Cyclacel Pharmaceuticals announces fourth quarter and year end 2006 financial results and corporate highlights

Conference call to be held today at 8:00 am EDT

BERKELEY HEIGHTS, NJ, March 15, 2007 – Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) (Nasdaq: CYCCP) today announced financial results and progress for the quarter and year ended December 31, 2006. Net loss for the fourth quarter of 2006 was $5.5 million or $0.34 per share. As of December 31, 2006 cash, cash equivalents and marketable securities totalled $54.0 million. On February 20, 2007 Cyclacel completed a registered direct financing with gross proceeds of $36.0 million.

“Cyclacel is committed to building a significant pipeline of novel cell cycle modulating compounds. We have made excellent progress in meeting this objective over the last year,” noted Spiro Rombotis, President and Chief Executive Officer of Cyclacel Pharmaceuticals. “With the resources from our financings, we are well positioned to pursue clinical programs with our three development-stage candidates, seliciclib, sapacitabine and CYC116, in multiple indications, as well as advance our preclinical pipeline consisting of multiple compounds from several classes.”

The company achieved key corporate milestones during the year and through early 2007:

- Initiated the “APPRAISE” trial for its CDK inhibitor seliciclib, a Phase IIb, multi-center, randomized, double-blinded study, which is evaluating the efficacy and safety of the compound as a single agent, for previously treated patients with non-small cell lung cancer (NSCLC). Enrollment for the study remains on track.
- Announced its intention to commence a Phase II randomized trial of seliciclib in patients with nasopharyngeal cancer (NPC).
- Presented in November 2006 Phase I data of its nucleoside analogue sapacitabine in solid tumors at the 18th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapies.
- Reported interim data from a Phase I trial of sapacitabine used as a single-agent in Advanced Myelogenous Leukemia (AML) and myelodysplastic syndromes (MDS) suggesting that the compound has anti-leukemic activity in AML and MDS patients in blast crisis refractory to ara-C or decitabine.
- Submitted to FDA an Investigational New Drug (IND) application to begin clinical trials in oncology patients of its third drug candidate, CYC116, an orally-available inhibitor of Aurora kinases A and B and VEGFR2.
- Strengthened the Company's management team with the appointment of John Womelsdorf, Ph.D., as Vice President, Business Development. Dr. Womelsdorf has more than 20 years of experience in business development with leadership roles at Johnson & Johnson, Roche and Baxter International.
- Strengthened its balance sheet by completing a $45.3 million private placement during the year and a $36.0 million registered direct offering in February 2007.
- Enhanced the Board of Directors with the appointment of Pierre Legault in March 2007 as a non-executive director and chairman of the Audit Committee. Mr. Legault is currently Executive Vice President, The Jean Coutu Group (PJC) Inc. and President US, Brooks Eckerd. He previously held senior financial and management positions in various pharmaceutical companies, including Sanofi-Aventis, as President and CEO, Dermatology division, Senior Vice President and Chief Financial Officer of Aventis (US & Europe), and other roles at Hoechst Marion Roussel and Marion Merrell Dow. With his appointment the number of directors increases to eight.

The Company anticipates a number of highlights for the remainder of 2007:

- Present preclinical data of seliciclib in combination with EGFR inhibitors in NSCLC at the American Association of Cancer Research (AACR) annual meeting in April 2007.
- Present study data from the Phase I trial of sapacitabine used as a single-agent in advanced leukemias and myelodysplastic syndromes at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2007.
- Begin Phase I clinical trials for CYC116, the company's orally-available inhibitor of Aurora kinases A and B and VEGFR2, during the second quarter of 2007.
- Present headline data from the “ APPRAISE” trial of seliciclib during the fourth quarter of 2007.
- Initiate several new Phase II clinical trials for seliciclib and sapacitabine in patients with both solid tumors and hematologic malignancies.

Financial Highlights

Total research and development (R&D) expenses in the fourth quarter of 2006 were $4.0 million as compared to $3.7 million in

the fourth quarter of 2005. The increase in R&D expense in the fourth quarter, compared to the same period in 2005, was primarily related to increased spending on clinical trials and personnel costs, including charges for stock-based compensation.

Total general and administrative expenses (G&A) for the fourth quarter of 2006 were $2.8 million as compared to $1.6 million in the fourth quarter of 2005. The increased spending in the fourth quarter of 2006 compared to the same period in 2005, was primarily related to increased expense related to compensation and benefits, including charges for stock-based compensation, facilities costs and fees associated with internal financial systems.

Cyclacel also reported financial results for the year ended December 31, 2006.

Total R&D expenses for the year ended December 31, 2006 were $21.2 million compared to $15.8 million in the year ended December 31, 2005. The overall increase is primarily related to (i) the increase in the charge for stock-based compensation expense of $6.5 million in the year ended December 31, 2006 compared to the same period in 2005 and (ii) the increase in R&D expenditure on CYC116 as activities focused on IND-directed studies of this program culminating in the filing of an IND on schedule in December 2006, offset by reduced spending on seliciclib with the completion of Phase IIa trials prior to initiating the “APPRAISE” trial during the second half of 2006.

Total G&A expenses for the year ended December 31, 2006 were $12.3 million compared to $5.3 million in the year ended December 31, 2005. The overall increase is primarily related to an increase in compensation and benefit expenses, including an increase in the charge for stock-based compensation of $3.4 million, as well as regulatory, insurance and facilities costs and fees associated with internal financial systems.

The net loss for the year ended December 31, 2006, was $32.1 million, or $2.40 per share, compared to a net loss for the year ended December 31, 2005 of $29.9 million, or $4.50 per share. In 2006, the company incurred a $9.6 million non-cash stock-based compensation expense.

In 2007, Cyclacel expects a net cash burn rate of approximately $29 million. The expected increase compared to 2006 is primarily attributable to clinical trial activities for seliciclib, sapacitabine and CYC116.

View the full press release in PDF format (178 KB)