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Financings Roundup

Cyclacel Boosts Clinical Work With $45M Private Placement

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Staff Writer

A month after gaining access to public markets through a merger with Xcyte Therapeutics Inc., Cyclacel Pharmaceuticals Inc. is adding $45.3 million through a private placement involving stock and warrants.

The company agreed to sell about 6.4 units, each consisting of one share of common stock plus a warrant to purchase 0.4 shares, priced at $7.05 per unit to institutional investors, including San Francisco-based Deerfield Management, Baltimore-based Red Abbey Ventures and Federated Kaufman Fund.

Cowen & Co. LLC, of New York, served as lead placement agent, and Needham & Co. LLC, also of New York, acted as co-placement agent for the offering.

Spiro Rombotis, president and CEO of the Short Hills, N.J.-based company, said it is "very important for us to have this $45 million available so we can continue to expand" development of "our drugs to affect the cancer cell cycle."

Cyclacel has two programs in the clinic, with a third expected later this year, so the financing "comes at a very timely moment," Rombotis said, "and will allow us to take those programs forward in a very dynamic way."

Combined with its existing cash, the company will have about $70 million to fund operations through 2008.

Its lead product, seliciclib, is a cyclin-dependent kinase (CDK) inhibitor in Phase II testing in non-small-cell lung cancer, a disease "known to be a major medical challenge," Rombotis said, with a five-year survival rate at less than 15 percent.

Although there have been drugs approved in the last few years for first- and second-line treatment of NSCLC, "by the time a patient is at third-line [treatment], there are very few drugs available," he added. So Cyclacel is "positioning our drug as a third-line treatment to address an area of urgent and serious medical need."

One drug was approved a few years ago for third-line NSCLC therapy. AstraZeneca plc's Iressa (gefitinib) won early approval by the FDA in 2003, but further trials failed to show a statistically significant survival benefit. The agency later edited the drug's label for use only in cancer patients who already had been taking it. (See *BioWorld Today*, Dec. 20, 2004.)

Cyclacel is preparing to conduct a large, randomized U.S. study comparing its twice-daily, oral seliciclib to the existing best supportive care, "which is a euphemism for receiving no therapy after the patients have failed the first-or second-line treatment," Rombotis said.

Results from that study are expected in the second half of 2007.

Seliciclib also has shown activity against nasopharyngeal cancer, a rare tumor type affecting an estimated seven out of 1 million people in North America. It's a disease believed to be caused by the Epstein-Barr virus (EBV).

Early Phase I and Phase II testing have demonstrated the drug is "inducing, as a single agent, clinical benefit to these patients," Rombotis told *BioWorld Today*, adding that investigators reported that treatment with seliciclib appeared to shrink patients' lymph nodes, as well as to reduce viral load of EBV.

Trials in nasopharyngeal cancer have been conducted by researchers outside Cyclacel, but "we're now carefully studying the possibilities of doing our own systematic evaluation," he said.

The company's second product, sapacitabine, is in Phase I trials in about 120 patients with various types of solid tumors, and there have been "indications of potential clinical benefit," in NSCLC, gastrointestinal stromal tumors, and kidney and bladder cancer, Rombotis said.

A Phase II program is anticipated to begin in early 2007, following Phase I testing of the drug in hematological cancers.

Sapacitabine is a chemical analogue of gemcitabine designed to be administered in an oral capsule. It was in-licensed from Tokyo-based Sankyo Co. Ltd. in 2003, in exchange for an up-front payment, milestones and royalties. Sankyo also retains first-negotiation rights to the product in Japan.

During the second half of the year, the company expects to file an investigational new drug application for its third cancer drug, CYC116, an Aurora kinase inhibitor discovered by Cyclacel's Polgen Division, based in Cambridge, UK.

Behind its clinical-stage programs, Cyclacel also is building a deep preclinical pipeline of eight additional programs, "the vast majority of which have been discovered within Cyclacel," Rombotis said. "Over the past eight years, we have built a pipeline that we hope will, over the course of time, reward the investors that have supported us."

Five of those eight preclinical programs are aimed at cancer, and the other three are targeting inflammatory kidney disease, Type II diabetes and HIV.

Cyclacel's goal is to take those products through Phase IIb proof-of-efficacy trials, before seeking partners for further development and commercialization.

The company, which withdrew plans for an initial public offering in 2004, citing unfavorable market conditions, gained a Nasdaq listing earlier this year through its merger with Seattle-base Xcyte.

Shares of Cyclacel (NASDAQ:CYCC) gained 68 cents Thursday to close at $7.68. ■