Cyclacel Pharmaceuticals, Inc.
Form 8-K
October 04, 2018

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