Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2017 Financial Results

March 28, 2018

Conference Call Scheduled March 28, 2018 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., March 28, 2018 (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 fourth quarter and full year ended December 31, 2017. The Company's net loss applicable to common shareholders for the three months and year ended December 31, 2017 was $2.1 million and $14.9 million, respectively. As of December 31, 2017, cash and cash equivalents totaled $23.9 million.

"We are greatly encouraged by our clinical progress in 2017, particularly in our transcriptional regulation program with CYC065, our lead CDK inhibitor candidate," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We have achieved clinical proof of mechanism with CYC065 by demonstrating durable reduction of Mcl-1 expression in Phase 1 patients for at least 24 hours after a single dose. We believe these unprecedented findings provide a strong rationale for evaluating CYC065 in combination with venetoclax in patients with chronic lymphocytic leukemia, or CLL, and neuroblastoma, a predominantly pediatric cancer with poor prognosis. In collaboration with an academic center and a pharmaceutical company we have developed a protocol for a Phase 1b/2 investigator-sponsored trial to evaluate combination treatment of an approved PARP inhibitor and sapacitabine in patients with BRCA mutant breast cancer. We have also completed analysis of the results from the SEAMLESS Phase 3 study of sapacitabine and plan to discuss the data with regulatory authorities. Finally, we improved our cash resources raising $14.9 million, net of expenses, which will fund currently planned programs through the first quarter of 2020. We look forward to reporting our progress during the remainder of 2018, including clinical data from our studies as they arise, such as the previously announced, oral presentation of Phase 1 data with CYC065 at the upcoming American Association for Cancer Research (AACR) 2018 Annual Meeting."

Fourth Quarter and Full-Year Highlights

Drug Development

Transcriptional Regulation Program: CYC065 CDK Inhibitor

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 recommended Phase 2 dose, or 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 were reported by investigators to have molecular features of their cancers associated with CYC065's mechanism of action, including amplification of Mcl-1, *MYC* or cyclin E. The trial is being conducted at the Dana Farber Cancer Institute in Boston. 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 Mcl-1, *MYC* or cyclin E, including subsets of high grade serous ovarian and uterine cancers. Several biomarkers relevant to CYC065's mechanism of action will be assessed.

The protocol for the Phase 1b study of a combination regimen of CYC065 and venetoclax in patients with relapsed or refractory CLL has been submitted to the US Food and Drug Administration or FDA. The study will evaluate safety, pharmacokinetics and pharmacodynamics of the combination, including biomarkers related to the mechanism of action of CYC065.

Discussions with principal investigators and/or cooperative groups progressed with the objective of evaluating CYC065 in both pediatric and adult patients with solid tumors. The Company is discussing with an investigator cooperative group a potential evaluation of CYC065 in patients with neuroblastoma, a mostly pediatric, life-threatening malignancy, frequently associated with *MYCN* amplification.

In another study, to be conducted as an investigator sponsored trial, CYC065 will be evaluated in adult and pediatric patients with leukemias, including acute myeloid leukemia, or AML, acute lymphocytic leukemia, or ALL, and in particular those with mixed lineage leukemia rearrangements, or MLL-r.

Preclinical data on the molecular rationale and therapeutic potential of CYC065 included an article published in the *Journal of National Cancer Institute*, reporting prominent antitumor activity against lung cancer cells through anaphase catastrophe, a novel, cancer specific, mechanism. CYC065 was found to be effective against lung cancer cell lines, including those with *KRAS* mutations. Additional preclinical data presented at the 2017 AACR Annual Meeting, demonstrated therapeutic potential of CYC065 as a targeted anticancer agent. CYC065 substantially inhibited growth, triggered apoptosis, and induced anaphase catastrophe in murine and human lung cancer cells with known high metastatic potential. This was in marked contrast to effects in immortalized pulmonary epithelial murine and human cells. CYC065 markedly inhibited migration and invasion of lung cancer cells and affected distinctive pathways involved in DNA damage response, apoptosis, cell cycle regulation and cell migration.

DNA Damage Response (DDR) Program

In collaboration with an academic center and a pharmaceutical company we have developed a protocol for a Phase 1b/2 investigator-sponsored trial to evaluate safety and efficacy of a combination regimen of an approved PARP inhibitor and sapacitabine in patients with BRCA mutant breast cancer.

Enrollment has been completed in an extension of part 1 of the Phase 1 study evaluating a combination regimen of sapacitabine and seliciclib, Cyclacel's first generation CDK inhibitor, in an enriched population of approximately 20 patients with BRCA positive advanced breast cancer. An ongoing part 3 of this study is testing a revised dosing schedule in additional patients, including BRCA positive, patients with breast, ovarian and pancreatic cancers.

SEAMLESS Phase 3 Study

Data from the SEAMLESS Phase 3 study of sapacitabine in elderly patients with AML were the subject of an oral presentation in December 2017 at the 59th ASH Annual Meeting. The presentation included additional data from prespecified and exploratory analysis of subgroups that may benefit from treatment with the sapacitabine-decitabine alternating regimen. The Company believes that the subgroup results have defined a patient population for whom the sapacitabine regimen may represent an improvement over low intensity treatment by decitabine alone.

The Company has completed further statistical and exploratory analyses of the results from the SEAMLESS study and is preparing briefing documents for submission to regulatory authorities with the objective of determining a potential regulatory pathway for sapacitabine in AML.

PLK1 Inhibitor; CYC140
At the 2017 AACR Annual Meeting, the Company presented preclinical data outlining the potential therapeutic utility of CYC140, a novel, polo-like kinase (PLK) 1 inhibitor, alone and in synergistic drug combinations, for the treatment of esophageal cancer and acute leukemia.

Investigator-Sponsored Trials (ISTs): Seliciclib in Rheumatoid Arthritis (RA)
The Independent Data Monitoring Committee, or IDMC, for the "TRAFIC" trial sponsored by the UK Medical Research Council, (ISRCTN 36667085) determined that part 1 of the study was successfully completed per protocol. The IDMC recommended continuation of the trial into part 2 to assess potential efficacy of seliciclib as an addition to existing anti-TNF therapy based on a composite outcome of response in patients with moderate to severe RA.

Corporate Developments
The Company raised net proceeds of approximately $13.7 million from an underwritten offering of common stock.

Cyclacel received notice from the European Patent Office of the grant of a European patent including claims to novel pharmaceutical formulations of sapacitabine.

2018 Key Upcoming Business Objectives

- Report updated CYC065 Phase 1 data in patients with advanced cancers
- Initiate CYC065 Phase 1b in relapsed/refractory CLL in combination with venetoclax
- Start enrollment in the Phase 1b/2 IST of a combination regimen of an approved PARP inhibitor and sapacitabine in patients with BRCA mutant breast cancer
- Start enrollment in the Phase 1b/2 IST of CYC065 in pediatric patients with neuroblastoma
- Update mature data from the part 1 extension of the sapacitabine and seliciclib combination in patients with BRCA positive advanced breast and complete part 3 enrollment of the sapacitabine and seliciclib combination in patients with BRCA positive, breast, ovarian and pancreatic cancers
- Submit CYC140, PLK1 inhibitor, IND application
- Conduct regulatory authority meetings regarding the SEAMLESS study of sapacitabine in AML

Financial Highlights
As of December 31, 2017, cash and cash equivalents totaled $23.9 million, compared to $16.5 million as of December 31, 2016. The increase of $7.4 million was primarily due to net proceeds of $13.7 million from a direct registered offering, $1.0 million from the sale of common stock through the ATM sales agreement with FBR Capital Markets & Co., $0.2 million warrant exercises and offset by $7.5 million of net cash used in operating activities.

There were no revenues for the three months and year ended December 31, 2017 compared to $0.3 million and $0.8 million for the same period of the previous year. The revenue is related to previously awarded, UK government grants being recognized over the period to progress IND-directed preclinical development of CYC140, a novel, PLK-1 inhibitor, which was completed in November 2016.

Research and development expenses were $0.7 million and $4.2 million for the three months and year ended December 31, 2017 as compared to $1.9 million and $9.5 million for the same periods in 2016. The decrease was primarily due to reduced study and clinical supply costs associated with completion of the SEAMLESS study and 2016 expenditure related the development of CYC140.

General and administrative expenses for the three months and year ended December 31, 2017 were $1.5 million and $5.3 million, compared to $1.5 million and $5.5 million for the same period of the previous year.

Other income (expense), net for the three months and year ended December 31, 2017 were $0.1 million and $1.0 million, compared to ($0.1) million and $0.4 million for the same period of the previous year. The increase is primarily related to income received under an Asset Purchase Agreement with Life Technologies Corporation, or LTC, (formerly Invitrogen Corporation and subsequently acquired by ThermoFisher Scientific), resulting from certain assets and intellectual property sold by the Company to LTC in December 2005.

United Kingdom research & tax credits were $0.2 million and $1.0 million for the three months and year ended December 31, 2017 as compared to $0.4 million and $2.0 million for the same periods in 2016.
Net loss for the three months and year ended December 31, 2017 were $1.9 million and $7.5 million compared to $2.8 million and $11.8 million for the same periods in 2016.

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 4857905
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 (LOSS)
(In $000s, except share and per share amounts)

	Year Ended December 31,	
	2016	**2017**
Revenues:		
Grant revenue	$ 843	$ -
Operating expenses:		
Research and development	9,477	4,237
General and administrative	5,516	5,254
Total operating expenses	14,993	9,491
Operating loss	(14,150)	(9,491)
Other income (expense):		
Foreign exchange gains (losses)	273	(39)
Interest income	37	118
Other income, net	66	949
Total other income (expense), net	376	1,028
Loss from continuing operations before taxes	(13,774)	(8,463)
Income tax benefit	1,983	993
Net loss	(11,791)	(7,470)
Dividend on convertible exchangeable preferred shares	(200)	(201)
Beneficial conversion feature of Series A convertible stock	—	(3,638)
Conversion of Series A convertible preferred stock	—	(3,537)
Net loss applicable to common shareholders	$ (11,991)	$ (14,846)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (3.50)	$ (1.95)
Weighted average common shares outstanding	3,424,976	7,631,152

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

	December 31, 2016	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,520	$ 23,910
Prepaid expenses and other current assets	3,097	$ 2,064
Total current assets	19,617	$ 25,974
Property and equipment, net	45	$ 29
Total assets	$ 19,662	$ 26,003
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,497	$ 1,558
Accrued and other current liabilities	2,762	$ 2,555
Total current liabilities	5,259	$ 4,113
Other liabilities	130	$ 124
Total liabilities	5,389	$ 4,237
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2016 and December 31, 2017; 6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2016 and December 31, 2017. Aggregate preference in liquidation of $4,006,512 at December 31, 2016 and December 31, 2017	—	—
Series A convertible preferred stock; 0 shares and 264 shares issued and outstanding at December 31, 2016 and December 31, 2017, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2016 and December 31, 2017; 4,256,829 and 11,997,447 shares issued and outstanding at December 31, 2016 and December 31, 2017, respectively.	4	12
Additional paid-in capital	350,051	$ 365,057
Accumulated other comprehensive loss	(743)	$ (794)
Accumulated deficit	(335,039)	$ (342,509)
Total stockholders' equity	14,273	$ 21,766
Total liabilities and stockholders' equity	$ 19,662	$ 26,003

SOURCE: Cyclacel Pharmaceuticals, Inc.

Primary Logo