

CYCLACEL PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

Filed 05/11/17 for the Period Ending 05/11/17

Address	200 CONNELL DRIVE SUITE 1500 BERKELEY HEIGHTS, NJ 07922
Telephone	908-517-7330
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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): May 11, 2017

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

Delaware
(State or other jurisdiction
of incorporation)

0-50626
(Commission File Number)

91-1707622
(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(e) under the Exchange Act (17 CFR 240.13e-4(e))

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 May 11, 2017, announcing certain financial results for the first quarter ended March 31, 2017.

The Company will conduct a conference call to review its financial results on May 11, 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 first quarter ended March 31, 2017, dated May 11, 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: May 11, 2017



Cyclacel Pharmaceuticals, Inc.

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

CYCLACEL PHARMACEUTICALS REPORTS FIRST QUARTER 2017 FINANCIAL RESULTS

— Conference Call Scheduled May 11, 2017 at 4:30 p.m. EDT —

Berkeley Heights, NJ, May 11, 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 first quarter ended March 31, 2017.

The Company's net loss applicable to common shareholders for the three months ended March 31, 2017 was \$1.6 million, or \$0.38 per share, compared to net loss applicable to common shareholders of \$3.1 million, or \$1.04 per share, for the first quarter of 2016. As of March 31, 2017, cash and cash equivalents totaled \$12.7 million.

"Our development priorities going forward are our transcriptional regulation and DNA damage response clinical stage programs," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "In the Phase 1 study of our CYC065 CDK inhibitor in patients with solid tumors, we are close to establishing the recommended Phase 2 dose. Biomarker analysis shows evidence of target engagement and preliminary clinical activity. In parallel, we are reviewing with investigators study designs to test CYC065 in combination with approved agents in hematological indications. We are expanding our BRCA positive, sapacitabine and CDK inhibitor study to evaluate patients with ovarian and pancreatic cancers in addition to breast. We look forward to reporting our progress with these programs and the outcome of our final analysis of SEAMLESS data."

Quarter and Recent Highlights

Transcriptional regulation program: cyclin dependent kinase (CDK) inhibitor

- In the ongoing Phase 1, first-in-human trial of CYC065, a CDK2/9 inhibitor, in heavily pretreated patients with advanced solid tumors, we are expanding the sixth dose escalation level to a total of 9 patients with the objective of determining the recommended Phase 2 dose. Following analysis of biomarkers from patient specimens obtained at baseline and during CYC065 treatment, evidence of pharmacodynamic engagement has been observed, including a reduction in Mcl-1 expression. Preliminary evidence of clinical activity has been observed in two patients with MYC and CCNE (cyclin E) amplifications. These observations are consistent with the Company's preclinical data and the drug's mechanism of action.
- At the American Association for Cancer Research 2017 Annual Meeting, independent researchers from The University of Texas MD Anderson Cancer Center presented preclinical data demonstrating therapeutic potential of CYC065 as a targeted anti-cancer agent. The poster titled "*The next generation CDK2/9 inhibitor CYC065 elicits marked antineoplastic effects in lung cancer by engaging anti-metastatic pathways*" detailed data which show CYC065's potential to cause anaphase catastrophe and inhibit migration and invasion of lung cancer cells including mutant KRAS, a key molecular features of such cancers.

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- Preclinical data published in the *Journal of National Cancer Institute* demonstrated that CYC065 had prominent antitumor activity against lung cancer through anaphase catastrophe, a novel, mitosis-specific mechanism of action.

DNA damage response program

- The Phase 1 combination of sapacitabine and seliciclib CDK inhibitor is continuing enrollment in an extension study in an enriched population of approximately 20 patients with BRCA positive advanced breast cancer.
- A part 3 of this study has been designed with the goal of testing a revised dosing schedule in additional patients, including BRCA mutation positive, ovarian and pancreatic cancer patients.

SEAMLESS study in acute myeloid leukemia (AML)

- In February 2017, the Company reported that the 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.

PLK inhibitor CYC140

During the quarter, Cyclacel announced a poster presentation at the American Association for Cancer Research (AACR) 2017 Annual Meeting. The poster, titled "*The novel PLK1 inhibitor, CYC140: Identification of pharmacodynamic markers, sensitive target indications and potential combinations*", detailed Cyclacel's preclinical study to identify sensitive target indications including acute leukemia and esophageal cancer. The data demonstrated antitumor 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. In addition, 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 March 31, 2017, cash and cash equivalents totaled \$12.7 million, compared to \$16.5 million as of December 31, 2016. The decrease of \$3.8 million was due to net cash used in operating activities. Net proceeds of approximately \$1.0 million were received in April 2017 from the sale of common stock through the Company's at the market facility.

There were no revenues for the three months ended March 2017 compared to \$0.1 million for the same period of the previous year. The revenue is related to previously awarded, UK government grants being recognized over the period to progress IND-directed preclinical development of CYC140, a novel, PLK-1 inhibitor, which was completed in November 2016.

Research and development expenses were \$1.3 million compared to \$2.5 million for the same period in 2016. The decrease was primarily due to reduced study and clinical supply costs associated with completion of the SEAMLESS study and 2016 expenditure related the development of CYC140.

General and administrative expenses were \$1.4 million for each of the three months ended March 31, 2016 and 2017.

Other income, net for the three months ended March 31, 2017, was \$0.8 million, compared to \$0.2 million for the same period of the previous year. The increase is primarily related to income received under an Asset Purchase Agreement with Life Technologies Corporation, or LTC, (formerly Invitrogen Corporation), in respect of certain assets and intellectual property sold by the Company to LTC in December 2005.

The United Kingdom research & tax credit was \$0.3 million for the three months ended March 31, 2017 compared to \$0.5 million for the same period in 2016. The cash receipt for the 2016 tax credit of approximately \$2.0 million is expected to be received in the second quarter of 2017.

After taking into account the expected \$2.0 million cash receipt above and sales of common stock totaling \$1.0 million from the at the market facility, *pro forma* cash at March 31, 2017 is approximately \$15.7 million. The Company expects current *pro forma* cash to fund operations and ongoing programs to the end of 2018.

Net loss for the three months ended March 31, 2017 was \$1.6 million compared to \$3.0 million for the same period in 2016.

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 19102819

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. Cyclacel's 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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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended March 31,	
	2016	2017
	(Unaudited)	
Revenues:		
Grant revenue	\$ 139	\$ -
Total revenues	<u>139</u>	<u>-</u>
Operating expenses:		
Research and development	2,499	1,312
General and administrative	1,384	1,381
Total operating expenses	<u>3,883</u>	<u>2,693</u>
Operating loss	<u>(3,744)</u>	<u>(2,693)</u>
Other income (expense):		
Foreign exchange gains	180	(59)
Interest income	10	12
Other income, net	20	879
Total other income, net	<u>210</u>	<u>832</u>
Loss from operations before taxes	<u>(3,534)</u>	<u>(1,861)</u>
Income tax benefit	493	306
Net loss	<u>(3,041)</u>	<u>(1,555)</u>
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	<u>\$ (3,091)</u>	<u>\$ (1,605)</u>
Net loss per share — basic and diluted	<u>\$ (1.04)</u>	<u>\$ (0.38)</u>
Weighted average common shares outstanding	<u>2,965,208</u>	<u>4,271,324</u>

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

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

	December 31, 2016	March 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,520	\$ 12,729
Prepaid expenses and other current assets	3,097	4,305
Total current assets	19,617	17,034
Property, plant and equipment (net)	45	39
Total assets	\$ 19,662	\$ 17,073
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,497	\$ 1,652
Accrued and other current liabilities	2,762	2,476
Total current liabilities	5,259	4,128
Other liabilities	130	127
Total liabilities	5,389	4,255
Stockholders' equity	14,273	12,818
Total liabilities and stockholders' equity	\$ 19,662	\$ 17,073

SOURCE: Cyclacel Pharmaceuticals, Inc.