August 14, 2012

Cyclacel Reports Second Quarter 2012 Financial Results

Conference Call Scheduled August 14, 2012 at 4:30 p.m. Eastern Time

BERKELEY HEIGHTS, N.J., Aug. 14, 2012 (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, 2012.

The net loss for each of the second quarters of 2012 and 2011 was $3.6 million. For the six months ended June 30, 2012, the Company reported a net loss of $6.5 million as compared to a net loss of $8.1 million for the six months ended June 30, 2011. As of June 30, 2012, cash and cash equivalents totaled $20.0 million. The Company's net loss applicable to common stockholders for the second quarter of 2012 was $3.8 million, or $0.06, per basic and diluted share, compared to a net loss applicable to common stockholders of $3.7 million, or $0.08, per basic and diluted share for the second quarter of 2011. The Company's net loss applicable to common stockholders for the six months ended June 30, 2012 was $6.9 million, or $0.12, per basic and diluted share, compared to a net loss applicable to common stockholders of $8.5 million, or $0.18, per basic and diluted share for the six months ended June 30, 2011.

"Cyclacel's focus remains on the successful execution of SEAMLESS, our Phase 3 study of sapacitabine as front-line treatment in acute myeloid leukemia (AML). With 35 clinical sites open and enrolling in the U.S., we anticipate reaching the second planned periodic safety review in late 2012 or early 2013," said Paul McBarron, Executive Vice President, Finance and Chief Operating Officer of Cyclacel. "Sapacitabine continues to demonstrate promising safety and efficacy thus far in both hematological malignancies and solid tumors. At ASCO 2012 we reported promising median overall survival of approximately 8.4 months for single-agent sapacitabine in patients with myelodysplastic syndromes (MDS), who had failed hypomethylating agents. At ASCO 2012 we also reported promising data from our Phase 1/2 study of sapacitabine in combination with our second drug, seliciclib, including responses and stable disease in patients who are BRCA-mutation carriers. In addition to continuing SEAMLESS enrollment, we look forward to overall survival data from the investigator-led, Phase 2/3 "Pick a Winner Programme / LI-1" study comparing single-agent sapacitabine to low dose cytarabine".

Business Highlights

- In June 2012 at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting, reported new data from an ongoing, multicenter, Phase 2 randomized trial of single-agent oral sapacitabine capsules, in older patients with MDS after treatment failure of the front-line hypomethylating agents, azacitidine (Vidaza®) and/or decitabine (Dacogen®). Median overall survival to date for all patients is 252 days or approximately 8.4 months.

- At the ASCO 2012 Annual Meeting, presented new data from an open label, single arm, Phase 1 escalation trial of a combination of the Company's drug candidates, sapacitabine and seliciclib, as an orally-administered sequential treatment regimen in heavily-pretreated patients with advanced solid tumors. The maximum tolerated dose (MTD) for the regimen was reported as sapacitabine 50 mg twice daily followed by seliciclib 1200 mg twice daily. Pharmacodynamic effects were observed in skin biopsies showing a 2.3-fold increase in H2AX staining post-sapacitabine (n=16; p=0.007) and a further 0.58-fold increase post-seliciclib (n=12; p=0.069). Among 19 patients treated at the MTD, 3 partial responses (PR) occurred in patients with breast, ovarian and pancreatic cancer and 1 stable disease in a patient with ovarian cancer. Thirteen of the 19 patients are BRCA-mutation carriers, of which 7 were poly ADP-ribose polymerase (PARP) inhibitor-naïve and 6 had prior PARP inhibitor treatment. All four responding patients were PARP inhibitor-naïve, BRCA-mutation carriers. Stable disease was achieved in 6 additional patients treated with the other dosing schedules. The number of treatment cycles administered ranged from 2 to over 15 cycles. The breast cancer patient who achieved PR remains on study with over 15 cycles and both ovarian cancer patients remain on study with over 2 and 12 cycles respectively.

- In May 2012, announced completion of enrollment of the Phase 2 portion of the investigator-led, Phase 2/3 multicenter, randomized trial comparing sapacitabine to low dose cytarabine (the "Pick a Winner Programme / LI-1 Trial") in patients aged 60 years or older with previously untreated AML or high risk MDS who are unfit for intensive chemotherapy. The study enrolled over 100 patients. The investigators anticipate that, as required by the protocol, the study's data safety monitoring board will meet within 2012 to review the data and assess overall survival.

- In April 2012, presented preclinical results for three Cyclacel compounds, sapacitabine, Polo-Like Kinase 1 and Aurora A

kinase inhibitors including CY116, at the 103rd Annual Meeting of the American Association of Cancer Research.

- In April 2012, announced that the U.S. Patent and Trademark Office issued U.S. Patent No. 8,124,593 ('593), which grants claims to a specified method of administration of sapacitabine and extends existing composition of matter US patent protection and supports US market exclusivity out to 2030.

- The Company also reported that Mr. McBarron, our Executive Vice President, Finance and Chief Operating Officer would be conducting the earnings call and would be performing additional duties as a result of Spiro Rombotis taking medical leave to recuperate from surgery that removed a mass discovered during a routine physical examination. Mr. Rombotis is expected to make a full recovery and reassume his full duties in early September 2012.

Second Quarter and Year to Date 2012 Financial Results

Product Revenue

Revenues for the three months ended June 30, 2012 and 2011 were $0.1 million and $0.2 million, respectively. Revenues for the six months ended June 30, 2012 and 2011 were $0.3 million and $0.4 million, respectively. Cyclacel's product revenues were comprised of sales of Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. On August 10, 2012, the Company entered into an agreement with Sinclair Pharmaceuticals Limited ("Sinclair") to early terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid. The agreement includes a minimum royalty arrangement based on future net revenues, under which Sinclair will pay the Company a minimum of approximately $1.0 million in quarterly instalments over the next three years ending on September 30, 2015.

Research and Development Expenses

Research and development expenses in the second quarter of 2012 were $1.7 million compared to $1.9 million for the same period in 2011. Research and development expenses for the six months ended June 30, 2012 and 2011 were $3.1 million and $4.9 million, respectively. The decrease in costs was primarily due to a contractual payment of $1.6 million to Daiichi Sankyo during the first quarter of 2011 related to a milestone payment triggered by the opening of enrollment in the SEAMLESS Phase 3 trial.

Selling, General and Administrative Expenses (SG&A)

Total SG&A expenses for the second quarter of 2012 were $2.4 million, compared to $2.0 million for the same period in 2011. Total SG&A expenses for the six months ended June 30, 2012 and 2011 were $4.3 million and $3.8 million, respectively. The increased expenses during 2012 were primarily related to professional and consultancy costs.

Cash and Cash Equivalents

As of June 30, 2012, Cyclacel's cash and cash equivalents were $20.0 million compared to $24.4 million as of December 31, 2011. The Company expects that its cash resources are sufficient to meet anticipated working capital needs and fund ongoing sapacitabine clinical trials for at least the next twelve months.

Cyclacel's Goals for 2012

- Continue enrollment in the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Report updated Phase 2 sapacitabine data in 2nd line MDS following previous treatment with hypomethylating agents;
- Report updated Phase 2 sapacitabine data in AML preceded by MDS following previous treatment with hypomethylating agents for the preceding MDS;
- Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors;
- Report updated Phase 2 sapacitabine data in non-small cell lung cancer (NSCLC); and
- Report survival data from the "Pick a Winner/LI-1" investigator-sponsored study in AML and other investigator-sponsored studies as they become available.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on August 14, 2012 at 4:30 p.m. Eastern Time to review the second quarter 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 15123322

For the live and archived webcast, please visit the Corporate Presentations 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 oral capsules is in the SEAMLESS Phase 3 trial being conducted under an SPA with the FDA as front-line treatment of acute myeloid leukemia (AML) in the elderly, Phase 2 studies for AML, myelodysplastic syndromes (MDS) and solid tumors including lung cancer and in investigator-led studies in a Phase 2/3 study comparing sapacitabine to low dose cytarabine as front-line treatment of elderly patients with AML or high risk MDS unfit for intensive chemotherapy and a Phase 2 study in chronic lymphocytic leukemia. Cyclacel's pipeline includes seliciclib oral capsules in Phase 2 studies for the treatment of lung cancer and nasopharyngeal cancer and in a Phase 1 trial in combination with sapacitabine. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and 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.

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2011	2012	2011	2012	2012
Revenues:					
Collaboration and research and development revenue	$ —	$ —	$ —	$ —	$ 3,100
Product revenue	168	120	360	281	3,302
Grant revenue	—	26	—	26	3,674
	168	146	360	307	10,076
Operating expenses:					
Cost of goods sold	72	89	178	183	1,935
Research and development	1,859	1,717	4,939	3,064	188,863

Selling, general and administrative	2,034	2,350	3,840	4,346	93,833
Goodwill and intangible impairment	—	—	—	—	7,934
Restructuring costs	—	—	—	—	2,634
Total operating expenses	3,965	4,156	8,957	7,593	295,199
Operating loss	(3,797)	(4,010)	(8,597)	(7,286)	(285,123)
Other income (expense):					
Costs associated with aborted 2004 IPO	—	—	—	—	(3,550)
Payment under guarantee	—	—	—	—	(1,652)
Change in valuation of Economic Rights	—	146	—	90	90
Change in valuation of other liabilities measured at fair value	125	8	203	50	6,377
Foreign exchange (losses)/gains	(19)	117	(87)	231	(4,098)
Interest income	13	6	24	12	13,737
Interest expense	—	—	—	—	(4,677)
Other income	—	29	—	76	76
Total other income (expense)	119	306	140	459	6,303
Loss before taxes	(3,678)	(3,704)	(8,457)	(6,827)	(278,820)
Income tax benefit	126	127	317	295	18,739
Net loss	(3,552)	(3,577)	(8,140)	(6,532)	(260,081)
Dividends on preferred ordinary shares	—	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	—	—	(3,515)
Dividend on convertible exchangeable preferred shares	(182)	(182)	(364)	(364)	(4,021)
Net loss applicable to common shareholders	$ (3,734)	$ (3,759)	$ (8,504)	$ (6,896)	$ (305,740)
Net loss per share — Basic and diluted	$ (0.08)	$ (0.06)	$ (0.18)	$ (0.12)	
Weighted average common shares outstanding	**46,582,915**	**58,997,078**	**46,577,577**	**56,879,349**	

CYCLACEL PHARMACEUTICALS, INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In $000s, except share amounts)

	December 31, 2011	March 31, 2012
		(Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,449	$ 19,964
Inventory	182	50
Prepaid expenses and other current assets	1,200	1,639
Total current assets	25,831	21,653
Property, plant and equipment (net)	167	149
Total assets	$ 25,998	$ 21,802
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,763	$ 1,544
Accrued liabilities and other current liabilities	4,664	4,174
Economic rights	—	1,007

Warrant and other liabilities measured at fair value	71	21
Total current liabilities	6,498	6,746
Total liabilities	6,498	6,746
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2011 and June 30, 2012; 1,213,142 shares issued and outstanding at December 31, 2011 and June 30, 2012. Aggregate preference in liquidation of $13,708,505 and $14,072,447 at December 31, 2011 and June 30, 2012, respectively	1	1
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2011 and June 30, 2012; 54,220,458 and 59,001,229 shares issued and outstanding at December 31, 2011 and June 30, 2012	54	59
Additional paid-in capital	276,452	278,514
Accumulated other comprehensive loss	57	78
Deficit accumulated during the development stage	(257,064)	(263,596)
Total stockholders' equity	19,500	15,056
Total liabilities and stockholders' equity	$ 25,998	$ 21,802

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