

Cyclacel Pharmaceuticals announces first quarter 2008 financial results

Conference Call Scheduled Today at 4:00pm EST

BERKELEY HEIGHTS, NJ – May 9, 2008 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today financial and operating results for the first quarter of 2008. The Company's net loss for the quarter was \$6.3 million or \$0.31 per share. As of March 31, 2008, the company had \$49.0 million in cash, cash equivalents and short-term investments.

"We made progress in all areas of the business during the first quarter," said Spiro Rombotis, President and CEO. "Enrollment in the ongoing studies of sapacitabine, seliciclib and CYC116 is on track. We fielded the sales force of our ALIGN subsidiary in January and began marketing our three oncology care products. We recorded our first revenues from product sales in the quarter. Our cash position remains strong and we believe it is sufficient to finance the company's clinical programs," added Mr. Rombotis.

Continued progress during the quarter in Cyclacel's ongoing clinical studies included the:

- Phase 2 trial of sapacitabine in elderly patients with acute myeloid leukemia (AML);
- Phase 2 trial of sapacitabine in patients with advanced cutaneous T-cell lymphoma (CTCL);
- Phase 2b APPRAISE trial of seliciclib in patients with non-small cell lung cancer (NSCLC);
- Phase 2 trial of seliciclib in patients with nasopharyngeal cancer (NPC);
- Phase 1 trial of CYC116 in patients with advanced solid tumors.

Recently Cyclacel presented eight posters with preclinical data at the annual meeting of the American Association for Cancer Research (AACR) demonstrating the ability of Cyclacel's cell cycle inhibitors to induce cell death, or apoptosis, by inhibiting key enzymes.

The company expects several milestones in the upcoming months including:

- Reaching target patient enrollment for interim analysis in the APPRAISE trial of seliciclib. APPRAISE is enrolling patients
 with advanced non-small cell lung cancer who have been treated with at least two prior systemic therapies. The study's
 main objective is to learn the anti-tumor activity of seliciclib as a single agent in refractory NSCLC and help determine
 further development strategies.
- Reporting preliminary safety data from the lead-in stage of the ongoing Phase 2 multicenter international randomized trial of seliciclib in patients with NPC. The objective of the lead-in stage of this study is to confirm the tolerability of two different dosing schedules of seliciclib and selection of the dosing schedule to be used in the ensuing randomized stage of the study.
- Completing enrollment and reporting preliminary Phase 2 data of sapacitabine in elderly AML. The primary objective of this study is to evaluate the 1-year survival rate of three dosing schedules of sapacitabine in elderly patients with previously untreated or first relapse AML. Secondary objectives are to assess the number of patients who have achieved complete remission (CR) or complete remission without blood count recovery (CRi), duration of CR or CRi, transfusion requirements, number of hospitalized days and safety.

Key Financials

Total revenue for the first quarter of 2008 was \$0.2 million. The revenue was mainly attributable to sales of the Xclair[™] and Numoisyn[™] products sold by the ALIGN subsidiary. Total research and development expenses in the first quarter of 2008 we \$5.9 million as compared to \$4.0 million in the first quarter of 2007. Clinical trial expense related to sapacitabine increased by \$0.9 million as a result of the commencement of the Phase 2 trial in elderly AML in December 2007. There was also an increase in CYC116 program costs of \$0.4 million as a result of the Phase 1 trial and product scale-up requirements during the first quarter of 2008.

Total selling, general and administrative expenses for the first quarter of 2008 were \$3.9 million as compared to \$2.6 million in the first quarter of 2007. The increased expense in the first quarter of 2008 compared to the same period in 2007 was primarily related to the establishment of the ALIGN sales force, marketing expenses and amortization charges related to the ALIGN asset acquisition.

Conference call and Webcast Information:

Cyclacel management will review its first quarter financials on a conference call on May 9, 2008 at 4:00 p.m. Eastern time. Conference call and webcast details are as follows:

US/Canada call: (877) 493-9121 / international call: (973) 582-2750 US/Canada archive: (800) 642-1687 / international archive: (706) 645-9291 Code for live and archived conference call is 44188667

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at <u>www.cyclacel.com</u>. The webcast will be archived for 90 days and the audio replay for 7 days.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanismtargeted drugs to treat human cancers and other serious disorders. Three Cyclacel drugs are in clinical development. Sapacitabine (CYC682), an orally-available cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly and cutaneous T-cell lymphoma (CTCL). Seliciclib (CYC202), an orally-available CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal cancer. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. Several additional programs are at an earlier stage. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair[™] Cream for radiation dermatitis, Numoisyn[™] Liquid and Numoisyn[™] Lozenges for xerostomia. Cycl**aceth**ategy is to build a diversified biopharmaceutical business focused in hematology, oncology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Please visit <u>www.cyclacel.com</u> 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, 2007, as supplemented by the interim quarterly reports, filed with the SEC.

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View the full press release in PDF format (40KB)