

# CYCLACEL PHARMACEUTICALS, INC.

## **FORM 8-K** (Current report filing)

Filed 08/09/17 for the Period Ending 08/09/17

Address	200 CONNELL DRIVE SUITE 1500 BERKELEY HEIGHTS, NJ 07922
Telephone	908-517-7330
CIK	0001130166
Symbol	CYCC
SIC Code	2834 - Pharmaceutical Preparations
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): August 9, 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(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 August 9, 2017, announcing certain financial results for the second quarter ended June 30, 2017.

The Company will conduct a conference call to review its financial results on August 9, 2017, at 4:30 p.m., Eastern Time.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press release announcing financial results for the second quarter ended June 30, 2017, dated August 9, 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: August 9, 2017

---



P R E S S   R E L E A S E

**CYCLACEL PHARMACEUTICALS REPORTS SECOND QUARTER 2017 FINANCIAL RESULTS**

*– Conference Call Scheduled August 9, 2017 at 4:30 p.m. EDT –*

**Berkeley Heights, NJ, August 9, 2017** - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP, "Cyclacel" or the "Company"), 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, today reported its financial results and business highlights for the second quarter ended June 30, 2017.

The Company's net loss applicable to common shareholders for the three months ended June 30, 2017 was \$2.2 million or \$0.50 per share, compared to net loss applicable to common shareholders of \$3.0 million, or \$1.01 per share for the second quarter of 2016. As of June 30, 2017, cash and cash equivalents totaled \$13.6 million. *Pro forma* cash and cash equivalents as of June 30, 2017 totaled \$27.4 million after including \$13.8 million in proceeds, net of expenses, received in the Company's underwritten offering completed on July 21, 2017.

"As a result of the completion of our recent offering, in which existing and new investors participated, we are able to advance the clinical investigation of CYC065, our Cyclin Dependent Kinase (CDK) 2/9 inhibitor, in selected, molecularly-defined patient populations," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We have selected a recommended Phase 2 dose for CYC065 from part 1 of a dose-escalating, Phase 1, first-in-human, study of CYC065. Data from this study evidenced durable target engagement and Mcl-1 biomarker suppression at well tolerated doses with initial evidence of anticancer activity in patients with Mcl-1 and/or cyclin E overexpression or amplification. Our top priority is to finalize designs for a Phase 1/2 study testing CYC065 in combination with venetoclax, a Bcl-2 inhibitor approved for chronic lymphocytic leukemia, an indication in which we believe Mcl-1 suppression may be beneficial. In parallel, we will enroll a new part 2 of the Phase 1 study in patients with advanced solid tumors testing additional dosing schedules. We look forward to reporting our progress, commencement of these studies and data, as they arise."

**Business Highlights**

***Transcriptional Regulation Program: CYC065 CDK inhibitor***

- Selected a recommended Phase 2 dose (RP2D) from part 1 of a dose-escalating, Phase 1, first-in-human, clinical study. RP2D was determined at dosing level 6, which enrolled 10 patients with advanced cancers. Prolonged reduction of the Mcl-1 biomarker was observed in 7 out of 9 evaluable patients for at least 24 hours following a single dose of CYC065, which was generally well tolerated. Preliminary anticancer activity was observed in three patients with Mcl-1, MYC and Mcl-1/cyclin E amplified cancers. The trial is being conducted at the Dana Farber Cancer Institute in Boston.
- Part 2 of the study will enroll patients with advanced solid tumors, in particular cyclin E amplified tumors. Such tumors include subsets of high grade serous ovarian and uterine cancers. Part 2 will evaluate CYC065 in a more intensive schedule for 2 days per week, for 2 weeks of a three-week cycle. Biospecimens will be collected for assessment of biomarkers related to CYC065's mechanism of action.

200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922, USA Tel +1 908 517 7330 Fax +1 866 271 3466

1 James Lindsay Place, Dundee, DD1 5JJ, UK Tel +44 1382 206 062 Fax +44 1382 206 067

[www.cyclacel.com](http://www.cyclacel.com) – [info@cyclacel.com](mailto:info@cyclacel.com)

### ***SEAMLESS Study***

- An abstract of the results of the Phase 3 study of oral sapacitabine in elderly patients with acute myeloid leukemia (AML) has been submitted to the American Society of Hematology (ASH), and if accepted, will be the subject of an oral or poster presentation at the 59<sup>th</sup> ASH Annual Meeting to be held December 9 - 12, 2017.

### ***July Underwritten Offering***

- On July 21, 2017, the Company announced the closing of an underwritten offering, with net proceeds of approximately \$13.8 million after deducting underwriting discounts and commissions and other estimated offering expenses, including full exercise of the underwriters' overallotment option. The Company issued and sold in the offering (i) 3,154,000 Class A Units, each consisting of one share of the Company's common stock, and a warrant to purchase one share of common stock, and (ii) 8,872 Class B Units, each consisting of one share of the Company's Series A Convertible Preferred Stock convertible into 500 shares of common stock at the initial conversion price, and a warrant to purchase a number of shares of common stock equal to \$1,000 divided by the conversion price. The price to the public in the offering was \$2.00 per Class A Unit and \$1,000 per Class B Unit.
- Subsequent to the closing of the offering, holders of 7,613 (86%) shares out of 8,872 shares outstanding of Series A Preferred Stock elected to convert their shares into 3,806,500 shares of common stock. Following such conversions, 11,400,447 shares of common stock and 1,259 (14%) shares of Series A Preferred Stock remain outstanding as of August 8, 2017.

### ***Financial Highlights***

As of June 30, 2017, cash and cash equivalents totaled \$13.6 million, compared to \$16.5 million on December 31, 2016. After the July offering, *pro forma* cash and cash equivalents are \$27.4 million.

Revenue for the three months ended June 30, 2017 were \$0 compared to \$0.2 million for the same period of the previous year. Revenue is primarily related to previously awarded grants from the UK government being recognized over the period to progress 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 \$1.2 million compared to \$2.6 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 completion of preclinical development of CYC140.

General and administrative expenses for the three months ended June 30, 2016 and 2017 remained flat at \$1.3 million.

Other income (expense), net for the three months ended June 30, 2017 was \$34,000, compared to \$0.2 million for the same period of the previous year. The decrease in other income (expense) is primarily related to foreign exchange movements.

The UK government research & development tax credit for the quarter was \$0.3 million, compared to \$0.6 million for the same period of the previous year. During the quarter, we also recognized cash received for the 2016 tax credit of \$1.8 million.

Net loss for the three months June 30, 2017 was \$2.2 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 64524973

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at [www.cyclacel.com](http://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'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](http://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](http://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**

Company: Paul McBarron, (908) 517-7330, [pmcbarron@cyclacel.com](mailto:pmcbarron@cyclacel.com)

Investor Relations: Russo Partners LLC, Alexander Fudukidis, (646) 942-5632, [alex.fudukidis@russopartnersllc.com](mailto:alex.fudukidis@russopartnersllc.com)

© Copyright 2017 Cyclacel Pharmaceuticals, Inc. All Rights Reserved. The Cyclacel logo and Cyclacel® are trademarks of Cyclacel Pharmaceuticals, Inc.



**CYCLACEL PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	Three Months Ended June 30,		Six months Ended June 30,	
	2016	2017	2016	2017
<b>Revenues:</b>				
Grant revenue	\$ 222	\$ -	\$ 361	\$ -
<b>Operating expenses:</b>				
Research and development	2,637	1,222	5,136	2,534
General and administrative	1,345	1,267	2,729	2,648
<b>Total operating expenses</b>	<u>3,982</u>	<u>2,489</u>	<u>7,865</u>	<u>5,182</u>
<b>Operating loss</b>	<u>(3,760)</u>	<u>(2,489)</u>	<u>(7,504)</u>	<u>(5,182)</u>
Other income (expense):				
Foreign exchange gains (losses)	138	16	318	(43)
Interest income	13	18	23	30
Other income, net	18	-	38	879
Total other income (expense)	169	34	379	866
<b>Loss before taxes</b>	<u>(3,591)</u>	<u>(2,455)</u>	<u>(7,125)</u>	<u>(4,316)</u>
Income tax benefit	626	268	1,119	574
<b>Net loss</b>	<u>(2,965)</u>	<u>(2,187)</u>	<u>(6,006)</u>	<u>(3,742)</u>
Dividend on convertible exchangeable preferred shares	(50)	(50)	(100)	(100)
<b>Net loss applicable to common shareholders</b>	<u>\$ (3,015)</u>	<u>\$ (2,237)</u>	<u>\$ (6,106)</u>	<u>\$ (3,842)</u>
<b>Basic and diluted earnings per common share:</b>				
Net loss per share – basic and diluted	<u>\$ (1.01)</u>	<u>\$ (0.50)</u>	<u>\$ (2.05)</u>	<u>\$ (0.88)</u>
Weighted average common shares outstanding	<u>3,000,192</u>	<u>4,434,441</u>	<u>2,982,508</u>	<u>4,353,333</u>

The accompanying notes are an integral part of these consolidated financial statements.

**CYCLACEL PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

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

	<u>December 31,</u> <u>2016</u>	<u>June 30,</u> <u>2017</u> <u>(Unaudited)</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,520	\$ 13,591
Prepaid expenses and other current assets	3,097	2,460
Total current assets	<u>19,617</u>	<u>16,051</u>
Property, plant and equipment (net)	45	32
Total assets	<u>\$ 19,662</u>	<u>\$ 16,083</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,497	\$ 2,038
Accrued and other current liabilities	2,762	2,281
Total current liabilities	<u>5,259</u>	<u>4,319</u>
Other liabilities	130	128
Total liabilities	<u>5,389</u>	<u>4,447</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2016 and June 30, 2017; 335,273 shares issued and outstanding at December 31, 2016 and June 30, 2017. Aggregate preference in liquidation of \$4,006,512 at December 31, 2016 and June 30, 2017.	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2016 and June 30, 2017; 4,256,829 and 4,439,947 shares issued and outstanding at December 31, 2016 and June 30, 2017 respectively.	4	4
Additional paid-in capital	350,051	351,148
Accumulated other comprehensive loss	(743)	(736)
Accumulated deficit	<u>(335,039)</u>	<u>(338,780)</u>
Total stockholders' equity	<u>14,273</u>	<u>11,636</u>
Total liabilities and stockholders' equity	<u>\$ 19,662</u>	<u>\$ 16,083</u>

SOURCE: Cyclacel Pharmaceuticals, Inc.