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): October 1, 2018

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))**

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). ☐

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 1.01: Entry Into A Material Definitive Agreement.

On October 1, 2018, Cyclacel Pharmaceuticals, Inc. (the "**Company**") entered into a Clinical Collaboration Agreement (the "**CCA**") with The University of Texas MD Anderson Cancer Center ("**MD Anderson**"). The main objective of the CCA is to clinically evaluate the safety and efficacy of three Cyclacel medicines in patients with hematological malignancies, including chronic lymphocytic leukemias ("**CLL**"), acute myeloid leukemias, myelodysplastic syndromes ("**MDS**") and other advanced leukemias. Under the terms of the CCA, MD Anderson will conduct four clinical studies with a total projected enrollment of up to 170 patients. The four protocols will study CYC065, CYC140 and sapacitabine either as single agents or in combination with approved drugs.

It is anticipated that the first study to be initiated under the CCA will be a Phase 1b trial evaluating a combination of CYC065, a cyclin dependent kinase inhibitor, and venetoclax, an approved drug targeting the Bcl-2 protein, in patients with relapsed or refractory CLL. The second study is expected to be a Phase 1, first-in-human evaluation of CYC140, a Polo-like kinase 1 inhibitor, in patients with advanced leukemias or MDS. Both of these studies have received institutional review board (IRB) approval, and two further protocols evaluating combinations of CYC065 and sapacitabine with approved agents are currently in development.

The Company shall be the regulatory sponsor of all studies governed by the CCA and is responsible for making the necessary filings with the Food and Drug Administration, and MD Anderson's principal investigators will lead such studies. Additionally, MD Anderson will assume the patient costs for all studies and Cyclacel will provide investigational drugs and other limited support. Upon first commercial sale in specific indications studied under the CCA, Cyclacel will make certain payments to MD Anderson.

The CCA shall remain in effect for the duration of the three-year period during which payments are due to MD Anderson. Additionally, each of the Company and MD Anderson may terminate the CCA if the other party commits a material breach of its obligations thereunder and fails to cure such breach within ninety (90) days of receiving notice from the non-breaching party.

The foregoing summary of the CAA does not purport to be complete and is qualified in its entirety by reference to the CAA, which will be filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ending September 30, 2018, with portions omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Item 8.01: Other Events.

On October 4, 2018, the Company issued a press release announcing that the Company had entered into the CCA described in Item 1.01 above. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01: Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 4, 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: October 4, 2018

Exhibit 99.1

Cyclacel Pharmaceuticals, Inc.

PRESS RELEASE

CYCLACEL PHARMACEUTICALS AND MD ANDERSON CANCER CENTER ANNOUNCE STRATEGIC ALLIANCE TO STUDY NOVEL CYCLACEL MEDICINES IN HEMATOLOGICAL MALIGNANCIES

- Multi-product agreement builds on long-term clinical collaboration in hematological malignancies-

Berkeley Heights, NJ and Houston, TX, October 4, 2018 – Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC, Nasdaq: CYCCP) ("Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, and The University of Texas MD Anderson Cancer Center today announced a three-year strategic alliance agreement that will enable clinical evaluation for safety and efficacy of three Cyclacel medicines in patients with hematological malignancies, including chronic lymphocytic leukemia (CLL), acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) and other advanced leukemias.

MD Anderson will conduct four clinical studies with a total projected enrollment of up to 170 patients, which will investigate CYC065, CYC140 and sapacitabine either as single agents or in combination with approved drugs. The collaboration leverages MD Anderson's expertise in clinical development of drugs for hematological malignancies and Cyclacel's novel drug portfolio that is based on the Company's knowledge of cell cycle biology and mechanisms of cancer cell resistance to medicines.

"MD Anderson is committed to identifying and evaluating innovative therapies to benefit patients with life- threatening hematological malignancies," said Hagop Kantarjian M.D., chair in the Department of Leukemia at MD Anderson. "This alliance will allow us to study three compounds in development that appear to have promising preclinical and clinical data supporting their further evaluation."

"We are excited to expand our partnership with this alliance and advance the clinical development of CYC065 (our lead program), CYC140 and sapacitabine," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "MD Anderson is forging novel collaborative models to accelerate development of promising therapies. The alliance will enable us to parallel track the development of multiple Cyclacel drugs over the next three years with the ultimate goal of benefiting patients with unmet medical needs."

Under the risk-sharing agreement MD Anderson will assume the patient costs for all studies and Cyclacel, who is the sponsor, will provide investigational drugs and other limited support. Upon first commercial sale in specific indications studied in the alliance, Cyclacel will make certain payments to MD Anderson.

The first study will be a Phase 1b trial evaluating a combination of CYC065, a cyclin-dependent kinase (CDK2/9) inhibitor with venetoclax, an approved drug targeting the Bcl-2 protein, in patients with relapsed or refractory CLL. The second study will be a Phase 1, first-in-human evaluation of CYC140, a Polo-like kinase 1 (PLK1) inhibitor, in patients with advanced leukemia or MDS. Both studies have received institutional review board (IRB) approval. Two further protocols evaluating combinations of CYC065 and sapacitabine either as single agents or in combination with approved agents are in development.

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. 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. CYC140, a polo-like-kinase 1 (PLK-1) 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.

About MD Anderson
The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution’s sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 49 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No.1 for cancer care in U.S. News & World Report’s “Best Hospitals” survey. It has ranked as one of the nation’s top two hospitals for cancer care since the survey began in 1990, and has ranked first 14 times in the last 17 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

About CYC065
CYC065, a second generation CDK2/9 inhibitor, has been evaluated in a first-in-human, Phase 1 trial in patients with advanced solid tumors and a recommended Phase 2 dose established. The study demonstrated that CYC065 durably suppresses Mcl-1, a member of the Bcl-2 family of survival proteins. CYC065 is under investigation in combination with other anticancer drugs, including Bcl-2 inhibitors such as venetoclax, or HER2 inhibitors such as trastuzumab. Preclinical data show that CYC065 may benefit adults and children with hematological malignancies, including acute myeloid leukemias (AML), acute lymphocytic leukemias (ALL), and in particular leukemias with rearrangement of the Mixed Lineage Leukemia gene (MLL-r), chronic lymphocytic leukemias (CLL), B-cell lymphomas, multiple myelomas, and patients with certain solid tumors, including breast and uterine cancers, and neuroblastomas.

About CYC140
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. CYC140 has completed IND-enabling studies, funded by a grant of approximately $3.7 million from the U.K. Government's Innovate UK, and is the subject of a translational biology program focused on acute leukemias and esophageal cancer.

About Sapacitabine
Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being studied in an ongoing, extension of a Phase 1 study evaluating a combination regimen of sapacitabine and seliciclib, a first generation CDK inhibitor. Parts 1 and 2 of the study evaluated approximately 90 patients with advanced cancers. Part 3 is ongoing in patients with BRCA positive, breast, ovarian and pancreatic cancer. Over 1,000 patients with hematological malignancies and solid tumors have received sapacitabine.

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.

Cyclacel Contacts:
Company: Paul McBarron, (908) 517-7330, pmcbarron@cyclacel.com
Investor Relations: Russo Partners LLC, Alexander Fudukidis, (646) 942-5632, alex.fudukidis@russopartnersllc.com

MD Anderson Contact: Ron Gilmore, (713) 745-1898, rlgilmore1@mdanderson.org