



May 13, 2013

Cyclacel Reports First Quarter 2013 Financial Results

Conference Call Scheduled on May 13, 2013 at 4:30 p.m. Eastern Time

BERKELEY HEIGHTS, N.J., May 13, 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 first quarter ended March 31, 2013.

The net loss for the first quarters of 2013 and 2012 was \$3.1 million and \$3.0 million, respectively. As of March 31, 2013, cash and cash equivalents totaled \$14.1 million, which does not include \$5.5 million received in April 2013 related to a non-dilutive transaction as detailed below. The Company's net loss applicable to common stockholders for the first quarter of 2013 was \$11.6 million, which includes a one-time non-cash charge of approximately \$8.4 million of deemed dividend on convertible exchangeable preferred shares, or \$1.18 per basic and diluted share, compared to a net loss applicable to common stockholders of \$3.1 million or \$0.40 per basic and diluted share for the first quarter of 2012.

"We continued to make progress in our SEAMLESS pivotal, Phase 3 study of sapacitabine as frontline treatment in elderly patients with acute myeloid leukemia (AML) having surpassed during the quarter one third of the required enrollment. We are excited that 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 double the expected median overall survival," said Spiro Rombotis, Cyclacel's President and Chief Executive Officer. "We are also encouraged by the responses seen from the ongoing Phase 1 study of the sequential administration of sapacitabine and seliciclib in patients with advanced solid tumors who carry BRCA mutations. We are pleased to have our data from this sapacitabine and seliciclib study highlighted at an American Association of Cancer Research (AACR) press conference regarding major developments reported during the AACR Annual Meeting. In addition, the \$ 5.5 million payment for the sale of four Cyclacel romidepsin-related patents and dismissal of the related litigation will allow us to concentrate on the development of our pipeline. We look forward to reporting updated data from our ongoing studies."

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 104th 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.
- Issued U.S. Patent 8,349,792 and European Patent 2,101,790 providing exclusivity until 2029 and 2027 respectively. Both patents include claims to combination treatment of sapacitabine with HDAC (histone deacetylase) inhibitors, compositions comprising sapacitabine and HDAC inhibitors, and methods of treating various cancers with such compositions, including leukemias, lymphomas and lung cancer.
- Issued an aggregate 1,513,653 common shares in exchange for an aggregate 792,460 preferred shares.

First Quarter 2012 Financial Results

Research and Development Expenses

Research and development expenses in the first quarter of 2013 were \$1.6 million compared to \$1.3 million for the same period in 2012 with the increase of \$0.3 million primarily due to clinical trial and manufacturing costs.

General and Administrative Expenses

Total general and administrative expenses for the first quarter of 2013 were \$2.7 million, compared to \$1.8 million for the same period in 2012 with the increase of \$0.9 million primarily related to professional and consultancy costs including legal fees.

Other

During the first quarter of 2013, issued an aggregate 1,513,653 common shares in exchange for an aggregate 792,460 preferred shares. As a result of these transactions, deemed dividends totaling approximately \$8.4 million were charged to the consolidated statement of operations as a one-time, non-cash expense. During the first quarter of 2013, issued 650,000 common shares to an institutional investor in consideration for aggregate proceeds of approximately \$3.4 million.

Cash and Cash Equivalents

As of March 31, 2013, Cyclacel's cash and cash equivalents were \$14.1 million compared to \$16.4 million as of December 31, 2012. The Company's cash and cash equivalents do not include the subsequent receipt of \$5.5 million for the sale of four Cyclacel romidepsin-related patents to Celgene. 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 2013

- Continue enrollment in the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Report upcoming DSMB reviews of SEAMLESS;
- Report updated Phase 2 sapacitabine 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 May 13, 2013 at 4:30 p.m. Eastern Time to review the first 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 70230723

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)

	Three Months Ended March 31,		Period from August 13, 1996 (inception) to March 31
	2012	2013	2013
Revenues:			
Collaboration and research and development revenue	\$ —	\$ —	\$3,100
Grant revenue	—	212	3,929
Total revenues	—	212	7,029
Operating expenses:			
Research and development	1,347	1,580	193,971
Selling, general and administrative	1,768	2,683	92,094
Goodwill and intangible impairment	—	—	2,747
Restructuring costs	—	—	2,634
Total operating expenses	3,115	4,363	291,446
Operating loss	(3,115)	(4,051)	(284,417)
Other income (expense):			
Costs associated with aborted 2004 IPO	—	—	(3,550)
Payment under guarantee	—	—	(1,652)
Non-cash consideration with stock purchase agreement	—	—	(423)
Change in valuation of Economic Rights	(56)	570	547
Change in valuation of other liabilities measured at fair value	42	—	6,378
Foreign exchange (losses)/gains	114	120	(3,885)
Interest income	6	1	13,748

Interest expense	—	—	(4,567)
Other income	47	4	81
Total other income (expense)	153	695	6,677
Loss from continuing operations before taxes	(2,962)	(3,356)	(277,740)
Income tax benefit	168	258	20,053
Net loss from continuing operations	(2,794)	(3,098)	(257,687)
Discontinued operations:			
(Loss) income from discontinued operations, net of tax of \$0 and \$10 for the three months ended March 31, 2012 and 2013, respectively	(161)	16	(12,130)
Net loss	(2,955)	(3,082)	(269,817)
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)	(122)	(4,507)
Net loss applicable to common shareholders	<u>\$ (3,137)</u>	<u>\$ (11,570)</u>	<u>\$ (324,328)</u>
Net loss per share, continuing operations — Basic and diluted	<u>\$ (0.38)</u>	<u>\$ (1.18)</u>	
Net income (loss) per share, discontinued operations — Basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.00)</u>	
Net loss per share — Basic and diluted	<u>\$ (0.40)</u>	<u>\$ (1.18)</u>	
Weighted average common shares outstanding	<u>7,823,089</u>	<u>9,790,474</u>	

CYCLACEL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In \$000s, except share amounts)

(Unaudited)

	As of December 31	As of March 31
	2012	2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$16,412	\$14,139
Prepaid expenses and other current assets	1,599	2,056
Current assets of discontinued operations	861	835
Total current assets	<u>18,872</u>	<u>17,030</u>
Property, plant and equipment (net)	129	184
Long-term assets of discontinued operations	353	272
Total assets	<u>\$19,354</u>	<u>\$17,486</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,259	\$2,825
Accrued liabilities and other current liabilities	5,601	3,534
Economic rights	1,120	550
Other liabilities measured at fair value	20	20
Current liabilities of discontinued operations	335	323
Total current liabilities	<u>9,335</u>	<u>7,252</u>
Total liabilities	<u>9,335</u>	<u>7,252</u>
Stockholders' equity:		

Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2012 and March 31, 2013; 1,213,142 and 420,682 shares issued and outstanding at December 31, 2012 and March 31, 2013, respectively. Aggregate preference in liquidation of \$14,436,390 and \$5,006,116 at December 31, 2012 and March 31, 2013, respectively	1	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2012 and March 31, 2013; 7,745,780 and 10,881,780 shares issued and outstanding at December 31, 2012 and March 31, 2013, respectively	9	11
Additional paid-in capital	280,211	292,114
Accumulated other comprehensive loss	48	(193)
Deficit accumulated during the development stage	<u>(270,250)</u>	<u>(281,698)</u>
Total stockholders' equity	<u>10,019</u>	<u>10,234</u>
Total liabilities and stockholders' equity	<u>\$19,354</u>	<u>\$17,486</u>

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