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): March 27, 2019

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))**

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 March 27, 2019, announcing certain financial results for the fourth quarter and full year ended December 31, 2018.

The Company will conduct a conference call to review its financial results on March 27, 2019, 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, 2018, dated March 27, 2019.

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: March 27, 2019

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 2018 FINANCIAL RESULTS

– Conference Call Scheduled March 27, 2019 at 4:30 p.m. EDT –

Berkeley Heights, NJ, March 27, 2019 - 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, 2018. The Company's net loss applicable to common shareholders for the three months and year ended December 31, 2018 was $2.1 million and $7.5 million, respectively. As of December 31, 2018, cash and cash equivalents totaled $17.5 million, not including net proceeds of approximately $4.1 million from a Common Stock Sales Agreement.

"We are executing on our targeted oncology strategy with the objective of delivering data readouts from multiple clinical programs," said Spiro Rombotis, President and Chief Executive Officer. "At the heart of our business strategy is targeting patients with overexpression of cancer resistance proteins, including Mcl-1, MYC, cyclin E, and inherited mutations in DNA damage pathways, such as BRCA. We believe CYC065 is the first investigational drug to have consistently demonstrated durable suppression of Mcl-1 at tolerable dosing in patients. We have treated patients in two out of four studies under our MD Anderson collaboration, the Phase 1 study of a combination of CYC065 and venetoclax in relapsed/refractory CLL and the first-in-human, Phase 1 study of CYC140 in advanced leukemias. Protocols for the other two studies have been finalized and will be submitted to institutional review boards. The first two patients with BRCA mutant breast cancer were treated in the sapacitabine and olaparib IST. With estimated capital on hand until the end of 2020 we look forward to reporting data from our ongoing clinical studies and realizing shareholder value from our targeted drug pipeline."

Fourth Quarter and Full-Year Highlights

Drug Development

CYC065 CDK Inhibitor
Initiated a Phase 1 clinical trial evaluating CYC065, a CDK2/9 inhibitor, in combination with venetoclax in patients with relapsed/refractory CLL. The first patient has been treated with this dose regimen without dose-limiting toxicity. The strong biological rationale of dual Mcl-1 and Bcl-2 suppression was presented at the 2018 AACR in a poster titled "Strategic combination of the cyclin-dependent kinase inhibitor CYC065 with venetoclax to target anti-apoptotic proteins in chronic lymphocytic leukemia." The data showed an enhanced effect of the combination of CYC065 and venetoclax in CLL tumor samples, including demonstrating activity in 17p deleted samples which were resistant to either agent alone.

Data from the Phase 1 part 1 clinical study of CYC065 monotherapy administered intravenously over 4 hours every 3 weeks in patients with advanced solid tumors were reported at an oral presentation at the 2018 AACR. Prolonged reduction of Mcl-1 expression was observed in 11 out of 13 patients treated at the recommended Phase 2 dose (RP2D) following a single dose of CYC065. Cyclacel continues to enroll patients in part 2 of the study evaluating CYC065 in a more intensive schedule for 2 days per week over 2 weeks of a three-week cycle. Part 3 of the study is planned to evaluate an oral CYC065 formulation.

Discussions with principal investigators and/or cooperative groups progressed with the objective of evaluating CYC065 in patients with certain hematological malignancies and solid tumors.

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DNA Damage Response (DDR) Program
The first two patients have been dosed in the Phase 1b/2 investigator-sponsored study of sapacitabine in combination with olaparib, an approved PARP inhibitor, in patients with BRCA mutant breast cancer. According to the investigators both patients achieved tumor shrinkage. Dual targeting of the DNA damage response pathway with the addition of sapacitabine to olaparib may enhance the efficacy of the current standard of care for such patients.

Patient enrolment has continued in part 3 of a Phase 1 study evaluating a revised dosing schedule of sequential sapacitabine and seliciclib, Cyclacel's first-generation CDK inhibitor, in BRCA mutation positive patients with advanced breast, ovarian and pancreatic cancer. New data on an expanded cohort from part 1 of this study will be the subject of a poster titled "Expansion cohort of Phase I study of oral sapacitabine and oral seliciclib in patients with metastatic breast cancer and *BRCA1/2* mutations" at the 2019 AACR.

CYC140 PLK1 Inhibitor
The first patient has been dosed in a Phase 1 first-in-human 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.

SEAMLESS Phase 3 Study
Stratified and exploratory subgroup analyses have defined a subgroup of patients for whom the sapacitabine regimen may represent an improvement over low intensity treatment by decitabine alone. Following consultation with three European regulatory authorities regarding a potential approval pathway for sapacitabine the Company intends to submit a request for scientific advice to the Scientific Advice Working Party (SAWP) of the European Medicines Agency.

Corporate Developments

Entered into a collaboration with The University of Texas MD Anderson Cancer Center to evaluate three Cyclacel medicines in patients with hematological malignancies. MD Anderson will evaluate CYC065, CYC140 and sapacitabine either as single agents or in combination with approved drugs, in up to 170 enrolled patients across four clinical trials.

Added Robert J. Spiegel, M.D. to the Company's Board of Directors. Dr. Spiegel brings over 30 years of R&D and operational experience in the biopharmaceutical industry as well as advisory experience to venture capital and private equity funds.

Entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC as sales agent, pursuant to which the agent may sell shares of common stock having an aggregate offering price of up to $5.0 million by any method that is deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act of 1933 as amended.

2019 Key Upcoming Business Objectives

- Report expansion cohort, Phase 1 clinical data with an oral sequential regimen of sapacitabine and seliciclib in patients with BRCA mutant metastatic breast cancer at the 2019 AACR
- Initiate CYC065-venetoclax Phase 1 study in patients with relapsed or refractory AML or MDS
- Initiate sapacitabine-venetoclax Phase 1 study in patients with relapsed or refractory AML or MDS
- Report initial data from the CYC065-venetoclax Phase 1 studies in leukemias

- Report initial data from the CYC140 Phase 1 First-in-Human study
- Report initial data and bioavailability from the Phase 1 study of an oral formulation of CYC065
- Report updated CYC065 Phase 1 data in patients with advanced solid cancers
- Report data from the IST Phase 1b/2 trial of sapacitabine-olaparib combination in patients with BRCA mutant metastatic breast cancer when reported by the investigators
- Determine regulatory pathway and submissibility of sapacitabine in elderly AML

Financial Highlights

As of December 31, 2018, cash and cash equivalents totaled $17.5 million, compared to $23.9 million as of December 31, 2017. The decrease of $6.4 million was primarily due to net cash used in operating activities of $6.7 million, net cash used in investing activities of $0.1 million, offset by $0.4 million of net cash provided by financing activities.

Revenues for the three months and year ended December 31, 2018 amounted to $0.2 million compared to nil revenue for the same periods in 2017. The revenue is related to a June 2015 collaboration, licensing and supply agreement with ManRos Therapeutics SA.

Research and development expenses were $1.1 million and $4.3 million for the three months and year ended December 31, 2018 as compared to $0.7 million and $4.2 million for the same periods in 2017. Research and development expenses relating to transcriptional regulation increased by $1.5 million from $1.1 million for the year ended December 31, 2017 to $2.5 million for the year ended December 31, 2018, as the clinical evaluation of CYC065 progresses. Research and development expenses relating to sapacitabine decreased by $1.7 million from $2.5 million for the year ended December 31, 2017 to $0.8 million for the year ended December 31, 2018, primarily as a result of a reduction in expenditures associated with the SEAMLESS Phase 3 trial and related costs.

General and administrative expenses for the three months and year ended December 31, 2018 were $1.5 million and $5.3 million, respectively compared to $1.5 million and $5.3 million for the same period of the previous year.

Total other income, net for the three months and year ended December 31, 2018 were $0.1 million and $0.9 million, compared to $0.1 million and $1.0 million for the same period of the previous year. The decrease of $0.1 million for the year ended December 31, 2018 is primarily related to a reduction in income received under an Asset Purchase Agreement with ThermoFisher Scientific Company and offset by a $0.2 million increase in interest income.

United Kingdom research & development tax credits were $0.4 million and $1.3 million for the three months and year ended December 31, 2018 as compared to $0.2 million and $1.0 million for the same periods in 2017.

Net loss for the three months and year ended December 31, 2018 were $2.0 million and $7.3 million compared to $1.9 million and $7.5 million for the same periods in 2017.

The Company raised net proceeds of approximately $4.7 million, of which $4.1 million was received in 2019, from its Common Stock Sales Agreement with H.C. Wainwright. This agreement is now complete. Together with cash resources of $17.5 million as of December 31, 2018 the Company estimates cash resources will fund currently planned programs through the end of 2020.

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 9719419.
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 using its expertise in cell cycle, transcriptional regulation and DNA damage response biology in cancer cells to develop innovative medicines. The transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced solid cancers and in combination with venetoclax in patients with advanced hematological malignancies, including CLL and AML. The DNA damage response program is evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in BRCA positive patients with advanced solid cancers and a concomitant regimen of sapacitabine and olaparib, a PARP inhibitor, in patients with BRCA mutant, metastatic breast cancer. CYC140, a PLK inhibitor, is in a Phase 1 first-in-human study in patients with advanced leukemias. 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)

	Twelve Months Ended December 31,	
	2017	**2018**
Revenues:		
Grant revenue	$ -	$ -
Collaboration and research and development revenue	-	150
Total revenues	-	150
Operating expenses:		
Research and development	4,237	4,327
General and administrative	5,254	5,371
Total operating expenses	9,491	9,698
Operating loss	(9,491)	(9,548)
Other income (expense):		
Change in valuation of financial instruments associated with stock purchase agreement	-	-
Foreign exchange gains (losses)	(39)	(90)
Interest income	118	331
Other income, net	949	682
Total other income (expense), net	1,028	923
Loss from continuing operations before taxes	(8,463)	(8,625)
Income tax benefit	993	1,342
Corporation Tax	-	(5)
Net loss from continuing operations	(7,470)	(7,288)
Net loss	(7,470)	(7,288)
Dividend on convertible exchangeable preferred shares	(201)	(201)
Beneficial conversion feature of Series A convertible stock	(3,638)	-
Conversion of Series A convertible preferred stock	(3,537)	-
Net loss applicable to common shareholders	$ (14,846)	$ (7,489)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (1.95)	$ (0.62)
Weighted average common shares outstanding	7,631,152	12,094,131

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

	December 31, 2017	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,910	$ 17,504
Prepaid expenses and other current assets	2,064	2,283
Total current assets	25,974	19,787
Property and equipment, net	29	36
Total assets	$ 26,003	$ 19,823
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,558	$ 2,719
Accrued and other current liabilities	2,555	1,732
Total current liabilities	4,113	4,451
Other liabilities	124	100
Total liabilities	4,237	4,551
Stockholders' equity	21,766	15,272
Total liabilities and stockholders' equity	$ 26,003	$ 19,823

SOURCE: Cyclacel Pharmaceuticals, Inc.