August 10, 2016

Cyclacel Pharmaceuticals Reports 2nd Quarter 2016 Financial Results

Conference Call Scheduled August 10, 2016 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., Aug. 10, 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 financial results and business highlights for the second quarter ended June 30, 2016.

The Company's net loss applicable to common shareholders for the second quarter ended June 30, 2016 was $3.0 million, or $1.01 per basic and diluted share, compared to net loss applicable to common shareholders of $3.4 million, or $1.19 per basic and diluted share for the second quarter ended June 30, 2015. As of June 30, 2016, cash and cash equivalents totaled $15.9 million.

"Subsequent to the end of the quarter, we achieved a key milestone in our acute myeloid leukemia (AML) SEAMLESS Phase 3 study," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The required number of events has been reached and preparations for final analysis and reporting of SEAMLESS outcomes are underway. Over the next several weeks, we will complete data cleaning and validation operations after which the database will be transferred to our statistical analysis vendor. We will subsequently report outcomes for the primary (overall survival) and secondary endpoints and determination of submissibility of the SEAMLESS data set to regulatory authorities in Europe and the United States.

In our DNA damage response program, durable antitumor activity was reported at an oral presentation at the 2016 ASCO Annual Meeting with a combination of sapacitabine and seliciclib, our CDK2/9 inhibitor, in heavily pretreated patients with breast, ovarian and pancreatic cancers who tested positive for BRCA mutations. A disease control rate of 35.6% was observed, with ongoing responding patients achieving treatment durations exceeding 1 and 4.7 years, respectively. We continue to enroll patients with solid tumors in a first-in-human, Phase 1 study of CYC065, our second-generation CDK2/9 inhibitor."

BUSINESS HIGHLIGHTS

SEAMLESS study

- Phase 3 study of oral sapacitabine capsules 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, reached the number of events required for final analysis.
- Preparations are underway for final analysis of study data.

DNA damage response program

- Oral presentation of data at 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.
- Phase 1 combination of sapacitabine and seliciclib as orally-administered treatment in 67 heavily-pretreated patients. Antitumor activity in subgroup of 45 patients with breast, ovarian and pancreatic cancers who tested positive for BRCA mutations. Disease control rate of 35.6% (1 CR, 5 PR and 10 SD). No CR or PR observed in BRCA negative patients.
- Ongoing extension cohort in BRCA positive patients with breast cancer.

Cyclin dependent kinase (CDK) inhibitor program

- Continued recruitment in Phase 1, first-in-human trial of CYC065, a CDK2/9 inhibitor, to evaluate safety, tolerability and pharmacokinetics in patients with solid tumors and lymphomas.

Corporate

- Received notification from the Listing Qualifications Staff of NASDAQ that the Company regained compliance with the minimum bid price rule for continued listing on The NASDAQ Capital Market.
- Effected a one-for-twelve reverse stock split of the Company's outstanding shares of common stock.
- Entered into an At Market Issuance Sales Agreement with FBR Capital Markets & Co. under which the Company may, from time to time, sell shares of the Company's common stock.
- Terminated Controlled Equity Offering^{SM} sales agreement with Cantor Fitzgerald & Co.

KEY UPCOMING MILESTONES

SEAMLESS study

- Study database locked in preparation for final data analysis.
- Report top-line data and determination of submissibility to regulatory authorities, anticipated in the fourth quarter 2016.
- Progress the Paediatric Investigation Plan for sapacitabine with the European Medicines Agency.

DNA damage response program

- Progress Phase 1 sapacitabine and seliciclib extension cohort in a breast cancer patient population enriched for BRCA mutations.
- Plan to add Phase 1, part 3 to include BRCA mutation positive, pancreatic and ovarian cancer patients.

CDK Inhibitor Program

- Report top-line results of the CYC065 Phase 1 trial in patients with solid tumors and lymphomas.
- Report data when available from ongoing investigator sponsored trials (ISTs) evaluating seliciclib in patients with Cushing's disease and rheumatoid arthritis. Additionally, seliciclib is being evaluated in cystic fibrosis though a license and supply agreement with ManRos Therapeutics.

Sapacitabine in myelodysplastic syndromes (MDS):

- Plan 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.

SECOND QUARTER 2016 FINANCIAL RESULTS

Grant Revenue

Revenue for the three months ended June 30, 2016 was $0.2 million, compared to $0.3 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 were $2.6 million for the three months ended June 30, 2016 and $2.6 million for the three months ended June 30, 2015.

General and Administrative Expenses

General and administrative expenses were $1.3 million for the three months ended June 30, 2016 and $1.3 million for the three months ended June 30, 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 first quarter of 2018.

CONFERENCE CALL AND WEBCAST INFORMATION:

Cyclacel will conduct a conference call on August 10, 2016 at 4:30 p.m. Eastern Time to review the second quarter 2016 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 59985383

For the live and archived webcast, please visit the Corporate Presentations and Events 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 Pharmaceuticals is a clinical-stage biopharmaceutical company using cell cycle control and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. The SEAMLESS randomized Phase 3 trial of sapacitabine as front-line treatment for AML in the elderly under an SPA with FDA has completed enrollment. Cyclacel's pipeline includes an oral combination of seliciclib (CDK2/9 inhibitor) and sapacitabine in Phase 1 in advanced solid tumors, including patients with BRCA mutations; sapacitabine in Phase 2 in MDS; and CYC065 (CDK2/9 inhibitor) in Phase 1 in solid tumors and lymphomas with potential utility based on preclinical data in other hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates. Please visit 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. 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.

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In $000s, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	**2016**	**2015**	**2016**
Revenues:				
Grant revenue	$ 296	$ 222	$ 808	$ 361
Operating expenses:				
Research and development	2,580	2,637	6,922	5,136
General and administrative	1,333	1,345	2,801	2,729
Total operating expenses	3,913	3,982	9,723	7,865
Operating loss	(3,617)	(3,760)	(8,915)	(7,504)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(4)	—	(24)	—
Foreign exchange (loss) gain	(195)	138	(573)	318
Interest income	2	13	3	23
Other income, net	62	18	82	38
Total other income (expense)	(135)	169	(512)	379
Loss before taxes	(3,752)	(3,591)	(9,427)	(7,125)
Income tax benefit	405	626	1,168	1,119
Net loss	(3,347)	(2,965)	(8,259)	(6,006)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(100)	(100)
Net loss applicable to common shareholders	$ (3,397)	$ (3,015)	$ (8,359)	$ (6,106)
Basic and diluted earnings per common share:				
Net loss per share?—?basic and diluted	$ (1.19)	$ (1.01)	$ (3.32)	$ (2.05)
Weighted average common shares outstanding	2,865,707	3,000,192	2,520,897	2,982,508

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In $000s, except share, per share, and liquidation preference amounts)

	December 31, 2015	June 30, 2016 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,440	$ 15,931

Prepaid expenses and other current assets	4,051	2,762
Current assets of discontinued operations	75	75
Total current assets	24,566	18,768
Property, plant and equipment (net)	198	109
Total assets	$ 24,764	$ 18,877
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,940	$ 1,898
Accrued and other current liabilities	3,738	3,592
Current liabilities of discontinued operations	75	75
Total current liabilities	5,753	5,565
Other liabilities	176	150
Total liabilities	5,929	5,715
Total stockholders' equity	18,835	13,162
Total liabilities and stockholders' equity	$ 24,764	$ 18,877

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