



## **Cyclacel Pharmaceuticals announces financial results for fourth quarter and year ended December 31, 2007**

### **Conference Call Scheduled Today at 10:00 EST**

**BERKELEY HEIGHTS, NJ, March 11, 2008** - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today financial results and milestone highlights for the fourth quarter and year ended December 31, 2007. Cyclacel also provided an overview of its 2008 business objectives.

The company reported a net loss for the fourth quarter of 2007 of \$11.4 million or \$0.56 per share, compared to a net loss for the fourth quarter of 2006 of \$5.5 million or \$0.36 per share. For the year ended December 31, 2007 Cyclacel reported a net loss of \$24.1 million or \$1.21 per share, compared to a net loss for the year ended December 31, 2006 of \$32.1 million or \$2.40 per share. As of December 31, 2007 cash, cash equivalents and short-term investments totaled \$58.8 million.

"We have made steady progress over the past year towards Cyclacel's objectives demonstrating our commitment to building a diversified biopharmaceutical business. In particular we are encouraged by the level of investigator interest in our ongoing Phase 2 study of sapacitabine in elderly patients with acute myeloid leukemia. Approximately 18 U.S. clinical centers have expressed interest in participating in the study and enrollment is on track," said Spiro Rombotis, President and CEO. "The primary objective of our randomized Phase 2 study is to evaluate the one-year survival rate of three dosing schedules of sapacitabine with secondary objectives of overall response rate and duration, transfusion requirements, number of hospitalized days and safety. We look forward to an exciting year in terms of clinical data, progressing our preclinical programs and integrating ALIGN into the business," continued Mr. Rombotis.

### **2007 Corporate Highlights**

- Reported sapacitabine Phase 1 data in patients with acute myeloid leukemia and MDS
- Initiated a sapacitabine Phase 2 randomized trial in elderly patients with acute myeloid leukemia
- Initiated a sapacitabine Phase 2 randomized trial in patients with cutaneous T-cell lymphoma
- Reported interim data from the APPRAISE Phase 2 double-blinded randomized trial in lung cancer
- Initiated a seliciclib Phase 2 randomized trial in patients with nasopharyngeal cancer
- Reported preclinical data indicating synergy of seliciclib in combination with EGFR inhibitors
- Initiated a CYC116 Phase 1 trial in patients with solid tumors
- Hired Dr. Greg Reyes, a veteran of Pfizer and Schering-Plough, as Senior Vice President, Research
- Raised gross proceeds of \$36 million in a registered direct common stock financing
- Entered into a committed equity financing facility of up to \$60 million
- Acquired the assets of ALIGN Pharmaceuticals including three marketed oncology care products

### **Fourth Quarter and Year End 2007 Financials**

For the fourth quarter of 2007 Cyclacel reported a net loss of \$11.4 million or \$0.56 per share, compared to a net loss for the fourth quarter of 2006 of \$5.5 million or \$0.36 per share. Total research and development (R&D) expenses in the fourth quarter of 2007 were \$6.8 million compared to \$4.0 million in the fourth quarter of 2006. The increase in R&D expenses in the fourth quarter compared to the same period in 2006 was primarily due to increased spending in the company's clinical trial programs.

Total selling, general and administrative expenses (SG&A) in the fourth quarter of 2007 were \$4.7 million compared to \$2.9 million in the fourth quarter of 2006. The increase in SG&A in the fourth quarter compared to the same period in 2006 was primarily due to expenditures related to the start of sales and marketing activities of ALIGN, an increase in stock-based compensation charges and legal fees.

For the year ended December 31, 2007, Cyclacel reported a net loss of \$24.1 million, or \$1.21 per share, compared to a net loss for the year ended December 31, 2006 of \$32.1 million, or \$2.40 per share. Total R&D expenses for the year ended December 31, 2007 were \$19.6 million compared to \$21.2 million in the same period in 2006. The decreased spending in 2007 compared to the same period in 2006 was primarily due to a decrease in preclinical outsourcing costs offset by an increase in spending on clinical trial programs and increase in stock-based compensation charges. Total SG&A expenses for the year ended December 31, 2007 were \$11.5 million compared to \$12.3 million for the same period in 2006. The decreased spending in 2007 compared to the same period in 2006 was primarily due to decreased stock-based compensation charges offset by the

start of sales and marketing activities of ALIGN and an increase in legal fees and human resources expenses.

The fair value of the warrants issued in connection with Cyclacel's registered direct financing of common stock and warrants in February 2007 was recorded as a liability in accordance with EITF 00-19 "*Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*". The value of these warrants is being marked to market. The change in valuation resulted in a reduction to the net losses of \$0.4 million and \$3.2 million for the quarter and year ended December 31, 2007 respectively.

Cash, cash equivalents and short-term investments totaled \$58.8 million as of December 31, 2007. For 2008 Cyclacel expects a net cash burn rate of approximately \$32 million.

## 2008 Outlook

The Company highlighted its main business objectives for 2008:

- Complete enrollment and report interim Phase 2 data of sapacitabine in elderly AML
- Initiate additional clinical studies of sapacitabine as a single agent and/or combination therapy
- Report interim Phase 2 data of sapacitabine in CTCL
- Complete enrollment and report APPRAISE Phase 2b topline data of seliciclib in NSCLC
- Report interim data from the lead-in stage of the Phase 2 study of seliciclib in NPC
- Initiate clinical development of seliciclib in combination with targeted therapies
- Report topline Phase 1 data of CYC116 in patients with solid tumors
- Initiate Phase 1 trial of CYC116 in hematological cancers
- Report further progress in preclinical programs
- Define a registration strategy for sapacitabine in hematological malignancies

## Sapacitabine Development Plan

The open-label, multicenter, randomized Phase 2 clinical trial of oral sapacitabine in elderly patients with acute myeloid leukemia (AML) who are previously untreated or in first relapse is currently enrolling patients. The study follows the encouraging anti-leukemic activity observed in a Phase 1 trial of sapacitabine in patients with advanced leukemias or myelodysplastic syndromes (MDS) in which 46 previously treated patients with AML or MDS achieved an overall response rate of 13%. The Phase 2 study is designed to examine three dosing schedules of sapacitabine. Completion of enrollment is expected to occur in late 2008 following which interim Phase 2 data on overall response rate would be reported in late 2008 or early 2009. One-year survival data is expected to be reported in 2009. Previous marketing approvals for drugs in acute leukemia were based on overall response rate data from single open-label non-randomized studies. If preliminary efficacy and safety data from the ongoing Phase 2 trial are promising, Cyclacel intends to discuss with regulatory authorities the prospects of seeking marketing approval based on response rate data for an indication in elderly AML. During the year Cyclacel plans to announce additional clinical studies of sapacitabine in other indications and a European clinical development and regulatory strategy for sapacitabine.

## Conference call and Webcast Information:

Cyclacel management will review its fourth quarter and year end financials as well as discuss the progress of its pipeline and review 2008 highlights on a conference call scheduled for Tuesday, March 11 at 10:00 a.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 38114266

Webcast: 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, mechanism-targeted 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. 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 [www.cyclacel.com](http://www.cyclacel.com) 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.

### **Contacts for Cyclacel:**

Cyclacel Pharmaceuticals, Inc.  
Corey Sohmer  
(908) 517-7330

WeissComm Partners  
Aline Schimmel  
(312) 284-4706

[View the full press release in PDF format](#) (63 KB)