Cyclacel Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Business Update

November 10, 2021

- Second Phase 1/2 Study of Fadraciclib Now Enrolling Patients in Leukemia -
- Cash Runway to Early 2023 -
- Conference Call Scheduled November 10, 2021 at 4:30 p.m. ET -

BERKELEY HEIGHTS, N.J., Nov. 10, 2021 (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 its financial results for the third quarter 2021. The quarter's business highlights include an update on the Company's progress with fadraciclib and CYC140, Cyclacel's novel CDK2/9 and PLK1 inhibitors, respectively.

"The Cyclacel team continued to execute on our plan during the quarter with the opening of two Phase 1/2 studies for oral fadraciclib and filing an IND for a Phase 1/2 study of our oral PLK1 inhibitor, CYC140," said Spiro Rombotis, President and Chief Executive Officer. "We have now enrolled a total of six patients across two dosing levels in our fadraciclib study in solid tumors and have started the first dose level in the fadraciclib study in leukemia. We are pleased with the strong investigator interest in our studies as we build a global network of participating institutions for our clinical studies and preclinical collaborations.

We are also looking forward to the near future with the planned initiation of two registration-enabling Phase 1/2 studies of CYC140 in patients with solid tumors and leukemias and reporting initial data for fadraciclib in solid tumors. We remain diligently focused on bringing innovative treatment options to cancer patients with unmet medical needs and realizing the promise of our pipeline."

Key Corporate Highlights

Oral fadraciclib program

- Six patients with advanced solid tumors treated in the first two dosing levels of 065-101, Phase 1/2, registration-directed study
- Two additional internationally-recognized cancer treatment centers added to 065-101 selected for their expertise with tumor types of interest; for a total of four sites
- First patient dosed in the 065-102, Phase 1/2, registration-directed study in patients with leukemia
- Multiple preclinical studies in progress which will inform fadraciclib's clinical development

Oral CYC140 program

- Filed with FDA an IND for a streamlined, registration-directed, Phase 1/2 study of orally-available CYC140 in solid tumors
- Initial data in preclinical models show that KRAS mutant cancers are sensitive to oral CYC140 inhibition
- Preclinical collaborative studies ongoing to support selection of histologies to be included in the Phase 1/2 study

Key Near-Term Business Objectives

- FDA clearance of IND filing and initiation of oral CYC140 Phase 1/2 advanced solid tumor study
- Initial data from first part of 065-101 study with oral fadraciclib in advanced solid tumors
- First patient to be dosed with oral CYC140 in Phase 1/2 leukemia study
- Initial data from first part of 065-102 study with oral fadraciclib in leukemia

Financial Highlights

As of September 30, 2021, cash and cash equivalents totaled $40.2 million, compared to $43.6 million as of June 30, 2021. The decrease of $3.4 million was primarily due to $6.3 million net cash used in operating activities, offset by $2.9 million cash provided by financing activities. The Company estimates that available cash resources will fund currently-planned programs through early 2023.

Research and development (R&D) expenses were $4.2 million for the three months ended September 30, 2021 as compared to $1.1 million for the same period in 2020. R&D expenses relating to fadraciclib increased by approximately $2.5 million for the three months ended September 30, 2021 due to clinical supply manufacturing and opening of clinical trial sites for the evaluation of fadraciclib in Phase 1/2 studies. Additionally, R&D expenses related to CYC140 increased $0.5 million for the quarter as preclinical evaluation and clinical trial supply manufacturing of CYC140 progressed.

General and administrative expenses for the three months ended September 30, 2021 were $1.8 million, compared to $1.5 million for the same period of the previous year due to increased legal, professional and recruitment costs relating to expansion of the clinical team.

United Kingdom research & development tax credits were $1.0 million for the three months ended September 30, 2021, as compared to $0.3 million for the same period in 2020 due to the increase in R&D expenditure.

Net loss for the three months ended September 30, 2021 was $5.0 million, compared to $2.3 million for the same period in 2020.

Conference call information:

Conference ID: CYCCQ321

US call: (877) 876-9173/ international call: +1 (785) 424-1667

Replay: US: (800) 938-2795 / international archive: +1 (402) 220-9029

Code for live and replay conference call is CYCCQ321 Webcast link.

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at www.cyclacel.com.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a clinical-stage, biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation and mitosis biology. The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, and the anti-mitotic program CYC140, a PLK1 inhibitor, in patients with both solid tumors and hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications. 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

Company:	Paul McBarron, (908) 517-7330, pmcbarron@cyclacel.com
Investor Relations:	LifeSci Advisors, LLC, Irina Koffler, (646) 970-4681, ikoffler@lifesciadvisors.com

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

	Three Months Ended September 30,	
	2020	**2021**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,075	4,217
General and administrative	1,497	1,781
Total operating expenses	2,572	5,998
Operating loss	(2,572)	(5,998)
Other income (expense):		
Foreign exchange gains (losses)	(25)	9
Interest income	4	4
Other income, net	56	-
Total other income (expense), net	35	13
Loss before taxes	(2,537)	(5,985)

Income tax benefit	281	998
Net loss	(2,256)	(4,987)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Beneficial conversion feature of Series B preferred stock	-	-
Net loss applicable to common shareholders	$ (2,306)	$ (5,037)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.47)	$ (0.54)
Weighted average common shares outstanding	4,863,984	9,368,056

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

	December 31, 2020	September 30, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,406	$ 40,219
Prepaid expenses and other current assets	2,063	3,156
Total current assets	35,469	43,375
Property and equipment, net	106	71
Right-of-use lease asset	1,227	44
Non-current deposits	-	1,509
Total assets	$ 36,802	$ 44,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 514	$ 1,515
Accrued and other current liabilities	1,972	2,076
Total current liabilities	2,486	3,591
Lease liability	1,057	44
Total liabilities	3,543	3,635
Stockholders' equity	33,259	41,364
Total liabilities and stockholders' equity	$ 36,802	$ 44,999

SOURCE: Cyclacel Pharmaceuticals, Inc.

Source: Cyclacel