Cyclacel Pharmaceuticals Reports First Quarter 2019 Financial Results

May 14, 2019

Conference Call Scheduled May 14, 2019 at 4:30 p.m. ET

BERKELEY HEIGHTS, N.J., May 14, 2019 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today reported financial results and business highlights for the first quarter 2019. The Company's net loss applicable to common shareholders for the three months ended March 31, 2019 was $1.9 million. As of March 31, 2019 cash and cash equivalents totaled $17.9 million.

“We continue to execute on our strategy to develop innovative therapies to overcome cancer resistance mechanisms through combinations of our candidates with approved drugs,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “Two Phase 1, dose escalation studies evaluating CYC065 in combination with venetoclax in patients with relapsed/refractory CLL and CYC140 as single agent in a first-in-human trial are open for accrual and patients have been dosed on both studies. Two additional studies evaluating combinations of CYC065 and sapacitabine with venetoclax are under review by institutional review boards. The Phase 1 study of single agent CYC065 has been amended to evaluate an oral form of CYC065. We are pleased to report that the first two patients with BRCA mutant breast cancer treated in the IST evaluating sapacitabine and olaparib have achieved tumor shrinkage. During the quarter, we also extended our projected cash runway to the end of 2020 through our ATM equity sales agreement.”

Key Company Highlights

- Data was presented at the 2019 AACR Annual Meeting from the Company's DNA damage response program with an oral, sequential regimen of sapacitabine and seliciclib from an expansion cohort in patients with BRCA mutant metastatic breast cancer. The data demonstrated that the regimen was safe and led to a clinical benefit rate of 30%. All eight PARP inhibitor naïve patients, half of the patients previously treated with platinum agents and one on previous PARP inhibitor responded. Progression on previous platinum or PARP inhibitors was associated with lack of benefit. Both sapacitabine and PARP inhibitors are more effective in cancer cells with BRCA mutations or other homologous recombination repair deficiencies.
- Based on data from the above study, the investigators are enrolling a Phase 1b/2 study with an oral, concomitant regimen of sapacitabine and olaparib in patients with BRCA mutant breast cancer. According to the investigators three patients have been dosed. The first two achieved tumor shrinkage and continue on treatment and the third has completed first cycle without dose-limiting toxicity. Dual targeting of the DNA damage response pathway with sapacitabine and olaparib may improve the current standard of care for such patients.
- Two patients have been treated in the Phase 1, dose escalation clinical trial evaluating CYC065 in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL. Preclinical data presented at the 2018 AACR showed synergistic activity of CYC065 and venetoclax combination in CLL tumor samples, including those with 17p deletions. The combination was also active in CLL samples resistant to either agent alone, suggesting that dual targeting of Mcl-1 and Bcl-2 dependent mechanisms could overcome intrinsic resistance to each individual compound.
- Two patients have been dosed in the recently opened Phase 1, first-in-human, dose escalation study evaluating CYC140 monotherapy in patients with advanced leukemias. CYC140 is a small molecule, selective polo-like-kinase 1 (PLK1) inhibitor that has demonstrated potent and selective target inhibition and high activity in xenograft models of human cancers.
- The Company raised net proceeds of approximately $4.1 million from its Common Stock Sales Agreement with H.C. Wainwright.

Key Upcoming Business Objectives

- Initiate CYC065-venetoclax Phase 1 study in patients with relapsed or refractory AML or MDS;
- Initiate sapacitabine-venetoclax Phase 1 study in patients with relapsed or refractory AML or MDS;
- Report initial data from the CYC065-venetoclax Phase 1 study in relapsed/refractory leukemias;
- Report initial data from the CYC140 Phase 1 First-in-Human study;
- Report initial data and bioavailability from the Phase 1 study of an oral formulation of CYC065;
- Report updated CYC065 Phase 1 data in patients with advanced solid cancers;

- Report data from the IST Phase 1b/2 trial of sapacitabine-olaparib combination in patients with BRCA mutant metastatic breast cancer when reported by the investigators;
- Determine regulatory pathway and submissibility of sapacitabine in elderly AML patients.

Financial Highlights

As of March 31, 2019, cash and cash equivalents totaled $17.9 million compared to $17.5 million as of December 31, 2018. The increase of $0.4 million in the three months was primarily due to net proceeds from a Common Stock Sales Agreement with H.C. Wainwright of $4.1m, offset by net cash used in operating activities of $3.7 million. The Sales Agreement was concluded in the first quarter 2019.

Research and development expenses were $1.0 million for the three months ended March 31, 2019 compared to $0.8 million for the same period in 2018.

General and administrative expenses were $1.2 million for the three months ended March 31, 2019 compared to $1.4 million for the same period in 2018.

Other income, net for the three months ended March 31, 2019 was $0.1 million compared to $0.6 million for the same period of the previous year.

The United Kingdom R&D and tax credit was $0.3 million for the three months ended March 31, 2019 compared to $0.2 million for the same period in 2018.

Net loss for the three months ended March 31, 2019 was $1.8 million compared to $1.3 million for the same period in 2018. With the projected cash-sparing benefits accruing from the MD Anderson alliance the Company believes that cash and marketable securities, which were approximately $17.9 million as of March 31, 2019, will be sufficient to finance operations through the end of 2020.

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 9383419

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 its expertise in cell cycle, transcriptional regulation and DNA damage response biology in cancer cells to develop innovative medicines. The transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced solid cancers and in combination with venetoclax in patients with advanced hematological malignancies, including CLL and AML. The DNA damage response program is evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in BRCA positive patients with advanced solid cancers and a concomitant regimen of sapacitabine and olaparib, a PARP inhibitor, in BRCA positive patients with breast cancer. CYC140, a PLK inhibitor, is in a Phase 1 first-in-human study in patients with advanced leukemias. 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.

Contacts

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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,	
	2018	**2019**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	798	1,012
General and administrative	1,364	1,192
Total operating expenses	2,162	2,204
Operating loss	(2,162)	(2,204)
Other income (expense):		
Foreign exchange gains (losses)	(4)	15
Interest income	69	79
Other income, net	566	-
Total other income (expense), net	631	94
Loss from continuing operations before taxes	(1,531)	(2,110)
Income tax benefit	182	268
Net loss from continuing operations	(1,349)	(1,842)
Net loss	(1,349)	(1,842)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (1,399)	$ (1,892)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.12)	$ (0.14)
Weighted average common shares outstanding	11,997,447	13,638,271

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

	December 31, 2018	March 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,504	$ 17,934
Prepaid expenses and other current assets	2,283	2,190
Total current assets	19,787	20,124
Property and equipment, net	36	33
Right-of-use lease asset	-	1,353
Total assets	$ 19,823	$ 21,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,719	$ 1,284
Accrued and other current liabilities	1,732	1,203
Total current liabilities	4,451	2,487
Lease liability	-	1,468
Other liabilities	100	-
Total liabilities	4,551	3,955
Stockholders' equity	15,272	17,555
Total liabilities and stockholders' equity	$ 19,823	$ 21,510

SOURCE: Cyclacel Pharmaceuticals, Inc.