Cyclacel Pharmaceuticals reports third quarter 2007 financial results and corporate update

BERKELEY HEIGHTS, NJ, November 7, 2007 — Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) (Nasdaq: CYCCP) today reported financial and operating results for the third quarter of 2007. The company had a net loss in the quarter of $4.2 million or $0.21 per share. At the end of the third quarter of 2007, the company had $68.5 million in cash, cash equivalents and marketable securities.

“We continued to make progress in our clinical development programs this quarter” said Spiro Rombotis, President and CEO of Cyclacel. “We also announced the acquisition of ALIGN Pharmaceuticals adding three marketed products and providing a commercial platform that is complementary to our oncology/hematology products in development.”

Company highlights during the quarter included:

- Cyclacel continues to enroll in a multicenter randomized Phase II clinical trial of sapacitabine (CYC682), a novel orally available nucleoside analog, in patients with advanced cutaneous T-cell lymphoma (CTCL). The primary objective of the study is to evaluate the tolerability and response rate of high-dose and low-dose regimens in patients with CTCL who have had progressive, recurrent, or persistent disease on or following two systemic therapies. Secondary objectives are to assess response duration, time to response, time to progression and relief of pruritus or itching. Cyclacel plans to announce headline results from this study by year end 2007.
- Enrollment continued in a Phase I clinical trial of sapacitabine in patients with advanced leukemias or myelodysplastic syndromes (MDS). Interim data from this study were previously presented at the 43rd annual meeting of the American Society of Clinical Oncology. In 35 patients with relapsed and refractory acute myelogenous leukemia (AML) or MDS treated with a 7-day schedule sapacitabine had a favorable safety profile and promising anti-leukemic activity. A further 5 patients were treated on an alternative 3-day schedule. Updated data from this Phase I study, including additional patients treated on the 3-day schedule, will be reported at the 2007 Annual Meeting of the American Society of Hematology this December. Depending on the updated results of this study, Cyclacel plans to initiate Phase II development of sapacitabine in hematological malignancies.
- Patient enrollment continued in the APPRAISE study, a double-blinded, randomized, Phase II study of single agent seliciclib versus best supportive care in patients with advanced NSCLC treated with at least two prior systemic therapies to assess tolerability and anti-tumor activity of seliciclib as a single agent. Cyclacel plans to announce headline results from this study by year end 2007.
- Seliciclib is also being evaluated for the treatment of patients with nasopharyngeal cancer (NPC). Cyclacel plans to commence a randomized Phase II study assessing tolerability and anti-tumor activity of seliciclib as a single agent in NPC patients by year end 2007.
- Enrollment continued in a dose escalation, multicenter Phase I pharmacologic clinical trial of CYC116, an orally-available inhibitor of Aurora kinases A and B and VEGFR2, in patients with advanced solid tumors. CYC116 is the only targeted drug in clinical trials in patients with cancer that combines both anti-mitotic and anti-angiogenesis mechanisms. The primary objective of the study is to determine the maximum tolerated dose. Secondary objectives are to evaluate the pharmacokinetic and pharmacodynamic effects of the drug and to document anti-tumor activity.

Additionally, on October 5, Cyclacel entered into a definitive purchase agreement to acquire substantially all of the assets of privately-held ALIGN Pharmaceuticals, LLC and ALIGN Holdings, LLC (Cary, North Carolina), collectively "ALIGN". The acquired business provides Cyclacel with three marketed products for the management of cancer patients following chemotherapy or radiotherapy. In addition it provides the foundation for a commercial organization focused on cancer that is complementary to Cyclacel’s oncology/hematology products in development and is part of Cyclacel’s strategy to build a diversified biopharmaceutical business.

The company expects several key milestones in the upcoming months including:

- Headline data from the Phase II trial of sapacitabine in CTCL
- Updated data from a Phase I study of sapacitabine in patients with advanced leukemias or myelodysplastic syndromes at the 2007 Annual Meeting of the American Society of Hematology
- Commencement of Phase II trials of sapacitabine in hematological cancers
- Headline data from the Phase IIb APPRAISE trial for seliciclib
- Commencement of a Phase II randomized trial of seliciclib in patients with NPC
- Commencement of a Phase I trial of CYC116 in hematological cancers

Key Financials

Total research and development (R&D) expense in the third quarter of 2007 was $4.4 million as compared to $4.1 million in the third quarter of 2006. The increase in R&D expense in the quarter, compared to the same period in 2006, was mainly due to an increase in preclinical program costs.

Total general and administrative expenses (G&A) for the third quarter of 2007 were $2.1 million as compared to $2.5 million in the third quarter of 2006. The decreased expense in the third quarter of 2007 compared to the same period in 2006 was primarily related to a reduction in audit and accountancy fees and recruitment costs.

The net loss for the three months ended September 30, 2007 was $4.2 million, or $0.21 per share, compared to a net loss for the same period in 2006 of $5.4 million, or $0.34 per share.

Cyclacel also reported results of its operations for the nine months ended September 30, 2007.

Total R&D expenses for the nine months ended September 30, 2007 were $12.7 million as compared to $17.2 million for the same period in 2006. The decrease in R&D expense for the first nine months, compared to the same period in 2006, was due to a reduction in the charge for stock-based compensation costs of $5.5 million offset by an increase in clinical development costs of $0.9 million.

Total G&A for the nine months ended September 30, 2007 were $6.9 million as compared to $9.5 million for the same period in 2006. The decreased expense in the first nine months, compared to the same period in 2006, was primarily related to a reduction in stock-based compensation costs of $2.6 million.

The net loss for the nine months ended September 30, 2007 was $12.7 million, or $0.65 per share, compared to a net loss for the same period in 2006 of $26.6 million, or $2.13 per share.

Conference call and webcast information:

US/Canada call: 888-603-6873; conference code 9425576

International call: 973-582-2706; conference code 9425576

Webcast: http://w.on24.com/r.htm?e=97465&s=1&k=CA8B0DCEB0CE76ADA4AE676803584A1B or via the Cyclacel Pharmaceuticals website at www.cyclacel.com.

The webcast will be archived for 90 days and the audio replay will be archived for 7 days. Access numbers for the audio replay are: 877-519-4471 (U.S./Canada) and 973-341-3080 (International); conference ID number is: 9425576.

About sapacitabine, seliciclib and CYC116

Sapacitabine is an oral nucleoside analog prodrug that acts through a novel mechanism. The compound interferes with DNA synthesis by causing single-strand DNA breaks and induces arrest of the cell division cycle. Both sapacitabine and its major metabolite, CNDAC, have demonstrated in preclinical studies potent anti-tumor activity in both hematological and solid tumors. Sapacitabine has been administered to approximately 170 patients enrolled in three Phase I clinical trials in solid tumors and a Phase I study in hematological tumors. Based on the positive efficacy signals observed in these studies, the Company plans to conduct several Phase II clinical trials to evaluate sapacitabine's potential in hematological and solid tumors.

Seliciclib is an orally available cyclin dependent kinase (CDK) inhibitor that selectively inhibits multiple enzyme targets that are central to the process of cell division and cell cycle control. Seliciclib has been administered to approximately 300 patients to date and is currently being evaluated in a Phase IIb randomized, double blinded study (“APPRAISE”) as a single agent treatment in patients with non-small cell lung cancer (NSCLC) treated with at least two prior systemic therapies. Cyclacel also plans to begin a randomized, Phase II clinical trial in patients with nasopharyngeal cancer (NPC), a disease associated with Epstein-Barr virus infection.

CYC116 is an orally-available inhibitor of Aurora kinases A and B and VEGFR2. CYC116 is currently being evaluated in a multicenter Phase I pharmacologic clinical trial in patients with advanced solid tumors. The company also plans to evaluate the potential of CYC116 in hematological tumors.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Cyclacel’s ALIGN Pharmaceuticals subsidiary markets

directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. Three Cyclacel drugs are in clinical development. Sapacitabine (CYC682), an orally-available, cell cycle modulating nucleoside analog, is in Phase II for the treatment of cutaneous T-cell lymphoma (CTCL) and in Phase I in patients with hematologic malignancies. Seliciclib (CYC202), an orally-available CDK (cyclin dependent kinase) inhibitor, is in Phase II for the treatment of lung cancer and is also being evaluated for nasopharyngeal cancer. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is in Phase I in patients with solid tumors. Several additional programs are at an earlier stage. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in oncology, hematology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Please visit http://www.cyclacel.com/cyc/investors/news/pressreleases for additional information. Note: The Cyclacel logo and Cyclacel® are trademarks of Cyclacel Pharmaceuticals, Inc. Numoisyn® and Xclair® are trademarks of Sinclair Pharma plc.

Risk Factors

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. These factors and others are more fully discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2006, as supplemented by the interim quarterly reports, filed with the SEC.

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