Cyclacel Pharmaceuticals Reports First Quarter Financial Results and Provides Business Update

May 14, 2024

- New Clinical Data to be Presented at ASCO Annual Meeting Highlighting Potential Precision Medicine Strategy with Oral Fadraciclib -
- First Patients Enrolled in Oral Fadraciclib Phase 2 Proof of Concept Study -
- Balance Sheet Bolstered with $8.0 million Private Placement Priced At-The-Market Under Nasdaq Rules -
- Management to Host Conference Call at 4:30 pm EDT Today -

BERKELEY HEIGHTS, N.J., May 14, 2024 (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 first quarter financial results and provided a business update.

“We are excited to report that we have begun enrolling patients in the Phase 2, proof of concept (PoC) stage of our 065-101 study of fadraciclib, our oral CDK2/9 inhibitor, and are on track to deliver key readouts this year,” said Spiro Rombotis, President and Chief Executive Officer. “Receipt of $8.0 million gross proceeds in a private placement together with existing resources support our ongoing clinical program. Pharmacokinetic, pharmacodynamic, safety and anticancer activity data from the Phase 1, dose escalation stage of 065-101 in patients with advanced solid tumors and lymphoma will be presented at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting. Data to date suggest that fadraciclib is differentiated from other next generation CDK inhibitors.”

“Having determined the recommended Phase 2 dose for fadraciclib we are now enrolling patients in the Phase 2 PoC stage of 065-101” said Brian Schwartz, M.D., interim Chief Medical Officer. “We are initially concentrating on the biomarker cohort which is enrolling patients prospectively selected for CDKN2A/CDKN2B alterations to be followed by patients with T-cell lymphoma. There are no approved medicines for patients with CDKN2A/CDKN2B alterations. Including currently opened trial sites, we expect a total of up to seven sites will participate with the majority in the United States. We are encouraged about fadra’s prospects and look forward to presenting emerging data from the 065-101 study later in the year.“

Key Upcoming Milestones for 2024

- 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 at the ASCO 2024 Annual Meeting
- Report interim data from initial cohorts in Phase 2 proof-of-concept stage of 065-101 study with oral fadraciclib in patients with advanced solid tumors and lymphoma

Financial Highlights

As of March 31, 2024, pro forma cash and cash equivalents totalled $9.9 million, including proceeds from this month’s private placement and $0.8 million received for the United Kingdom research & development tax credit. Cash and cash equivalents as of March 31, 2024, totalled $2.8 million, compared to $3.4 million as of December 31, 2023.

Net cash used in operating activities was $0.5 million for the three months ended March 31, 2024, which includes $2.9 million received in March in respect of the United Kingdom research & development tax credit, compared to $6.9 million for the same period of 2023. The Company estimates that its current cash resources will fund planned programs into the fourth quarter of 2024.

Research and development (R&D) expenses were $2.8 million for the three months ended March 31, 2024, as compared to $5.7 million for the same period in 2023. R&D expenses relating to fadraciclib were $1.8 million for the three months ended March 31, 2024, as compared to $4.1 million for the same period in 2023 due to a decrease in clinical trial and other non-clinical expenditures. R&D expenses related to plogosertib were $1.0 million for the three months ended March 31, 2024, as compared to $1.4 million for the same period in 2023 due to a decrease in manufacturing and other non-clinical expenditures.

General and administrative expenses remained relatively flat at approximately $1.6 million for each of the three months ended March 31, 2024 and 2023.

Total other expenses, net, for the three months and year ended March 31, 2024, were $0.1 million, compared to $0.2 million for the same period of the previous year.

United Kingdom research & development tax credits for the three months March 31, 2024, were $1.4 million, which includes $0.8 million related to the 2023 claim which was received in May 2024, compared to $1.3 million for the same period of the previous year and are directly correlated to qualifying research and development expenditure.

Net loss for the three months March 31, 2024, was $2.9 million (including non-cash stock-based compensation expense of $0.2 million), compared to $5.8 million (including non-cash stock-based compensation expense of $0.4 million) for the same period in 2023.

Conference call information:

Call: (888) 632-3384 / international call: (785) 424-1794

Archive: (800) 938-1584 / international archive: (402) 220-1542

Code for live and archived conference call is CYCCQ124. 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 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, among other things, statements related to the intended use of proceeds from the private placement, 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 market and other conditions, 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 risks associated with reliance on collaborative partners for further clinical trials, development and commercialization of product candidates and Cyclacel's ability to regain and maintain compliance with Nasdaq's continued listing requirements. 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 March 31,	
	2024	**2023**
Revenues	$ 29	$ -
Operating expenses:		
Research and development	2,802	5,674
General and administrative	1,582	1,645
Total operating expenses	4,384	7,319
Operating loss	(4,355)	(7,319)
Other income (expense):		
Foreign exchange gains (losses)	1	(87)
Interest income	2	116
Other income, net	52	166
Total other income (expense), net	55	195
Loss before taxes	(4,300)	(7,124)
Income tax benefit	1,354	1,320
Net loss	(2,946)	(5,804)
Dividend on convertible exchangeable preferred shares	-	(50)
Net loss applicable to common shareholders	$ (2,946)	$ (5,854)

Basic and diluted earnings per common share:		
Net loss per share – basic and diluted (common shareholders)	$ (2.27)	$ (7.00)
Net loss per share – basic and diluted (redeemable common shareholders)	$ -	$ (7.00)
Weighted average common shares outstanding	1,296,547	835,946

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

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,798	$ 3,378
Prepaid expenses and other current assets	2,037	4,066
Total current assets	4,835	7,444
Property and equipment, net	7	9
Right-of-use lease asset	79	93
Non-current deposits	1,244	1,259
Total assets	$ 6,165	$ 8,805
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,200	$ 3,543
Accrued and other current liabilities	3,150	4,618
Total current liabilities	8,350	8,161
Lease liability	21	37
Total liabilities	8,371	8,198
Stockholders' equity	(2,206)	607
Total liabilities and stockholders' equity	$ 6,165	$ 8,805