



November 12, 2012

## Cyclacel Reports Third Quarter 2012 Financial Results

**- Enrollment in SEAMLESS Phase 3 study of sapacitabine proceeding as planned; updated survival data from the pilot/lead-in stage of SEAMLESS to be presented at the upcoming annual meeting of the American Society of Hematology -**

**- Conference Call Scheduled November 12, 2012 at 4:30 p.m. Eastern Time -**

BERKELEY HEIGHTS, N.J., Nov. 12, 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 third quarter ended September 30, 2012.

The Company's net loss applicable to common stock shareholders, which includes the discontinuation of the ALIGN business, for the third quarter of 2012 was \$2.1 million, or \$0.25, per basic and diluted share, compared to a net loss applicable to common stock shareholders, of \$3.6 million, or \$0.47 per basic and diluted share, for the third quarter of 2011. For the nine months ended September 30, 2012 the Company's net loss applicable to common stock shareholders was \$9.0 million, or \$1.09 per basic and diluted share, compared to a net loss applicable to common stock shareholders of \$12.1 million, or \$1.73 per basic and diluted share. As of September 30, 2012, cash and cash equivalents totaled \$17.8 million.

"Cyclacel continues to execute on its plan for the SEAMLESS pivotal, Phase 3 study of sapacitabine as front-line treatment in acute myeloid leukemia (AML) in elderly patients who are not candidates for or have refused induction chemotherapy," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "After opening 36 clinical sites in the US, we have achieved a few weeks ago the enrollment milestone of surpassing 100 patients. With the randomized stage of SEAMLESS currently reaching its first anniversary, we are encouraged to see that the study has strong support by investigators. In addition, we look forward to reporting at the upcoming 2012 Annual Meeting of the American Society of Hematology (ASH) updated survival data from the entire population enrolled in the pilot/lead-in stage of SEAMLESS. In parallel, we are preparing regulatory submissions with the goal of defining a registration pathway for sapacitabine in patients with myelodysplastic syndromes (MDS) who failed treatment with front-line hypomethylating agents. Sapacitabine is part of Cyclacel's deep pipeline of novel medicines designed to target and stop uncontrolled cell division."

### Business Highlights

- Published results from a Phase 2 randomized trial of single-agent sapacitabine in elderly patients aged 70 years or older with newly diagnosed AML or AML in first relapse in *The Lancet Oncology*.
- Presented updated data at two separate sessions at The Eighth Annual Hematologic Malignancies 2012 Conference from an ongoing, multicenter, Phase 2 randomized trial of sapacitabine in older patients with intermediate-2 or high-risk MDS after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®). Median overall survival to date for all 63 patients in the Phase 2 study is approximately 8 months. For 41 out of 63 patients with 10% to 19% blasts in their bone marrow median overall survival is approximately 9 months. Twenty-two percent of patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival of each arm.
- Received a grant of approximately \$1.9 million from the UK Government's Biomedical Catalyst to complete investigational new drug (IND)-directed preclinical development of CYC065, a novel, orally available, second generation, cyclin-dependent kinase (CDK) inhibitor.
- Highlighted in multiple poster presentations the personalized medicine potential of Cyclacel's innovative and diverse oncology pipeline at the 8th National Cancer Research Institute (NCRI) Cancer Conference, including translational findings demonstrating the combination potential of sapacitabine in patients with BRCA1/2 or homologous recombination repair (HRR) pathway defects and the Company's Polo-Like Kinase 1 (Plk1) inhibitors.
- Entered into an agreement with Sinclair Pharmaceuticals Limited ("Sinclair") to terminate, effective September 30, 2012, the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid in exchange for a minimum of approximately \$1 million in royalty revenues over a period ending in September 2015.
- Implemented a 1-for-7 reverse stock split of shares of common stock in order to satisfy the \$1.00 minimum bid requirement for continued listing on the NASDAQ Global Market.

### Third Quarter and Year to Date 2012 Financial Results

## Research and Development Expenses

Research and development expenses in the third quarter of 2012 were \$1.5 million compared to \$2.1 million for the same period in 2011. Research and development expenses for the nine months ended September 30, 2012 and 2011 were \$4.6 million and \$7.0 million, respectively. The decrease in research and development expenses 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 third quarter of 2012 were \$2.0 million, compared to \$1.8 million for the same period in 2011. Total SG&A expenses for the nine months ended September 30, 2012 and 2011 were \$5.9 million and \$5.1 million, respectively. The increased expenses during 2012 were primarily related to professional and consultancy costs.

## Discontinued Operations

In August 2012, we entered into an agreement with Sinclair to 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 Cyclacel a minimum of approximately \$1.0 million in quarterly installments over the next three years ending on September 30, 2015.

## Cash and Cash Equivalents

As of September 30, 2012, Cyclacel's cash and cash equivalents were \$17.8 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 the remainder of 2012 and 2013

- Continue enrollment in the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Report updated survival data of the pilot /lead-in stage of SEAMLESS at the 2012 Annual Meeting of the American Society of Hematology;
- Report updated Phase 2 sapacitabine data in 2<sup>nd</sup> line MDS following treatment failure after 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 updates from investigator-sponsored trials (IST) including the "Pick a Winner/LI-1" IST in AML & high-risk MDS and other ISTs in leukemia and lymphoma as they become available.

## Conference call and Webcast Information:

Cyclacel will conduct a conference call on November 12, 2012 at 4:30 p.m. Eastern Time to review the third 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 69718892

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at [www.cyclacel.com](http://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. The Company's most advanced oral product candidate, sapacitabine, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment of acute myeloid leukemia (AML) in the elderly and Phase 2 studies for AML, myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer. Cyclacel's pipeline includes seliciclib, a CDK inhibitor, in Phase 2 for lung and nasopharyngeal cancer and in Phase 1 in combination with sapacitabine; and CYC065, a

second generation CDK inhibitor, in IND-directed development. 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](http://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](http://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.

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**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In \$000s, except share and per share amounts)**  
**(Unaudited)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2011</b>	<b>2012</b>	<b>2011</b>	<b>2012</b>
<b>Revenues:</b>				
Collaboration and research and development revenue	\$ —	\$ —	\$ —	\$ —
Grant revenue	—	38	—	64
Total revenues	—	38	—	64
<b>Operating expenses:</b>				
Research and development	2,066	1,532	7,005	4,596
Selling, general and administrative	1,814	2,028	5,136	5,917
Goodwill and intangible impairment	—	—	—	—
Restructuring costs	—	—	—	—
<b>Total operating expenses</b>	<b>3,880</b>	<b>3,560</b>	<b>12,141</b>	<b>10,513</b>
Operating loss	(3,880)	(3,522)	(12,141)	(10,449)
<b>Other income (expense):</b>				
Costs associated with aborted 2004 IPO	—	—	—	—
Payment under guarantee	—	—	—	—
Change in valuation of Economic Rights	—	(63)	—	27
Change in valuation of other liabilities measured at fair value	440	1	643	51
Foreign exchange (losses)/gains	28	6	(59)	237
Interest income	9	5	33	17

Interest expense	—	—	—	—
Other income	—	1	—	77
Total other income (expense).	477	(50)	617	409
<b>Loss from continuing operations before taxes</b>	(3,403)	(3,572)	(11,524)	(10,040)
Income tax benefit	126	419	443	714
<b>Net loss from continuing operations</b>	(3,277)	(3,153)	(11,081)	(9,326)
<b>Discontinued operations:</b>				
Income (loss) from discontinued operations, net of tax	(168)	1,263	(504)	904
<b>Net loss</b>	(3,445)	(1,890)	(11,585)	(8,422)
Dividends on preferred ordinary shares	—	—	—	—
Deemed dividend on convertible exchangeable preferred shares	—	—	—	—
Dividend on convertible exchangeable preferred shares	(182)	(182)	(546)	(546)
<b>Net loss applicable to common shareholders</b>	<u>\$ (3,627)</u>	<u>\$ (2,072)</u>	<u>\$ (12,131)</u>	<u>\$ (8,968)</u>
Net loss per share, continuing operations — Basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.37)</u>	<u>\$ (1.58)</u>	<u>\$ (1.13)</u>
Net income (loss) per share, discontinued operations — Basic and diluted	<u>\$ (0.02)</u>	<u>\$ 0.15</u>	<u>\$ (0.07)</u>	<u>\$ 0.11</u>
Net loss per share — Basic and diluted	<u>\$ (0.47)</u>	<u>\$ (0.25)</u>	<u>\$ (1.73)</u>	<u>\$ (1.09)</u>
Weighted average common shares outstanding.	<u>7,673,096</u>	<u>8,429,269</u>	<u>6,997,391</u>	<u>8,227,721</u>

**CYCLACEL PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(In \$000s, except share amounts)**

	<b>December 31, 2011</b>	<b>September 30, 2012</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 24,449	\$ 17,837
Prepaid expenses and other current assets	1,069	1,235
Current assets of discontinued operations	<u>313</u>	<u>881</u>
<b>Total current assets</b>	25,831	19,953
Property, plant and equipment (net)	167	140
Long-term assets of discontinued operations	<u>—</u>	<u>433</u>
<b>Total assets</b>	<u>\$ 25,998</u>	<u>\$ 20,526</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,717	\$ 1,642
Accrued liabilities and other current liabilities	4,183	4,127
Economic rights	—	1,070
Other liabilities measured at fair value	71	20
Current liabilities of discontinued operations	<u>527</u>	<u>438</u>
<b>Total current liabilities</b>	<u>6,498</u>	<u>7,297</u>
<b>Total liabilities</b>	<u>6,498</u>	<u>7,297</u>
<b>Stockholders' equity:</b>		

Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2011 and September 30, 2012; 1,213,142 shares issued and outstanding at December 31, 2011 and September 30, 2012. Aggregate preference in liquidation of \$13,708,505 and \$14,254,419 at December 31, 2011 and September 30, 2012, respectively	1	1
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2011 and September 30, 2012; 7,745,779 and 8,434,292 shares issued and outstanding at December 31, 2011 and September 30, 2012, respectively	8	8
Additional paid-in capital	276,498	278,655
Accumulated other comprehensive loss	57	51
Deficit accumulated during the development stage	<u>(257,064)</u>	<u>(265,486)</u>
<b>Total stockholders' equity</b>	<u>19,500</u>	<u>13,229</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 25,998</u>	<u>\$ 20,526</u>

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