



May 14, 2012

## Cyclacel Reports First Quarter 2012 Financial Results

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

BERKELEY HEIGHTS, N.J., May 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 first quarter ended March 31, 2012.

The net loss for the first quarter of 2012 was \$3.0 million as compared to a net loss of \$4.6 million for the same period in 2011. As of March 31, 2012, cash and cash equivalents totaled \$23.6 million. The Company's net loss applicable to common stockholders for the first quarter of 2012 was \$3.1 million or \$0.06 per basic and diluted share, compared to a net loss applicable to common stockholders of \$4.8 million or \$0.10 per basic and diluted share for the first quarter of 2011.

"Cyclacel continues to open new sites and enroll patients in the SEAMLESS Phase 3 trial of sapacitabine as front-line treatment in acute myeloid leukemia, or AML," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are excited about the interest that investigators are showing in sapacitabine, as evidenced by the completion of enrollment in the Phase 2 portion of the investigator-led, randomized Phase 2/3 "Pick a Winner Programme / LI-1 Trial" comparing sapacitabine with low-dose cytarabine, and look forward to the results of the study later this year. We are also encouraged by the interim results reported earlier this year with sapacitabine as a second line treatment of older patients with myelodysplastic syndromes (MDS) and the ongoing Phase 1 study of sapacitabine in patients with solid tumors. We look forward to reporting new data from both of these studies shortly."

### Business Highlights

- In February 2012, reported new topline response data from an ongoing, multicenter, Phase 2 randomized trial of oral sapacitabine capsules, a novel nucleoside analogue, in older patients with MDS after treatment failure of hypomethylating agents, such as azacitidine and/or decitabine. More than 50% of patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival.
- In March 2012, entered into a purchase agreement with certain existing institutional stockholders raising \$2.9 million of proceeds, net of certain fees and expenses. The proceeds from the financing will be used to fund ongoing litigation-related expenses involving specified Cyclacel intellectual property.
- In April 2012, presented preclinical results for three Cyclacel compounds, sapacitabine, Polo-Like Kinase 1 (Plk1) and Aurora A kinase inhibitors including CY116, at the 103<sup>rd</sup> Annual Meeting of the American Association of Cancer Research.
- 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 to date. Approximately 40% of patients are still alive and longer follow-up is needed to assess overall survival.

### First Quarter 2012 Financial Results

#### Product Revenue

Revenues for both of the three months ended March 31, 2012 and 2011 were \$0.2 million. Cyclacel's product revenues were comprised of sales of Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

#### Research and Development Expenses

Research and development expenses in the first quarter of 2012 were \$1.3 million compared to \$3.1 million for the same period in 2011. The decrease in costs of \$1.8 million was primarily due to \$1.6 million of contractual expenses recognized during the three months ended March 31, 2011, related to a milestone payment to Daiichi Sankyo triggered by the opening of enrollment

in the SEAMLESS Phase 3 trial.

## **Selling, General and Administrative Expenses**

Total selling, general and administrative expenses for the first quarter of 2012 were \$2.0 million, compared to \$1.8 million for the same period in 2011 with the \$0.2 million increase primarily related to professional and consultancy costs.

## **Cash and Cash Equivalents**

As of March 31, 2012, Cyclacel's cash and cash equivalents were \$23.6 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 on-going 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 2<sup>nd</sup> 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 May 14, 2012 at 4:30 p.m. Eastern Time to review the first quarter results. Conference call and webcast details are as follows:

Conference call information:

U.S./Canada call: (877) 493-9121/ international call: (973) 582-2750  
U.S./Canada archive: (800) 585-8367 / international archive: (404) 537-3406  
Code for live and archived conference call is 78862915

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. Sapacitabine (CYC682), an orally-available, cell cycle modulating, nucleoside analogue, is in the SEAMLESS Phase 3 trial being conducted under an SPA with the FDA for the front-line treatment of acute myeloid leukemia (AML) in the elderly and Phase 2 studies for AML, myelodysplastic syndromes, solid tumors including lung cancer and chronic lymphocytic leukemia. Seliciclib (CYC202 or R-roscovitine), an orally-available, CDK (cyclin dependent kinase) inhibitor, is 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 ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. 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](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)**

	Three Months Ended		Period from
	March 31,	March 31,	August 13, 1996 (inception) to March 31,
	2011	2012	2012
<b>Revenues:</b>			
Collaboration and research and development revenue	\$ —	\$ —	\$ 3,100
Product revenue	192	161	3,182
Grant revenue	—	—	3,648
	<u>192</u>	<u>161</u>	<u>9,930</u>
<b>Operating expenses:</b>			
Cost of goods sold	106	94	1,846
Research and development	3,080	1,347	187,146
Selling, general and administrative	1,806	1,996	91,483
Goodwill and intangible impairment	—	—	7,934
Restructuring costs	—	—	2,634
<b>Total operating expenses</b>	<u>4,992</u>	<u>3,437</u>	<u>291,043</u>
Operating loss	(4,800)	(3,276)	(281,113)
<b>Other income (expense):</b>			
Costs associated with aborted 2004 IPO	—	—	(3,550)
Payment under guarantee	—	—	(1,652)
Change in valuation of Economic Rights	—	(56)	(56)
Change in valuation of other liabilities measured at fair value	78	42	6,413
Foreign exchange (losses)/gains	(68)	114	(4,259)
Interest income	11	6	13,731
Interest expense	—	—	(4,677)
Other income	—	47	47
Total other income (expense)	<u>21</u>	<u>153</u>	<u>5,997</u>
<b>Loss before taxes</b>	(4,779)	(3,123)	(275,116)
Income tax benefit	191	168	18,612
<b>Net loss</b>	<u>(4,588)</u>	<u>(2,955)</u>	<u>(256,504)</u>
Dividends on preferred ordinary shares	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	(3,515)
Dividend on convertible exchangeable preferred shares	<u>(182)</u>	<u>(182)</u>	<u>(3,839)</u>
<b>Net loss applicable to common shareholders</b>	<u>\$ (4,770)</u>	<u>\$ (3,137)</u>	<u>\$ (301,981)</u>

Net loss per share — Basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>
Weighted average common shares outstanding	<u>46,572,180</u>	<u>54,761,620</u>

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

	<b>December 31, 2011</b>	<b>March 31, 2012</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 24,449	\$ 23,640
Inventory	182	109
Prepaid expenses and other current assets	<u>1,200</u>	<u>1,423</u>
<b>Total current assets</b>	<b>25,831</b>	<b>25,172</b>
Property, plant and equipment (net)	<u>167</u>	<u>166</u>
<b>Total assets</b>	<b><u>\$ 25,998</u></b>	<b><u>\$ 25,338</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,763	\$ 1,116
Accrued liabilities and other current liabilities	4,664	4,504
Economic rights	—	1,153
Warrant and other liabilities measured at fair value	<u>71</u>	<u>29</u>
<b>Total current liabilities</b>	<b>6,498</b>	<b>6,802</b>
<b>Total liabilities</b>	<b><u>6,498</u></b>	<b><u>6,802</u></b>
<b>Stockholders' equity:</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2011 and March 31, 2012; 1,213,142 shares issued and outstanding at December 31, 2011 and March 31, 2012. Aggregate preference in liquidation of \$13,708,505 and \$13,890,476 at December 31, 2011 and March 31, 2012, respectively	1	1
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2011 and March 31, 2012; 54,220,458 and 58,993,414 shares issued and outstanding at December 31, 2011 and March 31, 2012	54	59
Additional paid-in capital	276,452	278,430
Accumulated other comprehensive loss	57	65
Deficit accumulated during the development stage	<u>(257,064)</u>	<u>(260,019)</u>
<b>Total stockholders' equity</b>	<b><u>19,500</u></b>	<b><u>18,536</u></b>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 25,998</u></b>	<b><u>\$ 25,338</u></b>

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