Cyclacel Pharmaceuticals Reports Second Quarter 2018 Financial Results

August 9, 2018

Conference Call Scheduled August 9, 2018 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., Aug. 09, 2018 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer biology, today reported financial results and business highlights for the second quarter 2018.

The Company's net loss applicable to common shareholders for the three months ended June 30, 2018 was $1.9 million. As of June 30, 2018, cash and cash equivalents totaled $19.8 million.

“Phase 1 data presented for CYC065, our lead CDK inhibitor, at the recent American Association for Cancer Research Annual Meeting highlighted CYC065’s potential for durable suppression of Mcl-1, a protein that enables cancer cells to survive,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “The oral presentation provided proof of the drug’s mechanism in patients with advanced solid tumors. Durable suppression of Mcl-1 for at least 24 hours was demonstrated in 11 of 13 patients after a single dose of CYC065 at the recommended Phase 2 level. Suppression of the Mcl-1 mediated survival pathway leads to rapid induction of apoptosis in Mcl-1 dependent cancer cells. CYC065’s mechanism has also been shown to reverse drug resistance associated with the addiction of cancer cells to cyclin E, a partner protein of CDK2. In furtherance of these findings, we will shortly initiate a CYC065 study in combination with venetoclax in patients with relapsed/refractory chronic lymphocytic leukemia, or CLL. We are also planning additional studies in advanced leukemias. During the quarter, we also achieved an important objective with the FDA’s clearance of the IND for CYC140, an internally-discovered, novel inhibitor of Polo-like-kinase 1, or PLK1.”

Key Company Highlights

- Patient enrollment continues for part 2 of the CYC065 monotherapy Phase 1 study in patients with advanced solid tumors. Part 2 is evaluating an increased dosing frequency of 2 days per week for 2 weeks of a three-week cycle. Part 2 will also look to evaluate the efficacy of CYC065 in Mcl-1, MYC or cyclin E amplified cancers through the monitoring of select biomarkers relevant to CYC065’s mechanism of action.

- Cyclacel continues to prepare for initiation of a Phase 1 clinical trial evaluating CYC065 in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL. A poster presented at the 2018 AACR highlighted preclinical data supporting the enhanced effect of combination therapy with CYC065 and venetoclax in CLL tumor samples, including those with 17p deletions. A CYC065-venetoclax combination regimen was active in two CLL samples resistant to either agent alone supporting the hypothesis that dual targeting of Mcl-1 and Bcl-2 dependent mechanisms could induce synergistic cell death.

- Patient enrollment continues for part 3 of the Phase 1 combination study evaluating sapacitabine and seliciclib (Cyclacel’s first-generation CDK inhibitor) in patients with advanced cancer, including BRCA positive breast, ovarian and pancreatic cancer patients. The objective of part 3 of the study is to test a revised dosing schedule to evaluate safety and initial efficacy.

- Cyclacel has submitted briefing documents and scheduled meetings with certain European regulatory authorities with the objective of determining a potential regulatory pathway for sapacitabine in elderly AML. The Company believes that the subgroup findings from the Phase 3 SEAMLESS study have defined a patient population for whom the sapacitabine regimen may represent an improvement over low intensity treatment by decitabine alone.

- The U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for CYC140, the Company’s internally-discovered, novel inhibitor of Polo-like-kinase 1, or PLK1. A first-in-human Phase 1 study is being planned.

Key Upcoming Business Objectives

- Initiate Phase 1b clinical trial evaluating CYC065 in combination with venetoclax in patients with relapsed or refractory CLL;

- Start enrollment in a Phase 1b/2 IST of sapacitabine and an approved PARP inhibitor combination treatment in patients with BRCA mutant breast cancer;

- Initiate CYC065 Phase 1b in advanced leukemias;
- Provide a clinical update from part 2 of the Phase 1 study evaluating CYC065 monotherapy in patients with advanced cancers;
- Conduct EU regulatory authority meetings regarding the SEAMLESS study of sapacitabine in elderly AML;
- Initiate Phase 1 trial evaluating CYC140, a PLK1 inhibitor; and
- Provide clinical update and complete enrollment of part 3 of the Phase 1 study of the sapacitabine and seliciclib combination in BRCA positive, breast, ovarian and pancreatic cancer patients.

Financial Highlights

As of June 30, 2018, cash and cash equivalents totaled $19.8 million, compared to $23.9 million as of December 31, 2017. The decrease of $4.1 million was primarily due to net cash used in operating activities.

Research and development expenses were $1.2 million for each of the three months ended June 30, 2018 and 2017.

General and administrative expenses were $1.3 million for each of the three months ended June 30, 2018 and 2017.

Other income, net for the three months ended June 30, 2018 was $0.1 million compared to $34,000 for the same period of the previous year.

The United Kingdom research and tax credits were $0.5 million for the three months ended June 30, 2018 compared to $0.3 million for the same period in 2017.

Net loss for the three months ended June 30, 2018 was $1.9 million compared to $2.2 million for the same period in 2017.

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 4689089

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 developing innovative medicines based on cancer biology. Cyclacel's transcriptional regulation program is evaluating CYC065, a dual CDK2/9 inhibitor, in patients with advanced cancers. 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. 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)

	Three Months Ended June 30,		Six months Ended June 30,	
	2017	**2018**	**2017**	**2018**
Revenues:				
Grant revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	1,222	1,182	2,534	1,980
General and administrative	1,267	1,283	2,648	2,647
Total operating expenses	2,489	2,465	5,182	4,627
Operating loss	(2,489)	(2,465)	(5,182)	(4,627)
Other income (expense):				
Foreign exchange gains (losses)	16	(39)	(43)	(43)
Interest income	18	84	30	153
Other income, net	-	66	879	632
Total other income (expense)	34	111	866	742
Loss before taxes	(2,455)	(2,354)	(4,316)	(3,885)
Income tax benefit	268	502	574	684
Net loss	(2,187)	(1,852)	(3,742)	(3,201)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(100)	(101)
Net loss applicable to common shareholders	$ (2,237)	$ (1,902)	$ (3,842)	$ (3,302)
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted	$ (0.50)	$ (0.16)	$ (0.88)	$ (0.28)
Weighted average common shares outstanding	4,434,441	11,997,447	4,353,333	11,997,447

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

	December 31, 2017	**June 30, 2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,910	$ 19,824
Prepaid expenses and other current assets	2,064	2,863
Total current assets	25,974	22,687
Property, plant and equipment (net)	29	43
Total assets	$ 26,003	$ 22,730
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,558	$ 1,675
Accrued and other current liabilities	2,555	2,319
Total current liabilities	4,113	3,994
Other liabilities	124	112
Total liabilities	4,237	4,106
Stockholders' equity	21,766	18,624
Total liabilities and stockholders' equity	$ 26,003	$ 22,730

SOURCE: Cyclacel Pharmaceuticals, Inc.

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