Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

March 19, 2024

– On Track to Start Oral Fadraciclib Phase 2 Proof of Concept in 1H 2024 –

– Expect to Report Final Data from Fadraciclib 065-101 Dose Escalation –

– Oral Plogosertib Preclinical Data Support Precision Medicine Strategy in ARID1A- and SMARCA-Mutated Cancers –

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

BERKELEY HEIGHTS, N.J., March 19, 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, today announced fourth quarter and full year 2023 financial results and provided a business update.

“Following the recently announced precision medicine strategy for oral fadraciclib, our CDK2/9 inhibitor, we have determined the recommended Phase 2 dose (RP2D) and are ready to start proof-of-concept studies,” said Spiro Rombotis, President and Chief Executive Officer. “We expect two key data readouts for fadraciclib this year. These include pharmacokinetic (PK), pharmacodynamic (PD), safety and activity data from the dose escalation part of the 065-101 Phase 1/2 study. In addition, we expect to report initial clinical activity from the Phase 2 proof of concept part, evaluating cohorts of patients selected for their mutational profile and/or Phase 1 activity in various solid tumors and lymphoma. At the upcoming AACR Annual Meeting 2024, independent investigators will present preclinical proof-of-concept data for fadraciclib further demonstrating fadraciclib’s differentiated properties from other next generation CDK inhibitors.”

“We have observed CDKN2A/CDKN2B alterations, including loss of function, in multiple, pretreated patients with various cancers, including gynecological, hepatobiliary, lung, and pancreatic, who benefitted from fadraciclib monotherapy. In addition, we have observed clinical activity in patients with T cell lymphoma,” said Brian Schwartz, M.D., interim Chief Medical Officer. "We expect to report final Phase 1 results including details on patient genomic profiles at an upcoming medical conference. A precision medicine strategy is also emerging for plogosertib, our PLK1 inhibitor. Preclinical data from independent groups have shown that certain ARID1A- and SMARCA-mutated cancers may benefit from treatment with plogosertib. Before testing this hypothesis in our 140-101 dose escalation study, we plan to switch to a new oral formulation of plogosertib with improved bioavailability. We are excited about the potential precision medicine strategies for both our clinical programs, with initial data from the fadraciclib Phase 2 proof-of-concept study."

Key Highlights for 2024

- First patient dosed with oral fadraciclib in Phase 2 proof-of-concept part of 065-101 study in patients with advanced solid tumors and lymphoma
- Report final data from dose escalation stage from the 065-101 study of oral fadraciclib in patients with advanced solid tumors and lymphoma
- Report interim data from initial cohorts in Phase 2 open label, proof-of-concept part of 065-101 study with oral fadraciclib in patients with advanced solid tumors and lymphoma
- Independent investigators to report preclinical proof-of-concept data for fadraciclib at the American Association for Cancer Research (AACR) Annual Meeting 2024

Financial Highlights

As of December 31, 2023, pro forma cash and cash equivalents totaled $6.3 million, including $2.9 million of United Kingdom research & development tax credits which were received after the end of the year. Cash and cash equivalents as of December 31, 2023, totaled $3.4 million, compared to $18.4 million as of December 31, 2022. Net cash used in operating activities was $16.1 million for the twelve months ended December 31, 2023 compared to $20.8 million for the same period of 2022. The Company estimates that its available cash, including the United Kingdom research & development tax credit of $2.9 million, will fund currently planned programs into the second quarter of 2024.

Research and development (R&D) expenses were $3.5 million and $19.2 million for the three months and year ended December 31, 2023, as compared to $6.7 million and $20.3 million for the same period in 2022. R&D expenses relating to fadraciclib were $2.7 million and $13.4 million for the three months and year ended December 31, 2023, as compared to $5.3 million and $14.0 million for the same period in 2022 due to decrease in clinical trial costs offset by an increase in manufacturing and other non-clinical expenditures. R&D expenses related to plogosertib were $0.7 million and $5.0 million for the three months and year ended December 31, 2023, as compared to $1.3 million and $5.5 million for the same period in 2022 due to decrease in manufacturing and other non-clinical expenditures.

General and administrative expenses for the three months and year ended December 31, 2023, were $1.9 million and $6.7 million, compared to $2.1 million and $7.4 million for the same period of the previous year due to a decrease in professional fees.

Total other income, net, for the three months and year ended December 31, 2023, were an expense of $0.3 million and expense of $0.1 million, compared to an expense of $0.2 million and income of $1.7 million for the same period of the previous year. The decrease of $1.8 million for the year ended December 31, 2023, is primarily related to royalty income received in the previous year.

United Kingdom research & development tax credits for the three months and year ended December 31, 2023 were $0.4 million and $3.0 million compared to $1.6 million and $4.7 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 and year ended December 31, 2023, was $5.3 million and $22.6 million (including stock based compensation expense of $0.3 million and $1.5 million respectively), compared to $7.4 million and $21.2 million (including stock based compensation expense of $0.3 million and $1.5 million respectively) for the same period in 2022.

Conference call information:

US/Canada call: (800) 579 2543 / international call: (785) 424 1789

US/Canada archive: (800) 839 9720 / international archive: (402) 220 6092

Code for live and archived conference call is CYCCQ423. (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 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 December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Clinical trial supply	31	-	420	-
Total revenues	31	-	420	-
Operating expenses:				
Research and development	3,518	6,702	19,155	20,274

General and administrative	1,873	2,143	6,718	7,382
Total operating expenses	5,391	8,845	25,873	27,656
Operating loss	(5,360)	(8,845)	(25,453)	(27,656)
Other income (expense):				
Foreign exchange gains (losses)	(356)	(281)	(414)	233
Interest income	23	122	266	210
Other income, net	-	3	50	1,298
Total other income (expense), net	(333)	(156)	(98)	1,741
Loss before taxes	(5,693)	(9,001)	(25,551)	(25,915)
Income tax benefit	422	1,581	2,996	4,717
Net loss	(5,271)	(7,420)	(22,555)	(21,198)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(201)	(201)
Net loss applicable to common shareholders	$ (5,321)	$ (7,470)	$ (22,756)	$ (21,399)
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted (common shareholders)	$ (6.23)	$ (8.94)	$ (26.75)	$ (28.70)
Net loss per share – basic and diluted (redeemable common shareholders)	$ -	$ -	$ -	$ (27.24)
Weighted average common shares outstanding	854,031	835,946	850,815	750,379

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,378	$ 18,345
Prepaid expenses and other current assets	4,066	6,066
Total current assets	7,444	24,411
Property and equipment, net	9	32
Right-of-use lease asset	93	142
Non-current deposits	1,259	3,465
Total assets	$ 8,805	$ 28,050
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,543	$ 2,561
Accrued and other current liabilities	4,618	4,950
Total current liabilities	8,161	7,511
Lease liability	37	106
Total liabilities	8,198	7,617
Redeemable common stock	-	4,494
Stockholders' equity	607	15,939
Total liabilities and stockholders' equity	$ 8,805	$ 28,050