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 7, 2017

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 8.01 Other Events.

On August 7, 2017, Cyclacel Pharmaceuticals, Inc. issued a press release announcing the selection of a recommended Phase 2 dose from part 1 of a dose-escalating, Phase 1, first-in-human clinical study of CYC065, a Cyclin Dependent Kinase 2/9 inhibitor. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and the information contained therein is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated August 7, 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 7, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release, dated August 7, 2017

Exhibit 99.1

Cyclacel Pharmaceuticals, Inc.

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

CYCLACEL ANNOUNCES SELECTION OF RECOMMENDED PHASE 2 DOSE FOR CYC065 AND EVIDENCE OF DURABLE TARGET ENGAGEMENT AND MCL-1 BIOMARKER SUPPRESSION

- Part 2 of study will focus on cyclin E amplified drug resistant solid tumors -

Berkeley Heights, NJ, August 7, 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, announced today the selection of a recommended Phase 2 dose (RP2D) from part 1 of a dose-escalating, Phase 1, first-in-human, clinical study of CYC065, a Cyclin Dependent Kinase (CDK) 2/9 inhibitor. RP2D was determined to be dosing level 6 which enrolled 9 evaluable patients with advanced cancers. Prolonged reduction of the Mcl-1 biomarker was observed in 7 out of the 9 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.

“Our early clinical results and selection of RP2D support progressing clinical evaluation of CYC065 in selected, molecularly-defined, patient populations,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “Durable reduction of Mcl-1 expression in the majority of patients at RP2D is an important differentiator, as other CDK inhibitors only do so transiently. Like other CDK inhibitors, we expect CYC065 to work best in combination with existing anticancer drugs. Indications of anticancer activity after a single dose of CYC065 alone in patients with molecular features related to the drug’s mechanism are unexpected and potentially exciting. We plan to apply part of the net proceeds from our July financing to progress CYC065 studies, alone and in combinations, in both liquid and solid cancers with such molecular features. There are currently no drugs available for patients with such features. Our highest 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, where we believe Mcl-1 suppression will be beneficial, while in parallel enrolling a new part 2 of the Phase 1 study in patients with advanced solid tumors.”

Phase 1 first-in-human trial

The objective of part 1 of the Phase 1 dose escalating, monotherapy study was to evaluate safety, pharmacokinetics (PK), pharmacodynamics (PD) and identify RP2D. Certain key features of the trial are as follows:

- 24 heavily treated patients with various advanced solid tumors were enrolled;
- The trial advanced through seven DL cohorts with a range of 8 to 288 mg/m^2/day, administered as a 4-hour intravenous infusion once every 3 weeks;
- Dose limiting toxicity at DL7 was reversible neutropenia, febrile neutropenia and diarrhea;
- Ten patients were treated at DL6, of which 9 are evaluable at present;

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- PK parameters have demonstrated dose proportional increases in CYC065 exposure with increasing dosing levels;
- A biologically effective dose was established from analysis of surrogate tissue, supporting a RP2D of 192 mg/m^2/day;
- Consistent Mcl-1 suppression over 24 hours after a single dose was observed in 7 out of 9 evaluable patients at DL6; and
- Anticancer activity was reported by the investigators in patients with Mcl-1 (ovarian cancer: reduction of CA-125 tumor marker levels), MYC (larynx: radiographic tumor shrinkage) and Mcl-1/cyclin E (ovarian: radiographic tumor shrinkage) amplified tumors.

Having successfully achieved the objectives of part 1 of the study, part 2 has been initiated aiming to enroll patients with advanced solid tumors, and 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.

About CYC065

Cyclacel's second generation CDK2/9 inhibitor, CYC065, is being evaluated in an ongoing, first-in-human, Phase 1 trial in patients with advanced solid tumors. In part 1, CYC065 was well tolerated, there were robust and durable effects on the Mcl-1 biomarker and the recommended Phase 2 dose has been selected. Evidence of target engagement was observed by decreases in target cyclin-dependent kinase substrate phosphorylation accompanied by robust and prolonged Mcl-1 suppression in peripheral blood cells in patient samples from the study, consistent with the Company's preclinical data. CYC065 is mechanistically similar but has much higher dose potency, *in vitro* and *in vivo*, and improved metabolic stability than seliciclib, Cyclacel's first generation CDK inhibitor. As with palbociclib, the first CDK inhibitor approved by FDA in 2015, and ribociclib approved in 2017, CYC065 may be most useful in combination with other anticancer agents, including Bcl-2 antagonists, such as venetoclax, or HER2 inhibitors, such as trastuzumab.

CYC065 is a highly-selective, orally- and intravenously-available, second generation inhibitor of CDK2 and CDK9. It causes apoptotic death of cancer cells at sub-micromolar concentrations. Antitumor efficacy has been achieved *in vivo* with once a day oral dosing at well tolerated doses in preclinical models. Evidence from published nonclinical studies show that CYC065 may benefit patients with adult and pediatric hematological malignancies, including certain Acute Myeloid Leukemias (AML), Acute Lymphocytic Leukemias (ALL), Chronic Lymphocytic Leukemias (CLL), B-cell lymphomas, multiple myelomas, and certain solid tumors, including breast and uterine cancers and neuroblastomas. Independent investigators published nonclinical evidence that CYC065 induced regression or tumor growth inhibition in a model of HER2-positive breast cancer addicted to cyclin E that is resistant to trastuzumab, reduced tumor growth in models of CCNE1-amplified uterine serous carcinoma and reduced tumor burden and prolonged survival in several neuroblastoma models *in vivo*.

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 is analyzing stratified and exploratory subgroups from a Phase 3 study of sapacitabine in elderly patients with AML. 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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