
**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 12, 2018

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 November 12, 2018, announcing certain financial results for the second quarter ended September 30, 2018.

The Company will conduct a conference call to review its financial results on November 12, 2018, 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 third quarter ended September 30, 2018, dated November 12, 2018.](#)

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 13, 2018



Cyclacel Pharmaceuticals, Inc.

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

CYCLACEL PHARMACEUTICALS REPORTS THIRD QUARTER 2018 FINANCIAL RESULTS
- Conference Call Scheduled November 12, 2018 at 4:30 p.m. ET -

Berkeley Heights, NJ, November 12, 2018 - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today reported financial results and business highlights for the third quarter 2018. The Company's net loss applicable to common shareholders for the three months ended September 30, 2018 was \$2.1 million. As of September 30, 2018, cash and cash equivalents totaled \$19.0 million.

"We continue to execute on our strategy to rapidly develop CYC065 and CYC140 in hematological malignancies and CYC065 in advanced solid tumors," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The Phase 1 study evaluating CYC065 in combination with venetoclax in patients with relapsed/refractory CLL and the CYC140 first-in-human study are open for enrollment. Two further protocols evaluating combinations of CYC065 and sapacitabine are in development. Our alliance with MD Anderson allows us to parallel track the development of our drugs in a cash-sparing manner while utilizing MD Anderson's expertise to recruit patients across four studies. We estimate that our cash resources will be sufficient to fund operations until the second quarter of 2020. We are also pleased to report that the IST evaluating sapacitabine and olaparib in BRCA positive patients with breast cancer has started to enroll."

Key Company Highlights

- Announced a three-year strategic alliance agreement with The University of Texas MD Anderson Cancer Center enabling clinical evaluation of three Cyclacel medicines in patients with hematological malignancies. MD Anderson will conduct four clinical studies, with a total projected enrollment of patients, investigating CYC065, CYC140 and sapacitabine either as single agents or in combination with approved drugs.
- Opened for enrollment the Phase 1 clinical trial evaluating CYC065 in combination with venetoclax, a Bcl-2 inhibitor, in patients with relapsed/refractory CLL. Preclinical data presented at AACR 2018 showed enhanced activity of CYC065 and venetoclax combination in CLL tumor samples, including those with 17p deletions. The combination also demonstrated activity in two CLL samples resistant to either agent alone, suggesting that dual targeting of Mcl-1 and Bcl-2 dependent mechanisms could induce synergistic cell death.
- First patient dosed in the Phase 1b/2 investigator-sponsored trial (IST) of sapacitabine with olaparib, an approved PARP inhibitor, in BRCA positive patients with breast cancer. Preclinical data support the hypothesis that dual targeting of the DNA damage response pathway by combining olaparib with sapacitabine may enhance the efficacy of standard of care treatment for BRCA positive patients with breast cancer.
- Activated the CYC140 first-in-human study in advanced leukemias. CYC140 is a novel, small molecule, selective polo-like-kinase 1 (PLK1) inhibitor. CYC140 is differentiated from other PLK1 inhibitors, demonstrating potent and selective target inhibition and high activity in xenograft models of human cancers when dosed orally at non-toxic doses.

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- Progressed patient enrollment in part 2 of the Phase 1 study evaluating CYC065 monotherapy in patients with advanced solid tumors including those with Mcl-1, MYC or cyclin E amplified cancers relevant to CYC065's mechanism of action. Part 2 is evaluating increased dosing frequency of two days per week for two weeks of a three-week cycle.
- Completed meetings with three European regulatory authorities with the objective of determining a potential regulatory pathway for sapacitabine in elderly AML. The regulators provided consistent guidance on next steps and Cyclacel is evaluating a potential request for a meeting with the Scientific Advice Working Party of the European Medicines Agency.
- Appointed Robert J. Spiegel, M.D. to the 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.

Financial Highlights

As of September 30, 2018, cash and cash equivalents totaled \$19.0 million compared to \$23.9 million as of December 31, 2017. The decrease of \$4.9 million in the nine-months was primarily due to net cash used in operating activities, including \$1.2 million of R&D tax credit received from the United Kingdom government.

Research and development expenses were \$1.2 million for the three months ended September 30, 2018 compared to \$1.0 million for the same period in 2017.

General and administrative expenses were \$1.3 million for the three months ended September 30, 2018 compared to \$1.2 million for the same period in 2017. Other income, net for the three months ended September 30, 2018 was \$0.1 million compared to \$36,000 for the same period of the previous year.

The United Kingdom R&D and tax credits were \$0.3 million for the three months ended September 30, 2018 compared to \$0.2 million for the same period in 2017.

Net loss for the three months ended September 30, 2018 was \$2.1 million compared to \$1.9 million for the same period in 2017. With the cash-sparing benefits accruing from the MD Anderson alliance the Company believes that cash and marketable securities, which were approximately \$19.0 million as of September 30, 2018, will be sufficient to finance operations until the second quarter 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 3775807

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. The DNA damage response program is evaluating a combination of sapacitabine and seliciclib, a CDK inhibitor, in BRCA positive patients with advanced solid cancers and sapacitabine and olaparib, a PARP inhibitor, in BRCA positive patients with breast cancer. CYC140, a PLK inhibitor, is ready to start investigation in cancer patients. 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 September 30,		Nine Months Ended September 30,	
	2017	2018	2017	2018
Revenues:				
Total revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	958	1,205	3,491	3,185
General and administrative	1,154	1,250	3,802	3,898
Total operating expenses	<u>2,112</u>	<u>2,455</u>	<u>7,293</u>	<u>7,083</u>
Operating loss	<u>(2,112)</u>	<u>(2,455)</u>	<u>(7,293)</u>	<u>(7,083)</u>
Other income (expense):				
Foreign exchange gains (losses)	(22)	1	(65)	(42)
Interest income	30	85	59	238
Other income, net	28	-	907	632
Total other income	<u>36</u>	<u>86</u>	<u>901</u>	<u>828</u>
Loss before taxes	<u>(2,076)</u>	<u>(2,369)</u>	<u>(6,392)</u>	<u>(6,255)</u>
Income tax benefit	219	301	793	985
Net loss	<u>(1,857)</u>	<u>(2,068)</u>	<u>(5,599)</u>	<u>(5,270)</u>
Dividend on convertible exchangeable preferred shares	(50)	(50)	(151)	(151)
Beneficial conversion feature of Series A convertible stock	(3,638)	-	(3,638)	-
Conversion of Series A convertible preferred stock	(3,373)	-	(3,373)	-
Net loss applicable to common shareholders	<u>\$ (8,918)</u>	<u>\$ (2,118)</u>	<u>\$ (12,761)</u>	<u>\$ (5,421)</u>
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted	<u>\$ (0.91)</u>	<u>\$ (0.18)</u>	<u>\$ (2.06)</u>	<u>\$ (0.45)</u>
Weighted average common shares outstanding	<u>9,835,441</u>	<u>11,997,447</u>	<u>6,200,783</u>	<u>11,997,447</u>

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

	<u>December 31,</u> <u>2017</u>	<u>September 30,</u> <u>2018</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,910	\$ 18,973
Prepaid expenses and other current assets	2,064	1,696
Total current assets	25,974	20,669
Property and equipment, net	29	38
Total assets	<u>\$ 26,003</u>	<u>\$ 20,707</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,558	\$ 1,411
Accrued and other current liabilities	2,555	2,592
Total current liabilities	4,113	4,003
Other liabilities	124	106
Total liabilities	4,237	4,109
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2017 and September 30, 2018; 6% Convertible Exchangeable preferred stock; 335,273 shares issued and outstanding at December 31, 2017 and September 30, 2018. Aggregate preference in liquidation of \$4,006,512 as of December 31, 2017 and September 30, 2018.	-	-
Series A convertible preferred stock, \$0.001 par value; 264 shares issued and outstanding at December 31, 2017 and September 30, 2018.	-	-
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2017 and September 30, 2018; 11,997,447 shares issued and outstanding at December 31, 2017 and September 30, 2018.	12	12
Additional paid-in capital	365,057	365,160
Accumulated other comprehensive loss	(794)	(796)
Accumulated deficit	(342,509)	(347,778)
Total stockholders' equity	21,766	16,598
Total liabilities and stockholders' equity	<u>\$ 26,003</u>	<u>\$ 20,707</u>

SOURCE: Cyclacel Pharmaceuticals, Inc.