



May 11, 2016

## Cyclacel Pharmaceuticals Reports First Quarter 2016 Financial Results

### Conference Call Scheduled May 11, 2016 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., May 11, 2016 (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, 2016.

The Company's net loss applicable to common shareholders for the first quarter ended March 31, 2016 was \$3.1 million, or \$0.09 per basic and diluted share, compared to net loss applicable to common shareholders of \$5.0 million, or \$0.19 per basic and diluted share for the first quarter ended March 31, 2015. As of March 31, 2016, cash and cash equivalents totaled \$17.1 million.

"In SEAMLESS, our Phase 3 pivotal study in acute myeloid leukemia (AML), approximately 2.6% of required events remain to be observed before mature data become available," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The primary endpoint of the study is overall survival. After top-line data readout, the mature data will be evaluated for submissibility to regulatory authorities. In parallel, we have been progressing our CDK inhibitor programs. We have reported encouraging interim data from the ongoing Phase 1/2 combination trial of seliciclib and sapacitabine in solid tumors, including durable partial responses and stable disease in patients with BRCA positive breast, ovarian and pancreatic cancers. Updated data from this combination study will be reported in an oral presentation at the 2016 ASCO Annual Meeting. In light of these data and investigator interest, we started enrollment of an extension cohort in a BRCA-enriched population of breast cancer patients. We continue to enroll patients in a first-in-human, Phase 1 study of CYC065, our second-generation CDK2/9 inhibitor, in patients with solid tumors and lymphomas. Data presented at the AACR Annual Meeting 2016 highlighted CYC065's potential as an agent to treat hematological malignancies, such as B-cell lymphoma. The Cyclacel team continues to pursue the vision of our founders, as appreciation of the importance of CDK inhibitors is increasing among the medical community."

### Recent Business Highlights

#### *SEAMLESS Study*

- | Continued follow up of patients enrolled in SEAMLESS, a Phase 3 study of orally-administered sapacitabine alternating with intravenous decitabine compared to decitabine alone, as first-line treatment in patients aged 70 years or older with AML who are unfit or refused intensive chemotherapy.
- | Approximately 2.6% of the pre-specified events remain to be observed until mature data become available for analysis.

#### *Cyclin Dependent Kinase (CDK) 2/9 Inhibitor Programs*

- | Continued patient follow-up in a Phase 1/2 combination study of seliciclib and sapacitabine in patients with advanced solid tumors. In the first part of the study, several patients with BRCA positive breast, ovarian and pancreatic cancers achieved durable partial responses and stable disease.
- | Started enrollment of an extension cohort in a BRCA-enriched population of patients with breast cancer.
- | Dosed the fourth dose escalation level in the first-in-human, Phase 1 trial of CYC065, a second-generation CDK2/9 inhibitor, to evaluate safety, tolerability and pharmacokinetic profile in patients with solid tumors and lymphomas.
- | Presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting 2016 demonstrating the therapeutic potential of CYC065 as a targeted anti-cancer agent in B-cell lymphoma, including double-hit lymphomas, and beneficial combinations with Bcl-2 (venetoclax) and BET inhibitors. The data validate the mechanism of action of CYC065, which is to reduce MYC and Mcl-1 levels, both of which can be elevated in B-cell lymphoma.

### Cyclacel's Key Milestones for 2016

#### *Sapacitabine in SEAMLESS*

- | Continue follow-up of patients until the requisite number of events occur, which is anticipated around the end of the first half of 2016.
- | Report top-line results.

- | Determine submissibility to regulatory authorities for marketing approval following analysis of the mature data set.
- | Progress a Paediatric Investigation Plan for sapacitabine with the European Medicines Agency.

### ***Sapacitabine in myelodysplastic syndromes (MDS):***

- | Initiate a Phase 1/2 trial of sapacitabine in combination with other agents to determine safety and tolerability.
- | Plan a Phase 2 randomized controlled trial (RCT) of sapacitabine in combination with other agents following review of all relevant clinical data with mature follow-up.

### ***CDK Inhibitor Programs***

- | Progress the seliciclib and sapacitabine Phase 1/2 extension study in a breast cancer patient population enriched for BRCA mutations.
- | Report at an oral presentation at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting updated seliciclib and sapacitabine Phase 1/2 data in patients with advanced solid tumors.
- | Report top-line results of the CYC065 Phase 1 trial in patients with solid tumors and lymphomas.
- | Report data when available from on-going investigator sponsored trials (ISTs) evaluating seliciclib in patients with Cushing's disease, rheumatoid arthritis, and in cystic fibrosis through a license and supply agreement with ManRos Therapeutics.

### **First Quarter 2016 Financial Results**

#### ***Grant Revenue***

Revenue for the three months ended March 31, 2016 was \$0.1 million compared to \$0.5 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 to IND and 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 decreased to \$2.5 million for the three months ended March 31, 2016 compared to \$4.3 million for the same period in the previous year. The decrease was primarily due to reduced study and clinical supply costs associated with the SEAMLESS Phase 3 trial, which completed enrollment in December 2014, offset by increased expenditures primarily related to the first-in-human, Phase 1 study of CYC065 and grant supported research and development.

#### ***General and Administrative Expenses***

General and administrative expenses for the three months ended March 31, 2016 decreased to \$1.4 million compared to \$1.5 million for the same period in 2015.

Based on current plans, the Company estimates that it has capital resources to reach beyond the final analysis of SEAMLESS and continue existing programs through the end of 2017.

#### ***Conference call and Webcast Information***

Cyclacel will conduct a conference call on May 11, 2016 at 4:30 p.m. EDT to review the quarterly 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 5438737

For the live and archived webcast, please visit the Corporate Presentations and Events 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, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial, which has completed enrollment and is being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other indications including myelodysplastic syndromes (MDS). Cyclacel's pipeline includes an oral regimen of seliciclib in combination with sapacitabine in a Phase 1/2

study of patients with solid tumors, including BRCA positive cancers, and CYC065, a novel CDK2/9 inhibitor, in a Phase 1 study of patients with solid tumors and lymphomas with potential utility in both hematological malignancies and solid tumors. 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 more 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.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In \$000s, except share and per share amounts)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2016</b>
<b>Revenues:</b>		
Grant revenue	\$ 512	\$ 139
<b>Total revenues</b>	<u>512</u>	<u>139</u>
<b>Operating expenses:</b>		
Research and development	4,342	2,499
General and administrative	1,468	1,384
<b>Total operating expenses</b>	<u>5,810</u>	<u>3,883</u>
<b>Operating loss</b>	<u>(5,298)</u>	<u>(3,744)</u>
Other income (expense):		
Change in valuation of financial instruments associated with stock purchase agreement	(20)	—
Foreign exchange gains (losses)	(378)	180
Interest income	1	10
Other income, net	20	20
Total other income (expense)	<u>(377)</u>	<u>210</u>
<b>Loss from continuing operations before taxes</b>	<u>(5,675)</u>	<u>(3,534)</u>
Income tax benefit	763	493
<b>Net loss</b>	<u>(4,912)</u>	<u>(3,041)</u>
Dividend on convertible exchangeable preferred shares	(50)	(50)
<b>Net loss applicable to common stockholders</b>	<u>\$ (4,962)</u>	<u>\$ (3,091)</u>
<b>Basic and diluted earnings per common share:</b>		
Net loss per share?—?basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.09)</u>
Weighted average common shares outstanding	<u>26,067,078</u>	<u>35,582,492</u>

**CYCLACEL PHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS**

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

	<b>December 31, 2014</b>	<b>March 31, 2015</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 20,440	\$ 17,115
Prepaid expenses and other current assets	4,051	4,120
Current assets of discontinued operations	75	75
Total current assets	24,566	21,310
Property, plant and equipment (net)	198	151
Total assets	\$ 24,764	\$ 21,461
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,940	\$ 1,582
Accrued and other current liabilities	3,738	3,739
Current liabilities of discontinued operations	75	75
Total current liabilities	5,753	5,396
Other liabilities	176	166
Total liabilities	5,929	5,562
Stockholders' equity	18,835	15,899
Total liabilities and stockholders' equity	\$ 24,764	\$ 21,461

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