UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 26, 2020

CYCLACEL PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**0-50626**	**91-1707622**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Connell Drive, Suite 1500
Berkeley Heights, NJ 07922
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (908) 517-7330

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ **Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)**

☐ **Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)**

☐ **Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))**

☐ **Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	CYCC	The Nasdaq Stock Market LLC
Preferred Stock, $0.001 par value	CYCCP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

The information set forth under this "Item 2.02. Results of Operations and Financial Condition," including the exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Attached as Exhibit 99.1 is a copy of a press release of Cyclacel Pharmaceuticals, Inc. (the "**Company**"), dated February 26, 2020, announcing certain financial results for the fourth quarter and full year ended December 31, 2019.

The Company will conduct a conference call to review its financial results on February 26, 2020, at 4:30 p.m., Eastern Time.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release announcing financial results for the fourth quarter and full year ended December 31, 2019, dated February 26, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CYCLACEL PHARMACEUTICALS, INC.

By: /s/ Paul McBarron
Name: Paul McBarron
Title: Executive Vice President—Finance,
Chief Financial Officer and Chief Operating Officer

Date: February 26, 2020

Exhibit 99.1

Cyclacel Pharmaceuticals, Inc.

P R E S S R E L E A S E

CYCLACEL PHARMACEUTICALS REPORTS FOURTH QUARTER AND FULL YEAR 2019 FINANCIAL RESULTS

– Anticancer Activity of Fadraciclib (CYC065) Monotherapy in Patients with MCL1 Amplified Solid Tumor and Fadraciclib-venetoclax Combination in Patients with Relapsed or Refractory AML/MDS and CLL –

– Conference Call Scheduled February 26, 2020 at 4:30 p.m. EDT –

Berkeley Heights, NJ, February 26, 2020 - 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, 2019. The Company's net loss applicable to common shareholders for the three months and year ended December 31, 2019 was $2.4 million and $8.0 million, respectively. As of December 31, 2019, cash and cash equivalents totaled $11.9 million. Based on current spending, cash on hand provides the Company with sufficient resources to fund all planned operations including research and development through Q1 2021.

“Our fadraciclib (CYC065) CDK inhibitor is establishing a leadership position among MCL1 suppressing compounds in clinical development,” said Spiro Rombotis, President and Chief Executive Officer. “After enrolling approximately 60 patients to date with multiple dosing schedules in three Phase 1 dose escalation studies in patients with relapsed or refractory (R/R) solid tumors and hematological malignancies, we have demonstrated safety, proof of mechanism by durable suppression of MCL1 and anticancer activity of fadraciclib as single agent and in combinations. Encouragingly, a heavily pretreated patient with MCL1 amplified endometrial cancer has received over 10 cycles of fadraciclib monotherapy achieved a confirmed partial response (PR) and a further reduction in her target tumor lesions of 73%. Based on data thus far, we are developing a precision medicine strategy to further evaluate fadraciclib as monotherapy and in combinations. In our Phase 1 trial of a combination of fadraciclib and venetoclax in patients with relapsed or refractory AML/MDS, we have enrolled 11 patients and reached dose level five and in CLL 3 patients and dose level two. Our clinical stage pipeline, comprising of fadraciclib, sapacitabine and CYC140, our PLK1 inhibitor, is a central element of our strategy of building an innovative pipeline addressing cancer resistance and DNA damage response.”

Key Corporate Highlights

- **CYC065-01 Phase 1 part 2 single agent i.v.** – In November 2019, we reported anticancer activity in a heavily pretreated a patient with MCL1 amplified endometrial cancer who achieved a radiographically confirmed partial response (PR) after 4 cycles at 213mg. The patient remains on study after 10 cycles and shrinkage of her target tumor lesions has reached 73%. An additional patient with cyclin E amplified ovarian cancer achieved stable disease after 4 cycles at 213mg with 29% tumor shrinkage. We are expanding the 213mg dose level to recruit additional patients and determine the recommended Phase 2 dose.

- **CYC065-01 Phase 1 part 3 single agent p.o.** – We are evaluating an oral capsule form of fadraciclib in patients with advanced solid tumors and have enrolled two patients at 75mg and 150mg once daily. Pharmacokinetic (PK) data in the two patients demonstrated a predictable PK profile closely overlapping the i.v. form with encouraging exposure levels.

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- **CYC065-03 Phase 1 fadraciclib i.v. and venetoclax p.o.** – We have dosed 11 heavily pretreated patients with R/R AML in five dose levels up to 200 mg/m^2 in combination with the BCL2 inhibitor venetoclax. Evidence of anticancer activity has been observed in multiple patients with blast reductions in peripheral blood. Preclinical AML data demonstrated synergy of fadraciclib and venetoclax, suggesting that targeting both BCL2 and MCL1 may be more beneficial than inhibiting either protein alone.

- **CYC065-02 Phase 1 fadraciclib i.v. and venetoclax p.o.** – We have dosed 3 patients with R/R CLL in two dose levels up to 85 mg/m^2 in combination with venetoclax. Evidence of anticancer activity has been observed in two patients who experienced reduction in lymph node size with one of them achieving MRD negative status. Preclinical CLL data demonstrated synergy of fadraciclib and venetoclax, suggesting that targeting both BCL2 and MCL1 may be more beneficial than inhibiting either protein alone.

- **CYC682-11 Phase 1b/2 part 2 sapacitabine p.o. and venetoclax p.o.**– We have enrolled 10 patients in two dose cohorts in our DNA Damage Response (DDR) program evaluating an oral combination of sapacitabine and venetoclax in patients with R/R AML/MDS. Sapacitabine is a nucleoside analogue that is active in AML and MDS R/R to prior therapy such as cytarabine or hypomethylating agents. Preclinical data demonstrated synergy of sapacitabine with BCL2 inhibition which may offer an effective, oral treatment regimen for patients who have failed front-line therapy.

- **CYC140-01 Phase 1 CYC140 i.v. -** We have enrolled 4 patients in our first-in-human, dose escalation study evaluating CYC140 in patients with advanced leukemias. CYC140 is a small molecule, selective polo-like-kinase 1 (PLK1) inhibitor that has demonstrated potent and selective target inhibition and high activity in xenograft models of human cancers.

More information on our clinical trials can be found at www.clinicaltrials.gov.

Key Business Objectives for 2020

- Report updated Phase 1 safety, PK and efficacy data for fadraciclib utilizing a frequent i.v. dosing schedule in patients with advanced solid cancers;

- Report initial safety and PK data from the Phase 1 study of an oral formulation of fadraciclib;

- Report initial safety and proof of concept data from the fadraciclib-venetoclax Phase 1 studies in R/R AML/MDS and CLL;

- Report initial data from the sapacitabine-venetoclax Phase 1b/2 study in patients with R/R AML/MDS;

- Report initial data from the CYC140 Phase 1 first-in-human study in R/R leukemias; and

- Report 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, 2019, cash and cash equivalents totaled $11.9 million, compared to $17.5 million as of December 31, 2018. The decrease of $5.6 million was primarily due to net cash used in operating activities of $9.4 million, offset by $3.8 million of net cash provided by financing activities.

Revenues for the three months and year ended December 31, 2019 amounted to $0 compared to $0.2 million for the same periods in 2018. The 2018 revenue related to a collaboration, licensing and supply agreement with ManRos Therapeutics, entered into in June 2015.

Research and development expenses were $1.4 million and $4.7 million for the three months and year ended December 31, 2019 as compared to $1.1 million and $4.3 million for the same periods in 2018. Research and development expenses relating to the transcriptional regulation, CDK inhibitor program with fadraciclib increased by $0.5 million from $2.5 million for the year ended December 31, 2018 to $3.0 million for the year ended December 31, 2019, as the clinical evaluation of fadraciclib progressed. Research and development expenses relating to the DDR, sapacitabine program decreased by $0.4 million from $0.9 million for the year ended December 31, 2018 to $0.5 million for the year ended December 31, 2019, primarily as a result of expenditure related to clinical trial drug supply manufacturing in 2018.

General and administrative expenses for the three months and year ended December 31, 2019 were $1.4 million and $5.0 million respectively, compared to $1.5 million and $5.4 million for the same periods of the previous year.

Total other income, net for the three months and year ended December 31, 2019 were $0.1 million and $0.6 million, compared to $0.1 million and $0.9 million for the same periods of the previous year. The decrease of $0.3 million for the year ended December 31, 2019 is primarily related to a reduction in income received under an Asset Purchase Agreement with ThermoFisher Scientific.

United Kingdom research & development tax credits were $0.4 million and $1.3 million for the three months and year ended December 31, 2019 as compared to $0.4 million and $1.3 million for the same periods in 2018.

Net loss for the three months and year ended December 31, 2019 were $2.3 million and $7.8 million compared to $2.0 million and $7.3 million for the same periods in 2018.

The Company raised net proceeds of approximately $4.1 million during 2019, from its Common Stock Sales Agreement with H.C. Wainwright, which is now completed.

The Company estimates that cash resources of $11.9 million as of December 31, 2019 will fund currently planned programs through the first quarter of 2021.

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 6761906.

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 DNA damage response biology. The transcriptional regulation program is evaluating fadraciclib as a single agent in solid tumors and in combination with venetoclax in patients with relapsed or refractory AML/MDS and CLL. The DNA damage response program is evaluating an oral combination of sapacitabine and venetoclax in patients with relapsed or refractory AML/MDS. An IST is evaluating an oral combination of sapacitabine and olaparib in patients with BRCA mutant breast cancer. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in advanced leukemias/MDS patients. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates. 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.

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,	
	2018	**2019**
Revenues:		
Total revenues	150	-
Operating expenses:		
Research and development	1,142	1,430
General and administrative	1,474	1,363
Total operating expenses	2,616	2,793
Operating loss	(2,466)	(2,793)
Other income (expense):		
Foreign exchange gains (losses)	(48)	(14)
Interest income	93	47
Other income, net	50	8
Total other income (expense), net	95	41
Loss before taxes	(2,371)	(2,752)
Income tax benefit	353	449
Net loss	(2,018)	(2,303)
Dividend on convertible exchangeable preferred shares	(50)	(51)
Net loss applicable to common shareholders	$ (2,068)	$ (2,354)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.17)	$ (0.14)
Weighted average common shares outstanding	12,381,031	17,199,974

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

	December 31, 2018	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,504	$ 11,885
Prepaid expenses and other current assets	2,283	2,132
Total current assets	19,787	14,017
Property and equipment, net	36	27
Right-of-use lease asset	-	1,264
Total assets	$ 19,823	$ 15,308
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,719	$ 890
Accrued and other current liabilities	1,732	1,530
Total current liabilities	4,451	2,420
Lease liability	-	1,191
Other liabilities	100	-
Total liabilities	4,551	3,611
Stockholders' equity	15,272	11,697
Total liabilities and stockholders' equity	$ 19,823	$ 15,308

SOURCE: Cyclacel Pharmaceuticals, Inc.