Cyclacel Pharmaceuticals Reports Third Quarter Financial Results and Provides Business Update

November 13, 2023

- Cyclacel Expects to Release Updated Phase 1/2 Clinical and Biomarker Data with Oral Fadraciclib and Provide Safety, Efficacy and Putative Mechanism Update for Oral Plogosertib -

- Management to Host Conference Call at 4:30 pm ET Today -

BERKELEY HEIGHTS, N.J., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, announced today third quarter financial results and provided a business update.

“Fadraciclib continues to show good tolerability and anticancer activity as a single agent,” said Spiro Rombotis, President and Chief Executive Officer. “After analyzing the genomic profile of several Phase 1 patients with clinical benefit, we have identified mutational and molecular patterns that may be predictive of clinical activity across broad cancer types. If confirmed, these findings may be relevant in the upcoming Phase 2 part of our 065-101 study. In our Phase 1/2 study of plogosertib good tolerability and anticancer activity as a single agent has been observed in multiple patients with various solid tumors. Preclinical data continues to suggest that plogosertib may work through an epigenetic mechanism and that certain mutational biomarkers may identify patients with sensitive tumors. We look forward to presenting data from these two programs and their mechanisms in the coming months.”

“In the 065-101 study of oral fadraciclib, our CDK2/9 inhibitor, as monotherapy, we are completing dose escalation level 6A with six patients and expect to select the recommended Phase 2 dosing schedule shortly. We are encouraged by the observations of anticancer activity and the related patient genomic profiles,” said Mark Kirschbaum, M.D., Chief Medical Officer. “We believe that fadraciclib’s inhibition of CDK2 and CDK9 may be superior to either CDK2 or CDK9 alone. Importantly, we have been able to give fadraciclib orally with repeat dosing which has led to transient suppression of anti-apoptosis proteins without hematological toxicity. In the 140-101 study of oral plogosertib, our PLK1 inhibitor as a single agent, we are recruiting patients at dose level 5. The anticancer activity observed at low levels of continuous exposure may be due to plogosertib’s novel epigenetic mechanism which we are continuing to investigate. If confirmed, we intend to design clinical studies that could exploit these findings.”

Key Milestones

- Report final data from dose escalation stage and RP2D determination from the 065-101 study of oral fadraciclib in patients with advanced solid tumors and lymphoma
- First patient dosed with oral fadraciclib in Phase 2 proof-of-concept stage of 065-101 study in patients with advanced solid tumors and lymphoma
- Report Phase 1 data from 140-101 study of oral plogosertib in patients with advanced solid tumors and lymphoma
- Disclose novel epigenetic mechanism of action of plogosertib

Financial Highlights

As of September 30, 2023, cash equivalents totaled $5.9 million, compared to $18.3 million as of December 31, 2022. Net cash used in operating activities was $12.2 million for the nine months ended September 30, 2023 compared to $15.7 million for the same period of 2022. The Company estimates that its available cash will fund currently planned programs through the end of 2023. The operating plan includes discretionary expenditures, which if not incurred could extend cash runway into the second quarter of 2024.

Research and development (R&D) expenses were $5.2 million for the three months ended September 30, 2023, as compared to $4.4 million for the same period in 2022. R&D expenses relating to fadraciclib were $3.6 million for the three months ended September 30, 2023, as compared to $2.5 million for the same period in 2022 due to due to increased costs associated with manufacture scale up and introduction of the tablet form. R&D expenses related to plogosertib were $1.5 million for the three months ended September 30, 2023, as compared to $1.7 million for the same period in 2022.

General and administrative expenses for the three months ended September 30, 2023 were $1.6 million, as compared to $2.1 million for the same period in 2022 due to non-recurring professional fees of $0.4 million in the prior period.

Total other income, net, for the three months ended September 30, 2023, was $0.1 million compared to an income of $0.4 million for the same period of the previous year.

United Kingdom research & development tax credits for the three months ended September 30, 2023 were $0.6 million compared to $1.0 million for the same period of the previous year due to taxation legislative changes that took effect in April 2023 and reduced the amount of tax credit that could be claimed. Research & development tax credits are directly correlated to qualifying research and development expenditure.

Net loss for the three months ended September 30, 2023, was $6.1 million, compared to $5.1 million for the same period in 2022.

Conference call information:

Call: (800) 245-3047 / international call: (203) 518-9765

Archive: (800) 688-7036 / international archive: (402) 220-1346

Code for live and archived conference call is CYCCQ323. Webcast link

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 is a clinical-stage, biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation, epigenetics and mitosis biology. The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, and the epigenetic/anti-mitotic program plogosertib, 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, the potential effects of the COVID-19 pandemic, 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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SOURCE: Cyclacel Pharmaceuticals, Inc.

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

	Three Months Ended September 30,	
	2023	**2022**
Revenues	$ 16	$ -
Operating expenses:		
Research and development	5,236	4,413
General and administrative	1,625	2,054
Total operating expenses	6,861	6,467
Operating loss	(6,845)	(6,467)
Other income (expense):		
Foreign exchange gains (losses)	104	276
Interest income	50	67
Other income, net	(8)	14
Total other income (expense), net	146	357
Loss before taxes	(6,699)	(6,110)
Income tax benefit	602	1,014
Net loss	(6,097)	(5,096)
Dividend on convertible exchangeable preferred shares	(50)	(50)

Net loss applicable to common shareholders	$ (6,147)	$ (5,146)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.49)	$ (0.42)
Weighted average common shares outstanding	12,642,822	12,314,679

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

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,944	$ 18,345
Prepaid expenses and other current assets	5,104	6,066
Total current assets	11,048	24,411
Property and equipment, net	16	32
Right-of-use lease asset	109	142
Non-current deposits	1,259	3,465
Total assets	$ 12,432	$ 28,050
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,571	$ 2,561
Accrued and other current liabilities	6,458	4,831
Total current liabilities	8,029	7,392
Lease liability	52	106
Total liabilities	8,081	7,498
Redeemable common stock	-	4,494
Stockholders' equity	4,351	16,058
Total liabilities and stockholders' equity	$ 12,432	$ 28,050