

# **Cyclacel Reports Second Quarter 2013 Financial Results**

## Conference Call Scheduled on August 14, 2013 at 4:30 p.m. Eastern Time

BERKELEY HEIGHTS, N.J., Aug. 14, 2013 (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, 2013.

The net income for the second quarter of 2013 was \$1.5 million and the net loss for the second quarter of 2012 was \$3.6 million. As of June 30, 2013, cash and cash equivalents totaled \$33.7 million. The Company's net income applicable to common shareholders for the second quarter of 2013 was \$1.4 million, which includes \$5.5 million of income received in April 2013 related to a transaction as detailed below, or \$0.10 per basic and diluted share, compared to a net loss applicable to common shareholders of \$3.8 million or \$0.45 per basic and diluted share for the second quarter of 2012.

"This quarter has been notable as we recorded a net income result, significantly strengthened our balance sheet and made progress in the clinic. We added approximately \$24 million to our cash through an underwritten offering and the sale of four Cyclacel romidepsin-related patients. We have enrolled over 40% of the required patients in SEAMLESS, our pivotal, Phase 3 study of sapacitabine as frontline treatment in elderly patients with acute myeloid leukemia (AML)," said Spiro Rombotis, Cyclacel's President and Chief Executive Officer. "We have also signed an agreement with a contract research organization to expand SEAMLESS into Western Europe, which we anticipate will approximately double the number of enrolling sites. Following recent capital inflows, we expect our existing cash to fund us beyond the planned completion of the SEAMLESS study."

"In other programs the updated survival data from our Phase 2 study of sapacitabine in older patients with myelodysplastic syndromes (MDS) after treatment failures of hypomethylating agents continue to be impressive and nearly doubled the expected median overall survival. We expect to report the final results from this study at an upcoming medical conference. We were also pleased to have our data from the ongoing Phase 1 study of the sequential administration of sapacitabine and seliciclib in patients with advanced solid tumors who carry BRCA mutations highlighted at an American Association of Cancer Research (AACR) press conference regarding major developments reported during the AACR Annual Meeting. In addition, dismissal of the litigation with Celgene will allow us to concentrate on the development of our pipeline. We look forward to reporting updated data from our other ongoing studies," added Mr. Rombotis.

#### **Business Highlights**

- Announced updated median overall survival data from an ongoing, multicenter, Phase 2 randomized trial of oral sapacitabine in older patients with intermediate-2 or high-risk MDS after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine. Median overall survival to date for all 63 patients treated is approximately 9 months. Median overall survival for each of the three randomization schedules is approximately 10 months for Arm G, 10 months for Arm H and 8 months for Arm I. The 30-day mortality for all patients is 5%.
- Reported at the 104th Annual Meeting of the AACR, updated data from an open label, single arm, Phase 1 escalation trial of the Company's sapacitabine, a nucleoside analogue, and seliciclib, a cyclin-dependent kinase (CDK) inhibitor, as an all-oral, sequentially-administered regimen in heavily-pretreated patients with advanced solid tumors. To date, 38 patients with incurable solid tumors and adequate organ function have been enrolled, 16 of which were found to be BRCA mutation carriers. Four patients with BRCA-deficient, breast, ovarian and pancreatic cancers achieved confirmed partial responses with promising durability, with the longest lasting more than 78 weeks. Stable disease of 12 weeks or more was observed in eight additional patients, including two with BRCA-deficient, ovarian and breast cancers, lasting 64 weeks and 21 weeks, respectively. The AACR Annual Meeting Program Committee selected this study for inclusion at a press conference highlighting major developments reported during the AACR's 104<sup>th</sup> Annual Meeting.
- Received \$5.5 million from Celgene Corporation ("Celgene") for the sale of four Cyclacel romidepsin-related patents to Celgene and dismissal of all claims in the related patent litigation.
- Closed an underwritten offering for net proceeds of approximately \$19.0 million after deduction of offering expenses.
- Announced that seliciclib, our oral CDK inhibitor, is to be evaluated in an investigator-initiated clinical study to treat
  rheumatoid arthritis (RA) supported by an approximately \$1.5 million grant from the UK's Medical Research Council.
  Enabled by the clinical development experience in solid tumors, investigators believe that seliciclib's mechanism of action
  and oral administration route may be of benefit in treating patients with RA.

#### Second Quarter 2013 Financial Results

#### **Research and Development Expenses**

Research and development expenses in the second quarter of 2013 were \$2.6 million compared to \$1.7 million for the same period in 2012 with the increase of \$0.9 million primarily due to clinical trial and manufacturing costs.

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

Total general and administrative expenses for the second quarter of 2013 were \$1.8 million, compared to \$2.1 million for the same period in 2012 with the decrease of \$0.3 million primarily related to professional and consultancy costs including legal fees.

## **Cash and Cash Equivalents**

As of June 30, 2013, Cyclacel's cash and cash equivalents were \$33.7 million compared to \$16.4 million as of December 31, 2012. The increase in cash and cash equivalents was due primarily to net proceeds of \$19.0 million from the underwritten offering and a net \$5.0 million from the sale of four Cyclacel patents partially offset by net spending on operating activities of \$6.7 million.

#### Cyclacel's Key Goals for the next 12 Months

- Continue enrollment in the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Report upcoming DSMB reviews of SEAMLESS for safety every 100 patients and for futility when 212 pooled events have been observed;
- Report primary endpoint Phase 2 sapacitabine survival data in MDS after treatment failure of hypomethylating agents;
- Announce registration-directed, clinical development plan for sapacitabine in MDS after treatment failure of hypomethylating agents; and
- Report updated data from the Phase 1 study of sapacitabine and seliciclib in patients with advanced solid tumors, including BRCA carriers.

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

Cyclacel will conduct a conference call on August 14, 2013 at 4:30 p.m. Eastern Time to review the second quarter results. Conference call and webcast details are as follows:

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 27460381

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, 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 BRCA 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 the Company's most recent Annual Report on Form 10-K and other periodic and other filings Cyclacel files 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 Cyclacel assumes 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)
(Unaudited)

Period from

	Three Mont		Six Month June		August 13, 1996 (inception) to June 30,
	2012	2013	2012	2013	2013
Revenues:					
Collaboration and research and development revenue	\$ <i>—</i>	<b>\$</b> —	\$ <i>—</i>	\$ <i>—</i>	\$3,100
Grant revenue	26	264	26	476	4,193
Total revenues	26	264	26	476	7,293
Operating expenses:					
Research and development	1,717	2,631	3,064	4,211	196,602
General and administrative	2,121	1,787	3,889	4,470	93,881
Goodwill and intangibles impairment	_	_	_	_	2,747
Other restructuring costs					2,634
Total operating expenses	3,838	4,418	6,953	8,681	295,864
Operating loss	(3,812)	(4,154)	(6,927)	(8,205)	(288,571)
Other income (expense):					
Costs associated with aborted 2004 IPO	_	_	_	_	(3,550)
Payment under guarantee	_	_	_	_	(1,652)
Non-cash consideration associated with stock purchase agreement	_	_	_	_	(423)
Change in valuation of Economic Rights	146	_	90	570	547
Change in valuation of liabilities measured at fair value	8	_	50	_	6,378
Foreign exchange gain (loss)	117	(101)	231	19	(3,986)
Interest income	6	3	12	4	13,751
Interest expense	_	_	_	_	(4,567)
Other income, net	29	5,500	<u>76</u>	5,504	5,581
Total other income	306	5,402	459	6,097	12,079
(Loss) income from continuing operations before taxes	(3,506)	1,248	(6,468)	(2,108)	(276,492)
Income tax benefit, net	127	230	295	488	20,283
Net (loss) income from continuing operations	(3,379)	1,478	(6,173)	(1,620)	(256,209)
Discontinued operations:					
(Loss) income from discontinued operations	(198)	24	(359)	50	(11,759)

Income tax on discontinued operations		(10)		(20)	(357)
Net (loss) income from discontinued operations	(198)	14	(359)	30	(12,116)
Net (loss) income	(3,577)	1,492	(6,532)	(1,590)	(268,325)
Dividends on preferred ordinary shares	_	_	_	_	(38,123)
Deemed dividend on convertible exchangeable preferred shares	_	_	_	(8,366)	(11,881)
Dividend on convertible exchangeable preferred shares	(182)	(63)	(364)	(185)	(4,570)
Net (loss) income applicable to common shareholders	\$ (3,759)	\$1,429	\$ (6,896)	\$ (10,141)	\$ (322,899)
Basic earnings per share of common stock:					
Net (loss) income per share, continuing operations	\$ (0.42)	\$0.10	\$ (0.80)	\$ (0.86)	
Net (loss) income per share, discontinued operations	\$ (0.02)	\$0.00	\$ (0.04)	\$0.00	
Net (loss) income applicable to common shareholders	\$ (0.45)	\$0.10	\$ (0.85)	\$ (0.86)	
Diluted earnings per share of common stock:					
Net (loss) income per share, continuing operations	\$ (0.42)	\$0.10	\$ (0.80)	\$ (0.86)	
Net (loss) income per share, discontinued operations	\$ (0.02)	\$0.00	\$ (0.04)	\$0.00	
Net (loss) income applicable to common shareholders	\$ (0.45)	\$0.10	\$ (0.85)	\$ (0.86)	
Weighted average shares of common stock outstanding:					
Basic	8,428,154	13,855,442	8,125,621	11,849,270	
Diluted	8,428,154	13,927,371	8,125,621	11,849,270	

# CYCLACEL PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

(In \$000s) (Unaudited)

	As of December 31, 2012	As of June 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$16,412	\$33,668
Prepaid expenses and other current assets	1,599	2,670
Current assets of discontinued operations	861	817
Total current assets	18,872	37,155
Property, plant and equipment (net)	129	169
Long-term assets of discontinued operations	353	186
Total assets	\$19,354	\$37,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,259	\$2,437
Accrued and other current liabilities	5,601	3,797
Economic Rights measured at fair value	1,120	_
Other liabilities measured at fair value	20	20
Current liabilities of discontinued operations	335	325

Total current liabilities	9,335	6,579
Total liabilities	9,335	6,579
Stockholders' equity:		
Preferred stock	1	_
Common stock	9	17
Additional paid-in capital	280,211	311,125
Accumulated other comprehensive income (loss)	48	(5)
Deficit accumulated during the development stage	(270,250)	(280,206)
Total stockholders' equity	10,019	30,931
Total liabilities and stockholders' equity	\$19,354	\$37,510

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