



Discovery Labs Initiates Two Phase 2 Clinical Trials - Surfaxin[®] for Bronchopulmonary Dysplasia and Aerosolized SRT to Treat Neonatal Respiratory Failures

Developing Solutions for Unmet Medical Needs in the NICU

Warrington, PA — January 6, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO) has initiated two Phase 2 clinical trials utilizing its Surfactant Replacement Therapy (SRT) to address respiratory disorders that are prevalent in premature infants in the Neonatal Intensive Care Unit (NICU). The Company has designed a Phase 2 clinical trial to assess the safety and efficacy of Surfaxin[®] for the prevention of Bronchopulmonary Dysplasia (BPD), a serious, chronic lung disease of newborn infants; and a Phase 2 pilot study to evaluate the safety, tolerability and device optimization for the delivery of aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP) as a non-invasive means to potentially treat neonatal respiratory failures.

Discovery will hold a conference call today at 10:30 AM EST. The call in number is 800-665-0669. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at <http://www.irconnect.com/primecast/dsco/477/index.html> and www.discoverylabs.com. It is recommended that participants log onto one of these sites at least 15 minutes prior to the call. The Internet broadcast will be available for up to 30 days after the call at both website addresses.

Surfaxin for the Prevention of Bronchopulmonary Dysplasia (BPD):

The Phase 2 BPD clinical trial is a double-blind, controlled trial that will enroll up to 210 very low birth weight premature infants born at risk for developing BPD. Infants will be randomized to receive one of two Surfaxin treatments, which will be administered in liquid form and injected through the patient's endotracheal tube, or the current standard of care – mechanical ventilation and support therapies. The trial will be conducted at approximately 25 sites throughout the United States, Chile and Poland. The study objective is to determine the safety and tolerability of Surfaxin administration in the first weeks of life as a therapeutic approach for the prevention of BPD and to determine whether such treatment can decrease the proportion of infants on mechanical ventilation or oxygen or the incidence of death or BPD. This trial is expected to be completed by the fourth quarter of 2005.

BPD is a costly syndrome that is associated with the prolonged use of mechanical ventilation and oxygen supplementation, usually associated with a premature infant being treated for Respiratory Distress Syndrome (RDS). Presently there are no approved drugs for the treatment of BPD. These babies suffer from abnormal lung development and typically have a need for respiratory assistance - oftentimes, for many months, as well as comprehensive care spanning years. It is

estimated that the cost of treating an infant with BPD in the United States can approach \$250,000 with approximately 50,000 infants developing BPD in the United States and Europe each year.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery commented, “These tiny premature babies are born with an insufficient amount of their own natural surfactant and are prone to devastating life-threatening diseases such as RDS and BPD. Treatments to prevent or ameliorate BPD are limited. The neonatal medical community would embrace an important medical advance such as a surfactant that can demonstrate a statistical benefit in reducing BPD compared to existing therapies. Data from our Phase 3 clinical trials for Surfaxin for RDS demonstrated a highly significant reduction in RDS related mortality and an improvement in survival of infants without BPD.”

Aerosolized SRT via nCPAP:

Discovery also is initiating an open label, Phase 2, multicenter pilot study to evaluate aerosolized SRT delivered via nCPAP in premature infants. This trial will be conducted at up to four centers in the United States and will enroll approximately 20 infants with a gestational age of 28-32 weeks who are suffering from RDS. Patients will receive, in two treatment regimens, aerosolized SRT delivered via nCPAP within thirty minutes of birth. The Company’s overall program is to begin with a pilot study to evaluate the safety and tolerability of aerosolized SRT delivered via Discovery’s proprietary nCPAP technology, initially within patients who suffer from RDS followed by additional studies to include other neonatal respiratory failures within the NICU. This pilot study is expected to be completed by mid 2005.

“For the range of respiratory disorders experienced in the NICU for which limited treatments exist, neonatologists make every effort to avoid mechanically ventilating these patients. There is growing recognition by the neonatal medical community for the potential utility of a non-invasive method of delivering SRT to treat neonates suffering from respiratory disorders including RDS, BPD, bronchiolitis, acute hypoxia, pneumonia, and transient tachypnea,” commented Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer. “Once we demonstrate proof of concept with our nCPAP technology, we plan to further expand its use into the broad range of respiratory diseases that occur within the NICU, potentially addressing unmet medical needs.”

About Discovery Laboratories

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery’s technology produces a precisely engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of Respiratory Distress Syndrome in premature infants. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome in adults, Bronchopulmonary Dysplasia (BPD) in infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome in full-term infants.

More information about Discovery is available on the Company's Web site at www.DiscoveryLabs.com.

To the extent that statements in this press release are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, events conditioned on stockholder or other approval, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this release are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Among the factors which could affect the Company's actual results and could cause results to differ from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, risks relating to the progress of the Company's research and development, the risk that the Company will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies), risk that the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that the Company's internal sales and marketing organization will not succeed in developing market awareness of the Company's products, risk that the Company's internal sales and marketing organization will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by the Company, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by the Company for any such drug product, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with adequate supplies of drug substance and drug products for completion of any of the Company's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of the Company's clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Company Contacts:

John G. Cooper, EVP and CFO
Kori Beer, IR & Communications
215-488-9300