478	(4,819)
Discontinued operations:		
Income from discontinued operations	24	10
Income tax on discontinued operations	(10)	(3)
Net income from discontinued operations	14	7
Net income (loss)	1,492	(4,812)
Deemed dividend on convertible exchangeable preferred shares	—	—
Dividend on convertible exchangeable preferred shares	(63)	(50)
Net income (loss) applicable to common shareholders	$ 1,429	$ (4,862)
Basic earnings per common share:		
Net income (loss) per share, continuing operations	$ 0.10	$ (0.22)
Net income (loss) per share, discontinued operations	$ 0.00	$ 0.00
Net income (loss) per share applicable to common shareholders	$ 0.10	$ (0.22)
Diluted earnings per common share:		
Net income (loss) per share, continuing operations	$ 0.10	$ (0.22)
Net income (loss) per share, discontinued operations	$ 0.00	$ 0.00

Net income (loss) per share applicable to common shareholders	$ 0.10	$ (0.22)
Weighted average shares of common stock outstanding:		
Basic	13,885,442	22,582,283
Diluted	13,927,371	22,582,283

CYCLACEL PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	December 31, 2013	June 30, 2014 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,146	$ 33,456
Prepaid expenses and other current assets	3,388	3,422
Current assets of discontinued operations	639	403
Total current assets	35,173	37,281
Property and equipment (net)	275	305
Long-term assets of discontinued operations	72	24
Total assets	$ 35,520	$ 37,610
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,545	$ 4,543
Accrued and other current liabilities	4,431	3,095
Other liabilities measured at fair value	20	—
Current liabilities of discontinued operations	260	145
Total current liabilities	7,256	7,783
Other liabilities	241	238
Total liabilities	7,497	8,021
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2013 and June 30, 2014; 335,273 shares issued and outstanding at December 31, 2013 and June 30, 2014. Aggregate preference in liquidation of $3,989,749 at December 31, 2013 and June 30, 2014.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2013 and June 30, 2014; 19,369,332 and 22,676,475 shares issued and outstanding at December 31, 2013 and June 30, 2014, respectively.	19	23
Additional paid-in capital	317,543	328,774
Accumulated other comprehensive income (loss)	(109)	(97)
Accumulated deficit	(289,430)	(299,111)
Total stockholders' equity	28,023	29,589
Total liabilities and stockholders' equity	$ 35,520	$ 37,610

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