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): November 9, 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). ☐

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 November 11, 2020, announcing certain financial results for the third quarter ended September 30, 2020.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangement of Certain Officers.

Effective November 9, 2020, the Board of Directors (the "Board") of the Company appointed Karin L. Walker to serve as a Class 1 Director until the 2022 annual meeting of the Company's stockholders.

There are no arrangements or understandings between Ms. Walker and any other person pursuant to which Ms. Walker was appointed as a director. There are no transactions to which the Company is a party and in which Ms. Walker has a material interest that is required to be disclosed under Item 404(a) of Regulation S-K.

Ms. Walker has not previously held any positions with the Company and has no family relations with any directors or executive officers of the Company.

On November 9, 2020, the Board granted, under and pursuant to the terms of the Company's 2018 Equity Incentive Plan, to Ms. Walker an option to purchase up to 5,200 shares of the Company's common stock at an exercise price of $3.33 per share for her services as a non-executive director of the Company, all of such options to vest on the first anniversary of the date of grant. The option expires on November 9, 2030.

In addition, Ms. Walker is entitled to receive an annual fee of $45,000 for her services as a non-executive director of the Company and $5,000 as a member of the Board's Audit Committee. Ms. Walker will also be reimbursed for certain customary business expenses in connection with attending the Board meeting.

Ms. Walker has over 30 years of extensive finance experience in biopharmaceuticals, including in public biotechnology companies and technology companies. Ms. Walker currently serves as the Chief Accounting Officer of Prothena Corporation plc, a late-stage clinical company with expertise in protein dysregulation and a pipeline of novel investigational therapeutics focused on neurodegenerative and rare peripheral amyloid diseases, and has held this position since 2013. Prior to joining Prothena, she was Vice President, Finance and Chief Accounting Officer of Affymax, Inc., a position she held from 2012 to 2013. From 2009 to 2012, Ms. Walker was Vice President, Finance and Corporate Controller at Amyris Inc. From 2006 to 2009, she was Vice President, Finance and Corporate Controller for CV Therapeutics, Inc. Ms. Walker also held senior financial leadership positions at Knight Ridder Digital, Accellion, Niku Corporation, Financial Engines, Inc. and NeoMagic Corporation. Ms. Walker earned her B.S. in business from the California State Polytechnic University, San Luis Obispo, and is a certified public accountant (CPA).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release announcing financial results for the third quarter ended September 30, 2020, dated November 11, 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: November 12, 2020

Exhibit 99.1

Cyclacel Pharmaceuticals, Inc.

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

CYCLACEL PHARMACEUTICALS REPORTS THIRD QUARTER 2020 FINANCIAL RESULTS
- Conference Call Scheduled November 11, 2020 at 4:30 p.m. ET -

Berkeley Heights, NJ, November 11, 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 for the third quarter 2020 and certain business highlights.

The Company's net loss applicable to common shareholders for the three months ended September 30, 2020 was $2.3 million. As of September 30, 2020, cash and cash equivalents totaled $23.1 million. Based on current spending, the Company estimates it has sufficient resources to fund planned operations, including research and development, through the end of 2022.

"We continue to execute on our clinical development plan for fadraciclib and CYC140 in both liquid and solid cancers," said Spiro Rombotis, President and Chief Executive Officer. "The recent ENA presentation highlighted fadraciclib's oral bioavailability and deepening confirmed response as a single agent. Recent publications elaborated the mechanistic rationale for fadraciclib highlighting dual inhibition of CDK2 and CDK9 cancer pathways. We are encouraged by evidence of antileukemic activity in our studies of fadraciclib in combination with venetoclax in hematological malignancies, including CLL. Dr. Mark Kirschbaum, our newly appointed CMO, is reviewing our programs and streamlining our clinical work flows to progress our clinical strategy and improve efficiency. We are looking forward to reporting data from ongoing studies and outlining our clinical development plans for fadraciclib and CYC140 to drive shareholder value."

Key Corporate Highlights

- **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. He has management experience in academic research, clinical practice and pharmaceutical industry settings. As CMO, he is responsible for advancing Cyclacel's pipeline and is leading clinical strategy, patient safety and medical affairs.

- **Fadraciclib Oral Presentation at the Plenary Session of the 32nd EORTC-NCI-AACR (ENA) Symposium 2020**
  - In part 2 of a Phase 1, dose escalation study, fadraciclib was administered intravenously as monotherapy to 24 heavily pretreated patients with various advanced solid tumors.
    - Out of 11 patients treated at the fourth dose level one achieved confirmed partial response (PR) and two stable disease (SD).
    - The PR was observed after a month and a half on fadraciclib in a patient with MCL1-amplified endometrial cancer who had failed seven lines of prior therapy. The patient remains on treatment after 16 months with 92% reduction in target tumor lesions.

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- § SD was observed in a patient with cyclin E amplified ovarian cancer who achieved 29% shrinkage in target tumor lesions after four months and a patient with fallopian tube adenocarcinoma with undetermined protein level.

- o In three patients treated in part 3 with oral fadraciclib high oral bioavailability and overlapping pharmacokinetics were observed compared to the intravenously administered, identical schedule in part 2.

- **CYC065-02 Phase 1 fadraciclib i.v. and venetoclax p.o. in CLL -** five patients with R/R CLL have been treated in four dose levels up to 150 mg/m^2 of fadraciclib in combination with venetoclax. Fadraciclib is administered after completion of venetoclax ramp. Antileukemic activity was observed in three patients who achieved MRD negativity on the combination, one in bone marrow and two in bone marrow and peripheral blood. The latter two patients have also demonstrated continued shrinkage of lymph nodes on the combination. In one patient all target lesions and in the other 2 out of 4 lesions have shrunk below 1.5cm. Both are waiting for confirmation of response. Preclinical data support a dual targeting strategy of both BCL2 and MCL1 in CLL.

- **CYC065-03 Phase 1 fadraciclib i.v. and venetoclax p.o. in AML/MDS –** fourteen heavily pretreated patients with relapsed/refractory (R/R) AML were treated in five dose levels up to 200 mg/m^2 of fadraciclib in combination with venetoclax. Antileukemic activity has been observed in four out of twelve patients available for assessment. Preclinical data in AML suggest that targeting both MCL1 and BCL2 may be more beneficial than inhibiting either protein alone.

- **CYC140-01 Phase 1 CYC140 i.v.** - We have enrolled 7 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. In parallel with hematological malignancies, we are planning studies of CYC140 in solid tumors.

- **CYC682-11 Phase 1 part 2 sapacitabine p.o. and venetoclax p.o.** - twelve patients have been enrolled in a dose escalation study in our DNA Damage Response (DDR) program evaluating an oral combination of sapacitabine and venetoclax in patients with R/R AML/MDS. Two patients, previously treated with combination therapies including hypomethylating agents, have achieved 5 and 6 cycles of treatment respectively. 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 a BCL2 inhibitor, which may offer an effective, oral treatment regimen for patients who have failed front-line therapy.

- **Appointed Karin L. Walker** to the Board of Directors. Ms. Walker brings over 30 years of extensive finance experience in biopharmaceuticals, including in public biotechnology companies, and technology companies. Ms. Walker currently serves as the Chief Accounting Officer of Prothena, a clinical-stage neuroscience company, and has held this position since 2013.

More information on our clinical trials can be found here.

Key Business Objectives

- Treat first patient with orally-administered fadraciclib in Phase 1/2 advanced solid tumors study;
- Report initial data from fadraciclib-venetoclax Phase 1 study in R/R AML/MDS & CLL;
- Report safety and PK data from Phase 1 study of fadraciclib oral formulation;
- Report initial data from CYC140 Phase 1 first-in-human study in R/R leukemias; and
- Report initial data from sapacitabine-venetoclax Phase 1 study in R/R AML/MDS;

Financial Highlights

As of September 30, 2020, cash and cash equivalents totaled $23.1 million, compared to $11.9 million as of December 31, 2019. The increase of $11.2 million was primarily due to net proceeds of $18.3 million from an equity financing in April 2020, offset by net cash used in operating activities of $6.8 million. There were no revenues for each of the three months ended September 30, 2020 and 2019.

Research and development expenses were $1.1 million for each of the three months ended September 30, 2020 and 2019. Research and development expenses relating to transcriptional regulation increased by approximately $0.1 million for the three months ended September 30, 2020 as we continue to progress the clinical evaluation of fadraciclib.

General and administrative expenses for the three months ended September 30, 2020 were $1.5 million, compared to $1.3 million for the same period of the previous year. The increase of $0.2 million for the three months ended September 30, 2020 is due to increased professional costs.

Total other income, net, for the three months ended September 30, 2020 was $35,000, compared to $174,000 for the same period of the previous year. The decrease of approximately $140,000 for the three months ended September 30, 2020 is primarily related to reductions in foreign exchange gains and interest income.

United Kingdom research & development tax credits were $0.3 million for each of the three months ended September 30, 2020 and 2019.

Net loss for the three months ended September 30, 2020 was $2.3 million compared to $1.9 million for the same period in 2019.

The Company estimates that cash resources of $23.1 million as of September 30, 2020 will fund currently planned programs through the end of 2022.

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 4884678.

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 anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in advanced leukemias/MDS patients. The DNA damage response program is evaluating an oral combination of sapacitabine and venetoclax in patients with relapsed or refractory AML/MDS. An investigator-sponsored trial (IST) is evaluating an oral combination of sapacitabine and olaparib in patients with BRCA mutant breast cancer. 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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Investor Relations: Russo Partners LLC, Eric Ando, (646) 218-4604, eric.ando@russopartnersllc.com

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (LOSS)
(In $000s, except share and per share amounts)

	Three Months Ended September 30,	
	2019	**2020**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,063	1,075
General and administrative	1,285	1,497
Total operating expenses	2,348	2,572
Operating loss	(2,348)	(2,572)
Other income (expense):		
Foreign exchange gains (losses)	79	(25)
Interest income	42	4
Other income, net	53	56
Total other income (expense), net	174	35
Loss before taxes	(2,174)	(2,537)
Income tax benefit	273	281
Net loss	(1,901)	(2,256)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (1,951)	$ (2,306)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (2.27)	$ (0.47)
Weighted average common shares outstanding	859,998	4,863,984

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

	December 31, 2019	September 30, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,885	$ 23,130
Prepaid expenses and other current assets	2,132	2,804
Total current assets	14,017	25,934
Property and equipment, net	27	64
Right-of-use lease asset	1,264	1,215
Total assets	$ 15,308	$ 27,213
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 890	$ 455
Accrued and other current liabilities	1,530	1,257
Total current liabilities	2,420	1,712
Lease liability	1,191	1,063
Total liabilities	3,611	2,775
Stockholders' equity	11,697	24,438
Total liabilities and stockholders' equity	$ 15,308	$ 27,213

SOURCE: Cyclacel Pharmaceuticals, Inc.