Cyclacel Pharmaceuticals Reports Second Quarter Financial Results and Provides Business Update

August 9, 2023

- Key Catalysts ahead with Multiple Value Generating Readouts-
- Expects to Release Phase 1/2 Data with Oral Fadraciclib -
- Signals of Single-agent Efficacy with Oral Plogosertib -
- Management to Host Conference Call at 4:30 pm EDT Today-

BERKELEY HEIGHTS, N.J., Aug. 09, 2023 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical leader in cell cycle checkpoint control developing innovative medicines based on cancer cell biology, announced today second quarter financial results and provided a business update.

“Both clinical programs with fadraciclib and plogosertib are progressing well, and we are on track to report on important readouts this year,” said Spiro Rombotis, President and Chief Executive Officer. “Based on data collected to date we believe that fadraciclib’s next generation CDK inhibitor profile is differentiated from other molecules in its class. Similarly plogosertib could emerge as a PLK1 inhibitor with novel epigenetic activity. We look forward to presenting data from these two programs in the coming months.”

“We are completing dose escalation level 6A with six patients in the 065-101 study of fadraciclib as a single agent and expect to select the recommended Phase 2 dosing schedule shortly. A patient with endometrial cancer in dose level 6A has documented tumor shrinkage after one cycle,” said Mark Kirschbaum, M.D., Chief Medical Officer. “In the 140-101 study of plogosertib as a single agent we are recruiting patients at dose level 5. Anticancer activity has been observed thus far in four out of twelve patients, with adenoid cystic carcinoma, biliary, non-small cell lung, and ovarian cancer respectively, who stayed on treatment for three to eight cycles. The activity at low level, continuous exposure may be due to the effects of plogosertib operating through a novel epigenetic mechanism which we are continuing to investigate. If confirmed, we will design clinical studies that could exploit these findings.“

Key Upcoming 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
- Elaborate novel mechanism of action of plogosertib

Financial Highlights

As of June 30, 2023, cash equivalents totaled $10.2 million, compared to $18.3 million as of December 31, 2022. Net cash used in operating activities was $8.2 million for the six months ended June 30, 2023 compared to $8.7 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 liquidity requirements into the second quarter of 2024.

Research and development (R&D) expenses were $4.7 million for the three months ended June 30, 2023, as compared to $4.2 million for the same period in 2022. R&D expenses relating to fadraciclib were $3.0 million for the three months ended June 30, 2023, as compared to $2.6 million for the same period in 2022 due to increased non-clinical expenditures. R&D expenses related to plogosertib were $1.4 million for the three months ended June 30, 2023, as compared to $1.5 million for the same period in 2022 due to clinical trial costs associated with the progression of the Phase 1/2 study.

General and administrative expenses for the three months ended June 30, 2023 and 2022, remained relatively flat at $1.6 million.

Total other expense, net, for the three months ended June 30, 2023, was $0.1 million compared to an income of $0.2 million for the same period of the previous year.

United Kingdom research & development tax credits for the three months ended June 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. Research & development tax credits are directly correlated to qualifying research and development expenditure.

Net loss for the three months ended June 30, 2023, was $5.4 million, compared to $4.6 million for the same period in 2022.

Conference call information:

Call: (800) 225-9448 / international call: (203) 518-9708

Archive: (800) 839-6136 / international archive: (402) 220-2572

Code for live and archived conference call is CYCCQ223. 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

Company:	Paul McBarron, (908) 517-7330, pmcbarron@cyclacel.com
Investor Relations:	Grace Kim, IR@cyclacel.com

SOURCE: Cyclacel Pharmaceuticals, Inc.

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

	Three Months Ended June 30,	
	2023	**2022**
Revenues	$ 373	$ -
Operating expenses:		
Research and development	4,727	4,205
General and administrative	1,575	1,580
Total operating expenses	6,302	5,785
Operating loss	(5,929)	(5,785)
Other income (expense):		
Foreign exchange gains (losses)	(76)	209
Interest income	77	17
Other income, net	(106)	-
Total other income (expense), net	(105)	226
Loss before taxes	(6,034)	(5,559)
Income tax benefit	586	984
Net loss	(5,448)	(4,575)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (5,498)	$ (4,625)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.44)	$ (0.46)

Weighted average common shares outstanding	12,551,794	10,136,089

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,164	$ 18,345
Prepaid expenses and other current assets	5,130	6,066
Total current assets	15,294	24,411
Property and equipment, net	24	32
Right-of-use lease asset	124	142
Non-current deposits	1,000	2,916
Total assets	$ 16,442	$ 27,501
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,169	$ 2,561
Accrued and other current liabilities	4,577	4,831
Total current liabilities	6,746	7,392
Lease liability	66	106
Total liabilities	6,812	7,498
Redeemable common stock	4,494	4,494
Stockholders' equity	5,136	15,509
Total liabilities and stockholders' equity	$ 16,442	$ 27,501