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### **For Immediate Release**

### **Copernicus Receives Orphan Drug Designation for Treatment of Cystic Fibrosis**

**Cleveland, OH May 2, 2005** – Copernicus Therapeutics, Inc. announced today that it was granted Orphan Drug Designation from the Food and Drug Administration Office of Orphan Products Development for its DNA drug intended to treat cystic fibrosis (CF). Orphan drug status is a category of drug products that are indicated for rare diseases or conditions (affecting less than 200,000 persons in the U.S.). The designation gives Copernicus access to tax credits for clinical research undertaken to generate required data for marketing approval of its drug and seven years of marketing exclusivity for the designated drug following approval by the FDA.

"The lung manifestations of CF represent a dire, unmet medical need that we believe can be addressed with our DNA nanoparticle technology," said Robert Moen, President and CEO of Copernicus. "Orphan drug status will facilitate the evaluation of our drug candidate in a series of lung aerosol clinical trials in CF subjects."

Cystic Fibrosis is the most common genetic disease in the caucasian population of North America and Europe, affecting an estimated 70,000 people. The defective gene results in thick, tenacious mucus that blocks lung passages and provides an environment for recurrent lung infections, leading to permanent lung damage and respiratory failure. The median lifespan of a person with cystic fibrosis is now thirty-three years. Copernicus' unique non-viral DNA drug is intended to deliver a normal copy of the CF gene to the affected airway cells of people with CF, and may eventually provide a long-term treatment for the lung manifestations of the disease.

*Copernicus Therapeutics, Inc., a privately held biotechnology company, is advancing novel targeting and delivery systems with broad applications in human therapeutics. Copernicus' technologies include a targeting platform enabling the efficient uptake of drugs by specific cells and tissues, and a multi-component delivery platform that can be applied to nucleic acids to develop therapies for a variety of human diseases. The Company's targeting and delivery platforms are complementary and can be combined to enhance the efficacy and safety of existing drugs, to create novel therapeutics, and to speed up the drug discovery process. Additional information about Copernicus is available at <http://www.cgsys.com>*

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