November 12, 2013

Cyclacel Reports Third Quarter 2013 Financial Results

Conference Call Scheduled on November 12, 2013 at 4:30 p.m. Eastern Time

BERKELEY HEIGHTS, N.J., Nov. 12, 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 third quarter ended September 30, 2013. The net loss for the third quarter of 2013 was $5.0 million versus a net loss for the third quarter of 2012 of $1.9 million. As of September 30, 2013, cash and cash equivalents totaled $34.5 million. The Company's net loss applicable to common shareholders for the third quarter of 2013 was $5.7 million, which includes $2.6 million of expense related to clinical trial drug supply, or $0.32 per basic and diluted share, compared to a net loss applicable to common shareholders of $2.1 million or $0.25 per basic and diluted share for the third quarter of 2012.

"We have been executing on our sapacitabine development plan by progressing enrollment in SEAMLESS, our pivotal, Phase 3 study in acute myeloid leukemia (AML) and our Phase 2 study in myelodysplastic syndromes (MDS). With approximately $35 million on our balance sheet, we have the resources to take us beyond the completion of SEAMLESS," stated Spiro Rombotis, Cyclacel's President and Chief Executive Officer. "SEAMLESS is close to the 50% enrollment mark from only US sites. In parallel we are expanding the study into Europe and expect to at least double the number of enrolling sites. Primary clinical outcomes from the MDS study will be reported at ASH 2013 with the aim of selecting a dosing schedule for Phase 3. We look forward to reporting the outcome of an upcoming DSMB review of SEAMLESS, MDS survival data at ASH 2013 and updates from other ongoing studies," added Mr. Rombotis.

Business Highlights

- Announced that researchers will present new data from an ongoing, multicenter, Phase 2 randomized trial of oral sapacitabine capsules, the Company's lead product candidate, in older patients with intermediate-2 or high-risk myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine, at the 55th Annual Meeting of the American Society of Hematology (ASH) in December 2013. The data will include the primary endpoint of one year survival which will enable selection of a dosing schedule for Phase 3.
- Reported that the US Patent and Trademark Office (USPTO) issued two patents extending the exclusivity of sapacitabine. The first patent claims, among others, methods of treating cancer comprising sapacitabine together with DNA methyltransferase inhibitors, including azacitidine and decitabine. The second patent claims methods of use for sapacitabine for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), including the dosing regimen used in SEAMLESS, the Company's pivotal Phase 3 study in front-line elderly AML.
- Announced updated data showing that sapacitabine has activity against a majority of ovarian cancer samples taken from patients, including resistant tumors. The data were reported at a poster presentation during the American Association of Cancer Research (AACR) conference "Advances in Ovarian Cancer from concept to clinic" held in September 2013.
- Announced that seliciclib, the Company's 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.
- Issued 805,787 additional shares of common stock allowed under a Common Stock Purchase Agreement with Aspire Capital in consideration for aggregate proceeds of $3.2 million.
- Converted 85,409 shares of preferred stock into 170,818 shares of common stock. As a result, 335,273 shares of preferred stock remain outstanding at September 30, 2013.

Third Quarter 2013 Financial Results

Research and Development Expenses

Research and development expenses in the third quarter of 2013 were $4.6 million compared to $1.5 million for the same period in 2012, with the increase of $3.1 million mainly attributable to clinical trial and manufacturing costs, including an expense of $2.6 million for clinical trial drug supply for the Company's pivotal, Phase 3 SEAMLESS trial.

General and Administrative Expenses

Total general and administrative expenses for the third quarter of 2013 were $1.5 million, compared to $2.0 million for the same period in 2012 with the decrease of $0.5 million primarily related to professional and consultancy costs, including legal fees.

Cash and Cash Equivalents

As of September 30, 2013, Cyclacel's cash and cash equivalents were $34.5 million compared to $16.4 million as of December 31, 2012. The increase in cash and cash equivalents was primarily due to net proceeds of $19.0 million from an underwritten public offering, proceeds of $6.6 million from the sale of common stock under a Common Stock Purchase Agreement, and $5.0 million, net of certain expenses, from the sale of four Cyclacel patents, partially offset by net spending on operating activities of $12.8 million.

Cyclacel's Key Goals for the next 12 Months

- Continue US enrollment and expand into Europe the SEAMLESS Phase 3 study of sapacitabine in AML;
- Report outcomes from upcoming DSMB periodic safety reviews of SEAMLESS every 100 patients and futility when 212 pooled events have been observed;
- Report at ASH 2013 the primary endpoint of the Phase 2 sapacitabine study in MDS after treatment failure of hypomethylating agents;
- Announce registration-directed, clinical development plan for sapacitabine in MDS after treatment failure of hypomethylating agents;
- Report updated data from the Phase 1 study of sapacitabine and seliciclib in patients with advanced solid tumors, including BRCA carriers; and
- Advance selected pipeline programs.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on November 12, 2013 at 4:30 p.m. Eastern Time to review the third 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 96409070

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 gBRCA 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.

CYCLACEL PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from August 13, 1996 (inception) to September 30,
	2012	2013	2012	2013	2013
Revenues:					
Collaboration and research and development revenue	$ --	$ --	$ --	$ --	$3,100
Grant revenue	38	309	64	785	4,502
Total revenues	38	309	64	785	7,602
Operating expenses:					
Research and development	1,532	4,575	4,596	8,786	201,177
General and administrative	2,028	1,529	5,917	5,999	95,410
Goodwill and intangibles impairment	--	--	--	--	2,747
Other restructuring costs	--	--	--	--	2,634
Total operating expenses	3,560	6,104	10,513	14,785	301,968
Operating loss	(3,522)	(5,795)	(10,449)	(14,000)	(294,366)
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	(63)	--	27	570	547
Change in valuation of liabilities measured at fair value	1	--	51	--	6,378
Foreign exchange gain (loss)	6	25	237	44	(3,961)
Interest income	5	8	17	12	13,759
Interest expense	--	--	--	--	(4,567)
Other income (expense), net	1	16	77	5,520	5,597
Total other (expense) income.	(50)	49	409	6,146	12,128
Loss from continuing operations before taxes	(3,572)	(5,746)	(10,040)	(7,854)	(282,238)
Income tax benefit	419	730	714	1,218	21,013
Net loss from continuing operations	(3,153)	(5,016)	(9,326)	(6,636)	(261,225)
Discontinued operations:					
(Loss) income from discontinued operations	1,263	20	904	70	(11,739)
Income tax on discontinued operations	--	(8)	--	(28)	(365)
Net income (loss) from discontinued operations	1,263	12	904	42	(12,104)
Net loss	(1,890)	(5,004)	(8,422)	(6,594)	(273,329)
Dividend on preferred ordinary shares	--	--	--	--	(38,123)
Deemed dividend on convertible exchangeable preferred shares	--	(661)	--	(9,027)	(12,542)

Dividend on convertible exchangeable preferred shares	(182)	(63)	(546)	(248)	(4,633)
Net loss applicable to common shareholders	$(2,072)	$(5,728)	$(8,968)	$(15,869)	$(328,627)
Net loss per share, continuing operations — Basic and diluted	$(0.40)	$(0.32)	$(1.20)	$(1.15)	
Net income per share, discontinued operations — Basic and diluted	$0.15	$0.00	$0.11	$0.00	
Net loss applicable to common shareholders — Basic and diluted	$(0.25)	$(0.32)	$(1.09)	$(1.15)	
Weighted average common shares outstanding	8,429,269	17,788,568	8,227,721	13,850,792	

CYCLACEL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In $000s)
(Unaudited)

	As of December 31, 2012	As of September 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$16,412	$34,487
Prepaid expenses and other current assets	1,599	2,440
Current assets of discontinued operations	861	792
Total current assets	18,872	37,719
Property, plant and equipment (net)	129	174
Long-term assets of discontinued operations	353	96
Total assets	$19,354	$37,989
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$2,259	$2,352
Accrued liabilities and other current liabilities	5,601	6,284
Economic Rights measured at fair value	1,120	--
Other liabilities measured at fair value	20	20
Current liabilities of discontinued operations	335	322
Total current liabilities	9,335	8,978
Total liabilities	9,335	8,978
Stockholders' equity:		
Preferred stock	1	--
Common stock	9	18
Additional paid-in capital	280,211	315,036
Accumulated other comprehensive income (loss)	48	(172)
Deficit accumulated during the development stage	(270,250)	(285,871)
Total stockholders' equity	10,019	29,011
Total liabilities and stockholders' equity	$19,354	$37,989

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