Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results

March 28, 2022

-Initial Data from Phase 1/2 Study of Oral Fadraciclib in Solid Tumors Expected in First Half of 2022 –

-Cash Runway to Mid 2023-

-Conference Call Scheduled for March 28, 2022, at 4:30 p.m. EDT-

BERKELEY HEIGHTS, N.J., March 28, 2022 (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 reported its financial results and business highlights for the fourth quarter and full year ended December 31, 2021.

“2021 was a year of solid execution, as the clinical and corporate objectives achieved by the Cyclacel team have positioned us to reach important milestones in 2022. These include initial data from the dose escalation stage of the ongoing Phase 1/2 study of fadraciclib, our CDK2/9 inhibitor, in advanced solid tumors,” said Spiro Rombotis, President and Chief Executive Officer. “Enrollment has gone well with three new patients treated at dose level 4 at our two U.S. sites and two internationally recognized, cancer centers in Asia and Western Europe who recently joined the study. In 2022 we plan to report new clinical and preclinical evidence supporting the unique properties and therapeutic potential of fadraciclib. We believe that fadraciclib is emerging as the only transcriptional CDK inhibitor in development to have demonstrated single-agent activity and tolerable daily dosing by mouth in patients with solid tumors. If confirmed with additional data, fadraciclib may emerge as an important alternative for the treatment of advanced solid tumors in patients failing available therapies.

In addition, we expect imminent dosing of the first patient with oral CYC140, our novel, PLK1 inhibitor, in a Phase 1/2 study in advanced solid tumors. We are also enrolling patients with hematological malignancies in the dose escalation stage of a Phase 1/2 study of oral fadraciclib. We look forward to providing updates and further clinical and preclinical data from our ongoing programs as they become available.”

Key Highlights

- **12 patients with advanced solid tumors treated in four dose levels of 065-101 study of oral fadraciclib.** Dose level 4 is 100mg given twice a day for 5 days for 3 weeks in a 4-week cycle. The proof-of-concept stage of this Phase 1/2 registration-directed study includes 7 histologically defined cohorts thought to be sensitive to the drug’s mechanism: breast, colorectal (including KRAS mutant), endometrial/ uterine, hepatobiliary, ovarian cancers and lymphomas. The study also includes a basket cohort which will enroll patients regardless of histology with biomarkers relevant to the drug’s mechanism, including MCL1, MYC and/or cyclin E amplified.

- Seoul National University Hospital, Seoul, South Korea and Vall d’Hebron University Hospital, Barcelona, Spain were added to the 065-101 oral fadraciclib study selected for their expertise with tumor types of interest.

- Two patients dosed in the 065-102 study of oral fadraciclib in patients with leukemia or myelodysplastic syndromes.

- **Opened 140-101, a registration-directed, Phase 1/2 study of CYC140 in solid tumors, now recruiting.** This Phase 1/2 registration-directed trial uses a streamlined design and will determine in dose escalation the recommended Phase 2 dose (RP2D) for single-agent oral CYC140. Once RP2D has been established, the trial will immediately enter into proof-of-concept, cohort stage, using a Simon 2-stage design. In this stage CYC140 will be administered to patients in up to seven mechanistically relevant cohorts plus a basket cohort which will enroll patients with biomarkers relevant to the drug’s mechanism.

- Preclinical studies are in progress to inform clinical development of fadraciclib and support selection of histologies for 140-101.

More information on our clinical trials can be found here.

Key Business Objectives for 2022

1H 2022

- Dose first patient with oral CYC140 in the 140-101 advanced solid tumor study
- Initial data from Phase 1 dose escalation of the 065-101 solid tumor study of oral fadraciclib

2H 2022

- Enter Phase 2 proof of concept stage in the 065-101 solid tumor study of oral fadraciclib in 8 cohorts (7 by histology and a basket cohort)
- Initial data from Phase 1 dose-escalation of the 065-102 leukemia study of oral fadraciclib

Financial Highlights

As of December 31, 2021, cash and cash equivalents totaled $36.6 million, compared to $33.4 million as of December 31, 2020. The increase of $3.2 million was primarily due to $21.7 million cash provided by financing activities, offset by $18.5 million net cash used in operating activities. The Company estimates that available cash resources will fund currently planned programs through mid-2023.

Research and development (R&D) expenses were $4.6 million and $15.5 million for the three months and year ended December 31, 2021, as compared to $1.4 million and $4.8 million for the same periods in 2020. R&D expenses relating to fadraciclib were $3.4 million and $11.1 million for the three months and year ended December 31, 2021, as compared to $1.1 million and $3.7 million for the same periods in 2020 due to clinical trial expenses for the evaluation of fadraciclib in Phase 1/2 studies and clinical supply manufacturing. Additionally, R&D expenses related to CYC140 were $1.1 million and $3.6 million for the three months and year ended December 31, 2021, as compared to $0.2 million and $0.6 million for the same periods in 2020 as preclinical evaluation and clinical trial supply manufacturing of CYC140 progressed.

General and administrative (G&A) expenses for the three months and year ended December 31, 2021, were $1.9 million and $7.5 million, compared to $1.8 million and $5.9 million for the same periods of the previous year due to increased legal and professional and personnel costs and a lease assignment. G&A expenses included non-cash stock compensation costs of $0.1 million and $0.8 million for the three months and full year ended December 31, 2021, compared to $0.1 million and $0.3 million for the same periods in 2020. United Kingdom research & development tax credits were $1.2 million and $3.8 million for the three months and year ended December 31, 2021, as compared to $0.4 million and $1.2 million for the same period in 2020 due to the increase in eligible R&D expenditure.

Net loss for the three months and year ended December 31, 2021, was $5.3 million and $18.9 million, compared to $2.8 million and $8.4 million for the same periods in 2020.

Conference call information:

US/Canada call: (866) 342-8591 / international call: (203) 518-9713

US/Canada archive: (800) 839-4199 / international archive: (402) 220-2989

Code for live and archived conference call is CYCCQ421. 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 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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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,	
	2020	**2021**	**2020**	**2021**
Revenues:	-			
Total revenues	-	-	-	-
Operating expenses:				
Research and development	1,415	4,593	4,759	15,477
General and administrative	1,753	1,941	5,877	7,461
Total operating expenses	3,168	6,534	10,636	22,938
Operating loss	(3,168)	(6,534)	(10,636)	(22,938)
Other income (expense):				
Foreign exchange gains (losses)	(20)	39	22	44
Interest income	6	4	42	16
Other income, net	-	-	891	144
Total other income (expense), net	(14)	43	955	204
Loss before taxes	(3,182)	(6,491)	(9,681)	(22,734)
Income tax benefit	378	1,197	1,236	3,847
Net loss	(2,804)	(5,294)	(8,445)	(18,887)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(201)	(201)
Beneficial conversion feature of Series B preferred stock	(3,775)	-	(3,775)	-
Net loss applicable to common shareholders	$ (6,629)	$ (5,344)	$ (12,421)	$ (19,088)
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted	$ (1.34)	$ (0.54)	$ (3.42)	$ (2.14)
Weighted average common shares outstanding	4,931,543	9,840,428	3,633,385	8,926,173

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

	December 31, 2020	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,406	$ 36,559
Prepaid expenses and other current assets	2,063	4,383
Total current assets	35,469	40,942
Property and equipment, net	106	64
Right-of-use lease asset	1,227	30
Non-current deposits	-	1,551
Total assets	$ 36,802	$ 42,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 514	$ 2,117
Accrued and other current liabilities	1,972	3,177
Total current liabilities	2,486	5,294
Lease liability	1,057	30
Total liabilities	3,543	5,324
Stockholders' equity	33,259	37,263
Total liabilities and stockholders' equity	$ 36,802	$ 42,587

SOURCE: Cyclacel Pharmaceuticals, Inc.