CYCLACEL PHARMACEUTICALS, INC.

FORM 8-K
(Current report filing)

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Sector	Healthcare
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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 28, 2017

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))**

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 28, 2017, announcing certain financial results for the fourth quarter and fiscal year ended December 31, 2016.

The Company will conduct a conference call to review its financial results on March 28, 2017, 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 fiscal year ended December 31, 2016, dated March 28, 2017.

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 28, 2017

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 2016 FINANCIAL RESULTS

-- Conference Call Scheduled March 28, 2017 at 4:30 p.m. EDT –

Berkeley Heights, NJ, March 28, 2017 - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company") a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, today reported its financial results and business highlights for the fourth quarter and full year ended December 31, 2016. The Company's net loss applicable to common shareholders for the three months and year ended December 31, 2016 was $2.9 million and $12.0 million, respectively. As of December 31, 2016, cash and cash equivalents totaled $16.5 million.

“Following the outcome of the SEAMLESS study and a review of our clinical development pipeline we will concentrate our resources on our transcriptional regulation and DNA damage response clinical stage programs,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “While we will discuss the SEAMLESS data with regulators after completing ongoing analyses, we are looking ahead with a clear strategy. We are dedicating our efforts and resources to progressing our CYC065 CDK inhibitor program and the promise in our BRCA positive stratified, sapacitabine and CDK inhibitor study. We are encouraged by the support received from various stakeholders, the recent success of commercial stage CDK inhibitors and early clinical data from our own CDK inhibitor trials."

Fourth Quarter and Full Year Highlights

Transcriptional Regulation Program -Cyclin Dependent Kinase (CDK) inhibitors

- Continued recruitment in Phase 1, first-in-human trial of CYC065, a CDK2/9 inhibitor, to evaluate safety, tolerability and pharmacokinetics in patients with solid tumors. Expanded sixth dose escalation level with the objective of determining maximum tolerated dose and recommended dosing for Phase 2.
- Data presented at the 2016 Annual Meeting of the American Association of Cancer Research demonstrated that CYC065 can induce cell death and combine beneficially with anti-cancer drugs from the Bcl-2 and BET (Bromodomain and Extra-Terminal) inhibitor classes, in *in vitro* models of B-cell lymphoma, including double-hit lymphomas. Combinations of CYC065 with the Bcl-2 inhibitor venetoclax (ABT-199) or BET inhibitors were both synergistic.
- Preclinical data published in the *Journal of the National Cancer Institute* demonstrated that CYC065 had promising antitumor activity against certain lung cancer cells through anaphase catastrophe, a novel, cancer-specific mechanism of action.

DNA Damage Response (DDR) program

- The extension of the Phase 1 study evaluating a sequential regimen of sapacitabine and the CDK inhibitor seliciclib is continuing enrollment in an enriched population of BRCA positive patients with advanced breast cancer.
- A part 3 of this study has been initiated to include BRCA positive patients with pancreatic and ovarian cancer.

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SEAMLESS Study in Elderly Patients with Acute Myeloid Leukemia (AML)

- In February 2017, the Company reported that the SEAMLESS study did not reach statistically significant superiority in overall survival (OS), although an improvement in complete remission rate was observed. In the stratified subgroup of patients with low baseline peripheral white blood cell count, comprising approximately two-thirds of the study's population, an improvement in OS was observed for the experimental arm.
- The Company is currently analyzing stratified and exploratory subgroups to identify patients who are most likely to benefit from treatment with the experimental arm. Depending on this analysis the Company may initiate discussions with European and U.S. regulators to determine a potential regulatory pathway.

Poster Presentation on the PLK Inhibitor CYC140 at the AACR Annual Meeting

Today, Cyclacel also announced a poster presentation at the American Association for Cancer Research 2017 Annual Meeting to be held April 1-5 in Washington, D.C. The poster is titled *"The novel PLK1 inhibitor, CYC140: Identification of pharmacodynamic markers, sensitive target indications and potential combinations"* (Poster Board 1, Abstract number 4178, Convention Center, Halls A-C, Poster Section 7). The poster details Cyclacel's preclinical study to identify target indications including acute leukemia and esophageal cancer. The results will be presented in a session titled "Targeting Protein Kinases and DNA Repair" on Tuesday Apr 4, 2017 1:00 PM - 5:00 PM Eastern Time.

Data presented in December 2016 at the 28 th EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium, demonstrated anti-tumor activity of CYC140 in preclinical xenograft models of acute leukemia and solid tumors, including esophageal cancer, with tumor growth delay, tumor regression and cures being observed. Several pharmacodynamic markers were identified and activity was demonstrated in a majority of malignant cell lines derived from AML, acute lymphoblastic leukemia (ALL) and esophageal cancer.

Financial Highlights

As of December 31, 2016, cash and cash equivalents totaled $16.5 million, compared to $20.4 million as of December 31, 2015. The decrease of $3.9 million was primarily due to $10.1 million of net cash used in operating activities, partially offset by net proceeds of $6.8 million from the sale of common stock through the ATM sales agreement with FBR Capital Markets & Co.

Revenue for the three months and year ended December 31, 2016 were $0.3 million and $0.8 million respectively, compared to $0.4 million and $1.9 million for the same periods of the previous year. The revenue is primarily related to previously awarded grants from the UK government being recognized over the period to progress CYC065 to IND, which was completed in 2015, and IND-directed preclinical development of CYC140, a novel, orally available, Polo-Like Kinase 1 (PLK 1) inhibitor, completed in November 2016.

Research and development expenses were $1.9 million and $9.5 million for the three months and year ended December 31, 2016 respectively, compared to $2.6 million and $12.4 million for the same periods of the previous year. The decrease was primarily due to reduced study and clinical supply costs associated with the completion of the SEAMLESS study.

General and administrative expenses for the three months and year ended December 31, 2016 were $1.5 million and $5.5 million respectively, compared to $1.7 million and $5.7 million for the same periods of the previous year.

Other income (expense), net for the three months and year ended December 31, 2016 were $(0.1) million and $0.4 million, compared to nil and $(0.3) million for the same period of the previous year. The increase in other income (expense) is primarily related to foreign exchange movements.

United Kingdom research & tax credits were $0.4 million and $2.0 million for the three months and year ended December 31, 2016 respectively, compared to $0.5 million and $2.1 million for the same periods of the previous year. The cash receipt for the 2016 tax credit of $2.0 million is expected to be received in the second quarter of 2017, which results in proforma cash and cash equivalents of $18.5 million as of December 31, 2016.

Net loss for the three months and year ended December 31, 2016 was $2.8 million and $11.8 million respectively, compared to $3.4 million and $14.3 million for the same periods of the previous year.

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 91915665

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 cell cycle, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. The transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced cancers. The DNA damage response program is evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in patients with BRCA positive, advanced solid cancers. Cyclacel is analyzing stratified and exploratory subgroups from a Phase 3 study of sapacitabine in elderly patients with AML. 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, Alexander Fudukidis, (646) 942-5632, alex.fudukidis@russopartnersllc.com

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

	Three Months Ended December 31,		Years Ended December 31,	
	2015	2016	2015	2016
		(Unaudited)		(Unaudited)
Revenues:				
Grant revenue	$ 424	$ 277	$ 1,694	$ 843
Collaboration and research and development revenue	—	—	250	—
Total revenues	424	277	1,944	843
Operating expenses:				
Research and development	2,559	1,932	12,382	9,477
General and administrative	1,726	1,513	5,732	5,516
Total operating expenses	4,285	3,446	18,114	14,993
Operating loss	(3,861)	(3,169)	(16,170)	(14,150)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	—	—	(51)	—
Foreign exchange gains	(14)	(96)	(368)	273
Interest income	4	6	9	37
Other income, net	(1)	(10)	94	66
Total other income (expense), net	(11)	(80)	(316)	376
Loss from operations before taxes	(3,872)	(3,249)	(16,486)	(13,774)
Income tax benefit	498	409	2,144	1,983
Net loss	(3,374)	(2,839)	(14,342)	(11,791)
Dividend on convertible exchangeable preferred shares	(51)	(50)	(201)	(200)
Net loss applicable to common shareholders	$ (3,425)	$ (2,945)	$ (14,543)	$ (11,991)
Net loss per share — basic and diluted	$ (1.18)	$ (0.69)	$ (5.36)	$ (3.50)
Weighted average common shares outstanding	2,914,689	4,256,706	2,713,096	3,424,976

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

(In $000s, except share, per share, and liquidation preference amounts)

	December 31,	
	2015	**2016**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,440	$ 16,520
Prepaid expenses and other current assets	4,126	3,097
Total current assets	24,566	19,617
Property, plant and equipment (net)	198	45
Total assets	$ 24,764	$ 19,662
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,940	$ 2,497
Accrued and other current liabilities	3,813	2,762
Total current liabilities	5,753	5,259
Other liabilities	176	130
Total liabilities	5,929	5,389
Stockholders' equity	18,835	14,273
Total liabilities and stockholders' equity	$ 24,764	$ 19,662

SOURCE: Cyclacel Pharmaceuticals, Inc.