Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results

February 25, 2021

Conference Call Scheduled February 25, 2021 at 4:30 p.m. EDT

BERKELEY HEIGHTS, N.J., Feb. 25, 2021 (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, 2020.

The Company's net loss applicable to common shareholders for the three months and year ended December 31, 2020 was $6.6 million and $12.4 million, respectively. As of December 31, 2020, cash and cash equivalents totaled $33.4 million. Additional proceeds of $4.3 million were received from the exercise of warrants after December 31, 2020. Based on current spending, the proforma cash on hand of $37.7 million provides the Company with sufficient resources to fund planned operations including research and development through early 2023.

“During 2020 we have reported on fadraciclib’s oral bioavailability and evidence of durable anticancer activity,” said Spiro Rombotis, President and Chief Executive Officer. “Independent evidence supporting the rationale for dual inhibition of CDK2 and CDK9 cancer pathways, the targets of fadraciclib, were published in peer-reviewed communications. Meanwhile our team, led by Dr. Mark Kirschbaum, our newly appointed CMO, has prepared a streamlined clinical development strategy to evaluate oral fadraciclib in multi-cohort, Phase 1b/2, registration-directed, studies for both solid and liquid cancers. A similar trial design will be applied to the development of CYC140, our selective PLK1 inhibitor, supported by extensive preclinical data demonstrating CYC140’s antimitotic mechanism and broad therapeutic potential in both solid and liquid cancers. We look forward to providing further details of our clinical development plans and our progress with fadraciclib and CYC140 to drive shareholder value.”

Key 2020 Highlights

Corporate

- Appointed Mark Kirschbaum, M.D. as Senior Vice President and Chief Medical Officer. Dr. Kirschbaum is a highly experienced hematologist/oncologist with over 30 years of experience in molecular medicine, new drug development, clinical trial design and patient care. Most recently, Dr. Kirschbaum served as Vice President, Hematology/Oncology at ArQule Inc.

- Appointed two new Directors to strengthen and broaden our Board’s skill base:

    - Brian Schwartz, M.D. has wide-ranging experience as a drug development expert in the biopharmaceutical industry primarily in oncology, hematology, and rare diseases. Brian was formerly Senior Vice President, Head of Research & Development and Chief Medical Officer of ArQule Inc., which was acquired by Merck & Co. in 2020 for $2.7 billion. Dr. Schwartz is a member of the Company’s Science & Technology Committee.

    - Karin L. Walker brings over 30 years of extensive finance experience in biopharmaceuticals, including public biotechnology and technology companies. Ms. Walker currently serves as the Chief Accounting Officer of Prothena Corporation plc. Ms. Walker has been appointed as Chair of the Audit Committee.

- Raised approximately $25 million in net cash in two equity financings, including a strategic investment by Acorn Bioventures of $6.9 million, net. An additional $8.8 million of proceeds have been received through warrant exercises ($4.3 million of which after year end).

Clinical studies

- Reported data from a Phase 1 study of fadraciclib as a single agent at the Plenary Session of the 32nd EORTC-NCI-AACR (ENA) Symposium:
    - Radiographically confirmed partial response (PR) after a month and a half on i.v. fadraciclib in a patient with MCL1-amplified endometrial cancer, who failed seven lines of prior therapy and is continuing treatment for more

than 18 months with 96% reduction in target tumor lesions.
    - High bioequivalence observed in five patients treated with oral fadraciclib.
- Enrolled 19 patients with relapsed or refractory AML/MDS and CLL receiving i.v. fadraciclib in combination with venetoclax with evidence of antileukemic activity.
- Enrolled seven patients evaluating i.v. CYC140 in patients with advanced leukemias.
- Enrolled 12 patients with relapsed or refractory AML/MDS in a Phase 1/2 study evaluating an oral regimen of sapacitabine in combination with venetoclax.
- Announced a peer-reviewed publication describing the discovery of fadraciclib in PLOS ONE. Authored by scientists from Cyclacel and The Institute of Cancer Research, London, the publication shows that targeting of CDK2 and CDK9 holds broad therapeutic potential.

More information on our clinical trials can be found here.

Key Business Objectives for 2021

- First patient dosed with oral fadraciclib in Phase 1b/2 advanced solid tumor and leukemia studies
- First patient dosed with oral CYC140 in Phase 1/2 advanced solid tumor and leukemia studies
- Manufacture clinical supplies of oral fadraciclib and oral CYC140 for registration-enabling studies
- Data on safety and antileukemic activity from the i.v. fadraciclib-venetoclax Phase 1 study in relapsed/refractory AML and CLL
- Data from the sapacitabine-venetoclax Phase 1/2 study in relapsed/refractory AML or MDS
- Initial data from the i.v. CYC140 Phase 1 First-in-Human study in patients with advanced leukemias
- Data from the Phase 1b/2 IST of sapacitabine-olaparib combination in patients with BRCA mutant metastatic breast cancer when reported by the investigators.

Financial Highlights

As of December 31, 2020, cash and cash equivalents totaled $33.4 million, compared to $11.9 million as of December 31, 2019. The increase of $21.5 million was primarily due to $29.5 million of net cash provided by financing activities, offset by net cash used in operating activities of $7.9 million and $0.1 million of net cash used in investing activities.

Research and development expenses were $1.4 million and $4.8 million for the three months and year ended December 31, 2020 as compared to $1.4 million and $4.7 million for the same periods in 2019. Research and development expenses relating to the transcriptional regulation, CDK inhibitor program with fadraciclib increased by $0.5 million from $3.1 million for the year ended December 31, 2019 to $3.6 million for the year ended December 31, 2020, as the clinical evaluation of fadraciclib progressed. Research and development expenses relating to CYC140 decreased by $0.1 million from $0.7 million for the year ended December 31, 2019 to $0.6 million for the year ended December 31, 2020, primarily as a result of a reduction in expenditures associated with drug supply manufacturing which were not required in 2020. Research and development expenses relating to other research and development decreased by $0.1 million from $0.4 million for the year ended December 31, 2019 to $0.3 million for the year ended December 31, 2020, due to a reduction in consultancy costs.

General and administrative expenses for the three months and year ended December 31, 2020 were $1.7 million and $5.9 million respectively, compared to $1.4 million and $5.0 million for the same periods of the previous year.

Total other income, net for the three months and year ended December 31, 2020 were $14,000 expense and $1.0 million income, compared to $41,000 and $0.6 million income for the same periods of the previous year. The increase of $0.4 million for the year ended December 31, 2020 is primarily related to income received under an Asset Purchase Agreement with ThermoFisher Scientific.

United Kingdom research & development tax credits were $0.4 million and $1.2 million for the three months and year ended December 31, 2020 as compared to $0.4 million and $1.3 million for the same periods in 2019.

Net loss for the three months and year ended December 31, 2020 were $2.8 million and $8.4 million compared to $2.3 million and $7.8 million for the same periods in 2019.

The Company raised net proceeds of approximately $29.7 million during 2020, from agreements to sell securities and warrant conversions. An additional $4.3 million in proceeds from warrant conversions was received after year end.

The Company estimates that proforma cash resources, including proceeds of recent warrant exercises after December 31, 2020,

of $37.7 million, will fund currently planned programs through early 2023.

Conference call information:
US/Canada call: (877) 493-9121 / international call: (973) 582-2750
US/Canada archive: (800) 585-8367 / international archive: (404) 537-3406

Code for live and archived conference call is 7389616. 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 Pharmaceuticals 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, in solid tumors and hematological malignancies. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in advanced cancers. 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, 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.

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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,	
	2019	**2020**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,430	1,415
General and administrative	1,363	1,753
Total operating expenses	2,793	3,168
Operating loss	(2,793)	(3,168)
Other income (expense):		

Foreign exchange gains (losses)	(14)	(20)
Interest income	47	6
Other income, net	8	-
Total other income (expense), net	41	(14)
Loss before taxes	(2,752)	(3,182)
Income tax benefit	449	378
Net loss	(2,303)	(2,804)
Dividend on convertible exchangeable preferred shares	(51)	(51)
Beneficial conversion feature of Series B preferred stock	-	(3,775)
Net loss applicable to common shareholders	$ (2,354)	$ (6,630)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (2.74)	$ (1.34)
Weighted average common shares outstanding	858,189	4,931,543

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

	December 31, 2019	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,885	$ 33,406
Prepaid expenses and other current assets	2,132	2,063
Total current assets	14,017	35,469
Property and equipment, net	27	106
Right-of-use lease asset	1,264	1,227
Total assets	$ 15,308	$ 36,802
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 890	$ 514
Accrued and other current liabilities	1,530	1,972
Total current liabilities	2,420	2,486
Lease liability	1,191	1,057
Total liabilities	3,611	3,543
Stockholders' equity	11,697	33,259
Total liabilities and stockholders' equity	$ 15,308	$ 36,802

SOURCE: Cyclacel Pharmaceuticals, Inc.

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