November 9, 2017

Cyclacel Pharmaceuticals Reports Third Quarter 2017 Financial Results

— Conference Call Scheduled November 9, 2017 at 4:30 p.m. ET —

BERKELEY HEIGHTS, N.J., Nov. 09, 2017 (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, 2017.

The Company's net loss applicable to common shareholders for the three months ended September 30, 2017 was $8.9 million, which includes a $7.0 million charge in the quarter related to accounting for the Series A Convertible Preferred Stock issued in the July financing, or $0.91 per share, compared to net loss applicable to common shareholders of $3.0 million, or $0.86 per share, for the third quarter of 2016. As of September 30, 2017, cash and cash equivalents totaled $26.0 million.

"Following selection of a recommended Phase 2 dose, or RP2D, for our CYC065 CDK inhibitor, we are advancing our clinical programs, led by CYC065 in selected, patient populations relevant to the drug's mechanism," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "In part 1 of an ongoing, Phase 1 study, CYC065 demonstrated durable target engagement and biomarker suppression at well tolerated doses in 11 out of 13 patients treated at the RP2D. Initial anticancer activity was observed in five patients, which included patients with relevant tumor molecular features. In parallel, we are progressing designs for further translational clinical studies to evaluate CYC065 in combination with venetoclax in chronic lymphocytic leukemia, or CLL; alone and with standard of care in solid tumors, in which we believe biomarker suppression may be beneficial; and in certain pediatric cancers. Data from the Phase 3 SEAMLESS study of sapacitabine have been selected for oral presentation at the American Society of Hematology, or ASH, Annual Meeting in December. The presentation will include additional data emerging from a comprehensive analysis of prespecified subgroups, e.g. low peripheral white blood cell count, which will form the basis of the Company's consultations with regulatory authorities. Following our July offering, we project cash resources to fund currently planned programs through the end of 2019."

Business Highlights

Transcriptional Regulation Program: CYC065 CDK inhibitor

- Part 2 of the Phase 1 translational study will evaluate additional dosing schedules in patients with advanced solid tumors, in particular those with amplification of cyclin E, Mcl-1 or MYC, including subsets of high grade serous ovarian and uterine cancers. Biospecimens will be collected for assessment of biomarkers related to CYC065's mechanism of action. In part 1 of an ongoing, first-in-human, single agent, ascending dose, Phase 1 study, prolonged reduction of Mcl-1 was observed in 11 out of 13 evaluable patients treated at the RP2D following a single dose of CYC065, which was generally well tolerated. Preliminary anticancer activity was observed in 5 patients, of which 4 were treated at the RP2D and 3 of which were reported by investigators to have molecular features of their cancers associated with CYC065's mechanism of action, including overexpression or amplification of Mcl-1, MYC and/or cyclin E. The trial is being conducted at the Dana Farber Cancer Institute in Boston.
- Discussions with principal investigators and/or cooperative groups are progressing with the objective of evaluating CYC065 in both pediatric and adult patients. One such study, to be conducted as an investigator sponsored trial, will evaluate the drug in patients with leukemias, including AML, and in particular those with mixed lineage leukemia rearrangements, or MLL-r. In parallel, the Company is discussing with investigators a potential evaluation of CYC065 in patients with neuroblastoma, a mostly pediatric life-threatening malignancy, frequently associated with MYC amplification.

DNA Damage Response (DDR) Program

- Enrollment has been completed in an extension of the Phase 1 study evaluating the combination regimen of sapacitabine and seliciclib, our first generation CDK inhibitor, in an enriched population of approximately 20 patients with BRCA positive advanced breast cancer.
- Part 3 of this study has been opened for enrolment with the objective of testing a revised dosing schedule in additional patients, including BRCA positive, ovarian and pancreatic cancer patients.

SEAMLESS Phase 3 Study

- Data from the SEAMLESS study of sapacitabine in acute myeloid leukemia, or AML, have been selected for oral presentation at the 59th ASH Annual Meeting in Atlanta, Georgia, on December 11, 2017.
- The presentation will include additional data from a comprehensive analysis of the SEAMLESS dataset with the objective of characterizing the prespecified subgroups of patients, e.g. those with low peripheral white blood cell count, who appeared to have clinically relevant benefit from the investigational treatment regimen.
- As previously reported, in the intent-to-treat population, the investigational arm of the SEAMLESS study did not reach statistically significant improvement in OS versus an active control. However, improvement in OS was observed in a stratified subgroup of patients with low baseline peripheral white blood cell count. The subgroup comprised approximately two-thirds of the study's population.
- Following analysis of the full SEAMLESS data set and database lock, the Company is developing submission materials to support consultations with European and US authorities with the objective of determining potential regulatory pathways.

July Underwritten Offering

- On July 21, 2017, the Company announced the closing of an underwritten offering, with net proceeds of approximately $13.7 million after deducting underwriting discounts and commissions and other estimated offering expenses, including full exercise of the underwriters' overallotment option. The Company issued and sold in the offering (i) 3,154,000 Class A Units, each consisting of one share of the Company's common stock, and a warrant to purchase one share of common stock, and (ii) 8,872 Class B Units, each consisting of one share of the Company's Series A Convertible Preferred Stock convertible into 500 shares of common stock at the initial conversion price, and a warrant to purchase a number of shares of common stock equal to $1,000 divided by the conversion price. The price to the public in the offering was $2.00 per Class A Unit and $1,000 per Class B Unit.
- To date, holders of 8,608 (97%) shares out of the 8,872 initially issued shares of Series A Preferred Stock have elected to convert their shares into 4,304,000 shares of common stock. Following such conversions, 11,904,521 shares of common stock and 264 (3%) shares of Series A Preferred Stock remain outstanding.

Business Highlights
Anticipated Upcoming Milestones

- Initiate CYC065 Phase 1b in relapsed/refractory CLL in combination with venetoclax, a Bcl-2 inhibitor
- Update mature data from the part 1 extension sapacitabine/seliciclib DDR study in the BRCA +ve breast cancer cohort
- Complete part 3 in the sapacitabine/seliciclib DDR study in patients with BRCA +ve cancers, including ovarian and pancreatic
- Submit CYC140 (PLK1 inhibitor) IND application
- Update CYC065 Phase 1 data in solid tumors
- Conduct regulatory authority meetings regarding the SEAMLESS study of sapacitabine in AML

Financial Highlights

Revenues for the three months and year ended September 30, 2017 were $0.0 million compared to $0.2 million for the same period of the previous year.

As of September 30, 2017, cash and cash equivalents totaled $26.0 million, compared to $16.5 million as of December 31, 2016.

Research and development expenses were $1.0 million compared to $2.4 million for the same periods in 2016.

General and administrative expenses for the three months ended September 30, 2017 decreased to $1.2 million compared to $1.3 million for the same period in 2016.

Other expense, net for the three months ended September 30, 2017 were $0.0 million, compared to $0.1 million for the same period of the previous year. The increase in other income (expense) is primarily related to foreign exchange movements.

The UK research & tax credit for the quarter was $0.2 million.

Net loss for the three months September 30, 2017 was $1.9 million compared to $2.9 million for the same period in 2016.

At of the end of the quarter the company had cash of $26.0 million.

Conference call information (November 9, 2017 at 4:30 p.m. ET):

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 4396538

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 Pharmaceuticals is a clinical-stage biopharmaceutical company using cell cycle, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. Cyclacel's transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced cancers. The DNA damage response program is evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in patients with BRCA positive, advanced solid cancers. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates. For additional information, please visit www.cyclacel.com.

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.

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

	Three Months Ended September 30,		Nine months Ended September 30,	
	2016	2017	2016	2017
Revenues:				
Grant revenue	$ 205	$ -	$ 566	$ -

Operating expenses:				
Research and development	2,409	958	7,545	3,491
General and administrative	1,273	1,154	4,002	3,802
Total operating expenses	3,682	2,112	11,547	7,293
Operating loss	(3,477)	(2,112)	(10,981)	(7,293)
Other income (expense):				
Foreign exchange gains (losses)	51	(22)	369	(65)
Interest income	8	30	31	59
Other income, net	18	28	56	907
Total other income	77	36	456	901
Loss before taxes	(3,400)	(2,076)	(10,525)	(6,392)
Income tax benefit	454	219	1,573	793
Net loss	(2,946)	(1,857)	(8,952)	(5,599)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(150)	(151)
Beneficial conversion feature of Series A convertible stock	-	(3,638)	-	(3,638)
Conversion of Series A convertible preferred stock	-	(3,373)	-	(3,373)
Net loss applicable to common shareholders	$ (2,996)	$ (8,918)	$ (9,102)	$ (12,761)
Basic and diluted earnings per common share:				
Net loss per share?—?basic and diluted	$ (0.86)	$ (0.91)	$ (2.89)	$ (2.06)
Weighted average common shares outstanding	3,473,696	9,835,441	3,145,730	6,200,783

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

	December 31, 2016	September 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,520	$ 26,025
Prepaid expenses and other current assets	3,097	1,792
Total current assets	19,617	27,817
Property, plant and equipment (net)	45	34
Total assets	$ 19,662	$ 27,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,497	$ 1,973
Accrued and other current liabilities	2,762	2,292
Total current liabilities	5,259	4,265
Other liabilities	130	128
Total liabilities	5,389	4,393
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2016 and September 30, 2017;		
6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2016 and September 30, 2017. Aggregate preference in liquidation of $4,006,512 at December 31, 2016 and September 30, 2017.	—	—
Series A preferred stock; 0 shares and 664 shares issued and outstanding at December 31, 2016 and September 30, 2017 respectively.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2016 and		

September 30, 2017; 4,256,829 and 11,697,021 shares issued and outstanding at December 31, 2016 and September 30, 2017 respectively.	4	12
Additional paid-in capital	350,051	364,843
Accumulated other comprehensive loss	(743)	(762)
Accumulated deficit	(335,039)	(340,635)
Total stockholders' equity	14,273	23,458
Total liabilities and stockholders' equity	$ 19,662	$ 27,851

SOURCE: Cyclacel Pharmaceuticals, Inc.