CYCLACEL PHARMACEUTICALS, INC.

FORM 8-K
(Current report filing)

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Address	200 CONNELL DRIVE SUITE 1500 BERKELEY HEIGHTS, NJ 07922
Telephone	908-517-7330
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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): November 14, 2016

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 November 14, 2016, announcing certain financial results for the third quarter ended September 30, 2016.

The Company will conduct a conference call to review its financial results on November 14, 2016, 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, 2016, dated November 14, 2016.

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 14, 2016

Exhibit 99.1

Cyclacel Pharmaceuticals, Inc.

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

CYCLACEL PHARMACEUTICALS REPORTS 3 rd QUARTER 2016 FINANCIAL RESULTS

Conference Call Scheduled November 14, 2016 at 4:30 p.m. ET

BERKELEY HEIGHTS, NJ, Nov. 14, 2016 — 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 financial results and business highlights for the third quarter ended September 30, 2016.

The Company's net loss applicable to common shareholders for the third quarter ended September 30, 2016 was $3.0 million, or $0.86 per basic and diluted share, compared to net loss applicable to common shareholders of $2.8 million, or $0.95 per basic and diluted share for the third quarter ended September 30, 2015. As of September 30, 2016, cash and cash equivalents totaled $18.0 million.

" SEAMLESS, a Phase 3 study of oral sapacitabine capsules, represents one of the largest clinical trials conducted in elderly patients with AML who are unfit or refused intensive chemotherapy. Following completion of follow-up at the beginning of the quarter, we have been conducting data validation operations, " said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “We are pleased to report that this process is nearing completion following which the database will be locked and transferred to our statistical analysis vendor. We anticipate reporting top line results late in the fourth quarter of 2016 or in early 2017.”

“The collection and processing of SEAMLESS Phase 3 data represent many years of effort in our search to offer a new treatment regimen for this older patient population. We will soon analyze the data and determine whether the results warrant regulatory submissions," said Dr. Judy Chiao, VP, Clinical Development and Regulatory Affairs. "We are grateful to the patients, their families, the investigators and their teams for their valuable contributions to this study.”

“During the quarter data presented at a pediatric cancer meeting demonstrated that CYC065, our second generation Cyclin Dependent Kinase (CDK) inhibitor, prolonged survival in *MYCN* -addicted neuroblastoma models. The data further validate the mechanism of CYC065 and provide a rationale for clinical investigation in neuroblastoma with *MYCN* amplification, a major oncogenic driver of this childhood cancer. MYC family proteins are important therapeutic targets in other oncology indications, including certain solid tumors, leukemias and lymphomas. Early clinical and preclinical data from our DNA damage response program suggest that our transcriptional CDK inhibitors may have a synergistic effect with other anticancer agents, including sapacitabine. We look forward to reporting new data from our ongoing clinical studies of sapacitabine and seliciclib in BRCA positive patients and of CYC065 in patients with solid tumors,” continued Mr. Rombotis.

BUSINESS HIGHLIGHTS

SEAMLESS study

- Phase 3 study of oral sapacitabine capsules alternating with intravenous decitabine compared to decitabine alone, as first-line treatment in patients aged 70 years or older with AML who are unfit or refused intensive chemotherapy; cleaned and validated dataset being finalized and database lock imminent.

DNA damage response program

- The Phase 1 combination of sapacitabine and seliciclib is continuing enrollment in an extension study in an enriched population of BRCA positive patients with advanced breast cancer.

Cyclin dependent kinase (CDK) inhibitor program

- 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. The sixth dose escalation level has been reached.

- Preclinical data presented at the Childhood Cancer Meeting 2016 demonstrated effectiveness of CYC065 against neuroblastoma models with an overexpression and amplification of *MYCN* , a driver of neuroblastoma.

KEY UPCOMING MILESTONES

SEAMLESS study

- Report top-line data and determination of submissibility to regulatory authorities, anticipated late fourth quarter 2016 or early 2017.
- Progress the Paediatric Investigation Plan for sapacitabine with the European Medicines Agency.

DNA damage response program

- Progress Phase 1 sapacitabine and seliciclib extension cohort in a breast cancer patient population enriched for BRCA mutations.
- Initiate Phase 1 part 3, to include BRCA mutation positive, pancreatic and ovarian cancer patients.

CDK Inhibitor Program

- Report top-line results of the CYC065 Phase 1 trial in patients with solid tumors.
- Report data when available from ongoing investigator sponsored trials (ISTs) evaluating seliciclib in patients with Cushing's disease and rheumatoid arthritis. Additionally, seliciclib is being evaluated in cystic fibrosis though a license and supply agreement with ManRos Therapeutics.

Sapacitabine in myelodysplastic syndromes (MDS)

- Plan Phase 1/2 trial of sapacitabine in combination with other agents to determine safety and tolerability.
- Plan a Phase 2 randomized controlled trial (RCT) of sapacitabine in combination with other agents following review of all relevant clinical data with mature follow-up.

THIRD QUARTER 2016 FINANCIAL RESULTS

Cash and cash equivalents totaled $18.0 million as of September 30, 2016 compared to $20.4 million at December 31, 2015. Approximately $5.2 million was raised from the sale of common stock through the Company's at-the-market facility with FBR Capital Markets. A further $1.5 million was received in October 2016 through this facility, resulting in a proforma cash balance as of September 30, 2016 of $19.5 million. Based on current plans, the Company estimates that it has capital resources to fund operations through the second quarter of 2018.

Revenue for the three months ended September 30, 2016 was $0.2 million, compared to $0.7 million for the same period of the previous year, with the decrease primarily related to grant revenue related to CYC065, for which the grant ended in December 2015.

Research and development expenses were $2.4 million for the three months ended September 30, 2016 and $2.9 million for the three months ended September 30, 2015.

General and administrative expenses were $1.3 million for the three months ended September 30, 2016 and $1.2 million for the three months ended September 30, 2015.

CONFERENCE CALL AND WEBCAST INFORMATION:

Cyclacel will conduct a conference call on November 14, 2016 at 4:30 p.m. Eastern Time to review the third quarter 2016 results. Conference call and webcast details are as follows:

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 14223368

For the live and archived webcast, please visit the Corporate Presentations and Events 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 control and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. The SEAMLESS randomized Phase 3 trial of sapacitabine as front-line treatment for AML in the elderly under an SPA with FDA has completed enrollment and follow-up. Cyclacel's pipeline includes an oral combination of seliciclib (CDK inhibitor) and sapacitabine in Phase 1 in advanced solid tumors, including patients with BRCA mutations; sapacitabine in Phase 2 in MDS; and CYC065 (CDK inhibitor) in Phase 1 in solid tumors with potential utility based on preclinical data also in hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates. Please visit www.cyclacel.com for more information.

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

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2016	2015	2016
Revenues:				
Grant revenue	$ 462	$ 205	$ 1,270	$ 566
Collaboration and research and development revenue	253	—	253	—
Total revenues	715	205	1,523	566
Operating expenses:				
Research and development	2,904	2,409	9,826	7,545
General and administrative	1,205	1,273	4,006	4,002
Total operating expenses	4,109	3,682	13,832	11,547
Operating loss	(3,394)	(3,477)	(12,309)	(10,981)
Other income (expense):				
Change in valuation of financial instruments associated with stock purchase agreement	(27)	—	(51)	—
Foreign exchange (loss) gain	(219)	51	(354)	369
Interest income	2	8	5	31
Other income, net	13	18	95	56
Total other income (expense)	207	77	(305)	456
Loss before taxes	(3,187)	(3,400)	(12,614)	(10,525)
Income tax benefit	478	454	1,646	1,573
Net loss	(2,709)	(2,946)	(10,968)	(8,952)
Dividend on convertible exchangeable preferred shares	(50)	(50)	(150)	(150)
Net loss applicable to common shareholders	$ (2,759)	$ (2,996)	$ (11,118)	$ (9,102)
Basic and diluted earnings per common share:				
Net loss per share – basic and diluted	$ (0.95)	$ (0.86)	$ (4.20)	$ (2.89)
Weighted average common shares outstanding	2,889,893	3,473,696	2,645,159	3,145,730

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

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

	December 31, 2015	September 30, 2016 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,440	$ 18,029
Prepaid expenses and other current assets	4,051	4,521
Current assets of discontinued operations	75	29
Total current assets	24,566	22,579
Property, plant and equipment (net)	198	73
Total assets	$ 24,764	$ 22,652
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,940	$ 1,979
Accrued and other current liabilities	3,738	3,562
Current liabilities of discontinued operations	75	29
Total current liabilities	5,753	5,570
Other liabilities	176	141
Total liabilities	5,929	5,711
Total stockholders' equity	18,835	16,941
Total liabilities and stockholders' equity	$ 24,764	$ 22,652

Source: Cyclacel Pharmaceuticals, Inc.