Cyclacel Pharmaceuticals Reports Fourth Quarter And Full Year 2022 Financial Results And Provides Business Update

March 6, 2023

- On Track to Start Oral Fadraciclib Phase 2 Proof of Concept in 1H 2023 and Report Interim data in 2H 2023 -

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

- Expect to Report Initial Data from Oral Plogosertib 140-101 Dose Escalation -

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

BERKELEY HEIGHTS, N.J., March 06, 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, today announced fourth quarter and full year 2022 financial results and provided a business update.

“After a productive 2022, we anticipate that 2023 will be even more exciting for Cyclacel. We plan to advance oral fadraciclib, our CDK2/9 inhibitor, into Phase 2 proof-of-concept evaluating multiple cancer cohorts, and also further explore the anti-cancer potential of our oral PLK1 inhibitor plogosertib,” said Spiro Rombotis, President and Chief Executive Officer. “We expect three key data readouts this year, including pharmacokinetic (PK), pharmacodynamic (PD), safety and activity data from the dose escalation part of our fadraciclib 065-101 Phase 1/2 study, initial clinical activity data from the Phase 2 proof of concept stage of the study and PK, PD, safety and activity data from the dose escalation part of our 140-101 Phase 1/2 study of plogosertib. These data have the potential to further demonstrate that fadraciclib and plogosertib are differentiated from other molecules in their respective classes.”

“We are pleased with our pipeline’s progress in 2022 and believe that we have the opportunity to demonstrate promising results for our two drug candidates, fadraciclib and plogosertib, in the year ahead,” said Mark Kirschbaum, M.D., Chief Medical Officer. “At the recent ENA 2022 Symposium we reported fadraciclib’s good tolerability profile and clear anti-cancer signals. We are currently recruiting patients at dose level 6a of 125mg administered orally twice daily for four out of four weeks. We plan to optimize the dosing schedule and move into Phase 2 testing of the tumor types that should be most sensitive to fadraciclib treatment. We are also advancing plogosertib through dose escalation and are now recruiting patients at dose level 4 in our Phase 1/2 solid tumor study. We have observed efficacy at lower dose levels with three patients on treatment for three to eight cycles. We expect to report additional data of our mechanistically differentiated PLK1 inhibitor from this trial later this year. We remain enthusiastic about Cyclacel’s advancing clinical-stage pipeline and look forward to presenting emerging data from these two programs during the year.“

Key Business Objectives for 2023

- 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 interim Phase 1 data from 140-101 study of oral plogosertib in patients with advanced solid tumors and lymphoma
- 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
- Report interim data from dose escalation stage of 065-102 study with oral fadraciclib in patients with advanced leukemia
- Report final data from dose escalation stage of 140-101 study with oral plogosertib in advanced solid tumors and lymphoma

Financial Highlights

As of December 31, 2022, cash and cash equivalents totaled $18.3 million, compared to $36.6 million as of December 31, 2021. Net cash used in operating activities was $20.8 million for the twelve months ended December 31, 2022 compared to $18.5 million for the same period of 2021. The Company estimates that its available cash, including the United Kingdom research & development tax credit receivable of $4.7 million, will fund currently planned programs into the fourth quarter of 2023.

Research and development (R&D) expenses were $6.7 million and $20.3 million for the three months and year ended December 31, 2022, as compared to $4.6 million and $15.5 million for the same period in 2021. R&D expenses relating to fadraciclib were $5.3 million and $14.0 million for the three months and year ended December 31, 2022, as compared to $3.4 million and $11.1 million for the same period in 2021 due to increased costs associated with ongoing clinical trials evaluating fadraciclib in Phase 1/2 studies and an increase in non-clinical expenditures. R&D expenses related to plogosertib were $1.3 million and $5.5 million for the three months and year ended December 31, 2022, as compared to $1.1 million and $3.5 million for the same period in 2021 due to clinical trial costs associated with the plogosertib Phase 1/2 study.

General and administrative expenses for the three months and year ended December 31, 2022, were $2.1 million and $7.4 million, compared to $1.9 million and $7.5 million for the same period of the previous year due to an increase in employment and professional costs.

Total other income, net, for the three months and year ended December 31, 2022, were an expense of $0.2 million and income of $1.7 million, compared to an income of $43,000 and $0.2 million for the same period of the previous year. The increase of $1.5 million for the year ended December 31, 2022, is primarily related to royalty income.

United Kingdom research & development tax credits for the three months and year ended December 31, 2022 were $1.6 million and $4.7 million compared to $1.2 million and $3.8 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, 2022, was $7.4 million and $21.2 million (including stock based compensation expense of $0.4 million and $1.5 million respectively), compared to $5.3 million and $18.9 million (including stock based compensation expense of $0.3 million and $1.2 million respectively) for the same period in 2021.

Conference call information:

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

US/Canada archive: (800) 925-9627 / international archive: (402) 220-5390

Code for live and archived conference call is CYCCQ422. (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

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

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,	
	2022	2021	2022	2021
Revenues:				
Collaboration and research and development revenue	-	-	-	-
Total revenues	-		-	
Operating expenses:				
Research and development	6,702	4,593	20,274	15,477
General and administrative	2,143	1,941	7,382	7,461
Total operating expenses	8,845	6,534	27,656	22,938

Operating loss	(8,845)	(6,534)	(27,656)	(22,938)
Other income (expense):				
Foreign exchange gains (losses)	(281)	39	233	44
Interest income	122	4	210	16
Other income, net	4	-	1,298	144
Total other income (expense), net	(155)	43	1,741	204
Loss before taxes	(9,000)	(6,491)	(25,915)	(22,734)
Income tax benefit	1,581	1,197	4,717	3,847
Corporation Tax	-	-	-	-
Net loss	(7,419)	(5,294)	(21,198)	(18,887)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(201)	(201)
Net loss applicable to common shareholders	$ (7,469)	$ (5,344)	$ (21,399)	$ (19,088)
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted	$ (0.60)	$ (0.54)	$ (1.90)	$ (2.14)
Weighted average common shares outstanding	12,539,189	9,840,428	11,255,677	8,926,173

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,345	$ 36,559
Prepaid expenses and other current assets	6,066	4,383
Total current assets	24,411	40,942
Property and equipment, net	32	64
Right-of-use lease asset	142	30
Non-current deposits	2,916	1,551
Total assets	$ 27,501	$ 42,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,561	$ 2,117
Accrued and other current liabilities	4,831	3,177
Total current liabilities	7,392	5,294
Lease liability	106	30
Total liabilities	7,498	5,324
Redeemable common stock	4,494	-
Stockholders' equity	15,509	37,263
Total liabilities and stockholders' equity	$ 27,501	$ 42,587