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): September 13, 2010

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)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On September 13, 2010, Cyclacel Pharmaceuticals, Inc. (the "**Company**") issued a press release announcing that it has reached agreement with the U.S. Food and Drug Administration regarding a Special Protocol Assessment on the design of a pivotal Phase 3 trial for the Company's sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia who are not candidates for intensive induction chemotherapy. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) The following exhibit is furnished with this Report:

Exhibit No.	Description
99.1	Press Release dated September 13, 2010

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: September 13, 2010

Exhibit 99.1

PRESS RELEASE

CYCLACEL PHARMACEUTICALS REACHES AGREEMENT WITH FDA ON A SPECIAL PROTOCOL ASSESSMENT FOR PIVOTAL PHASE 3 TRIAL OF SAPACITABINE IN AML

BERKELEY HEIGHTS, NJ – September 13, 2010 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of a pivotal Phase 3 trial for the Company's sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia (AML) who are not candidates for intensive induction chemotherapy.

"The SPA agreement with FDA represents an important milestone for Cyclacel and provides a clear registration pathway for sapacitabine," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "If it reaches the market, sapacitabine would be the first orally-administered drug to be offered to this patient population with the potential to serve as induction, consolidation and maintenance treatment of this life-threatening disease. In addition to progressing to Phase 3 in AML, we look forward to reporting sapacitabine Phase 2 data in myelodysplastic syndromes (MDS) and non-small cell lung cancer (NSCLC)."

The Phase 3, registration-directed, clinical trial of sapacitabine oral capsules to be conducted under the SPA will be a randomized study against an active control drug with the primary objective of demonstrating an improvement in overall survival. Sapacitabine will be administered as an outpatient treatment. Cyclacel plans to begin patient enrollment in this Phase 3 trial before the end of 2010. Additional information on the design of the trial will be provided after initiation of the study.

"We are pleased to receive the SPA Agreement letter from the FDA stating that the design and planned analysis of the pivotal Phase 3 study adequately address the objectives necessary to support the submission of a New Drug Application (NDA)," said Judy Chiao, M.D., Vice President of Clinical Development and Regulatory Affairs of Cyclacel. "AML in the elderly is a life-threatening disease with high unmet medical need. Patients with AML aged 70 years or older have a poor prognosis as the majority of these patients are not candidates for intensive induction chemotherapy because of poor tolerability to such therapy and a high risk of relapse because of the lack of effective consolidation and maintenance therapy. We will now concentrate our efforts on initiating the Phase 3 study in AML in collaboration with our clinical investigators."

In addition to the Cyclacel-sponsored trials of sapacitabine, the company has been approached by cooperative groups seeking to conduct, largely at their expense, investigator-initiated studies of sapacitabine with alternative study designs.

About Acute Myeloid Leukemia (AML)

AML is a cancer of the blood cells that progresses rapidly and if not treated, could be fatal in a few months. AML is generally a disease of older people and is uncommon before the age of 40. The average age of a patient with AML is about 67 years. There are more than 12,300 new cases of AML, of which about half are elderly, and nearly 9,000 deaths caused by this cancer each year in the United States. A recently published review of The University of Texas M. D. Anderson Cancer Center's historical experience with front-line intensive induction chemotherapy for elderly AML patients aged 70 years or older demonstrated that while 45% of patients achieved a complete remission, median overall survival was only 4.6 months and 36% of patients died within the first 8 weeks of treatment, underscoring the unmet need in this patient setting. †

About Special Protocol Assessment (SPA)

A Special Protocol Assessment is a binding written agreement with the FDA that the sponsor's proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval. Final marketing approval depends on efficacy results, adverse event profile and an evaluation of the benefit/risk of a treatment as demonstrated in the trial. For further information regarding the SPA process, please visit the FDA website, www.fda.gov.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being evaluated in Phase 2 trials in patients with hematological malignancies and solid tumors. Sapacitabine acts through a dual mechanism, interfering with DNA synthesis by causing single-strand DNA breaks and inducing arrest of cell cycle progression mainly at G2-Phase. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies. Over 200 patients have received sapacitabine in Phase 2 studies in AML, MDS, cutaneous T cell lymphoma (CTCL) and non-small cell lung cancer (NSCLC). Sapacitabine has been administered to approximately 170 patients in five Phase 1 studies with both hematologic malignancies and solid tumors. In December 2009 at the 51st Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported data from a randomized Phase 2 study including promising 1-year survival in elderly patients with AML aged 70 years or older. Sapacitabine is part of Cyclacel's pipeline of small molecule drugs designed to target and stop uncontrolled cell division.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. Three product candidates are in clinical development: Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, completed Phase 2 studies for the treatment of acute myeloid leukemia in the elderly and is in Phase 2 for myelodysplastic syndromes and lung cancer. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 studies for the treatment of lung cancer and nasopharyngeal cancer and in a Phase 1 trial in combination with sapacitabine. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in a Phase 1 trial in patients with solid tumors. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development 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, the risk that Cyclacel will not obtain approval to market its products, 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 current filings that have been filed 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.

Contact for Cyclacel Pharmaceuticals, Inc.

Investors/Media:
Corey Sohmer, (908) 517-7330
csohmer@cyclacel.com

† *Blood First Edition Paper, prepublished online July 28, 2010; DOI 10.1182/blood-2010-03-276485 (http://bloodjournal.hematologylibrary.org/cgi/content/abstract/blood-2010-03-276485v1).*