



Discovery Labs Presents Surfaxin[®] and Aerosurf[™] Data at the Pediatric Academic Societies Annual Meeting

Surfaxin[®] Phase 2 BPD Clinical Data Selected and Presented as Platform Presentation

Aerosurf[™] Utilizing Chrysalis Aerosol-Generator Technology Demonstrates Optimal Functional Activity

Warrington, PA - May 8, 2007 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, announced that results from its previously completed Phase 2 clinical trial of Surfaxin[®] (lucinaactant intratracheal suspension) for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) were selected and presented as a platform presentation at the *Pediatric Academic Societies (PAS)* Annual Meeting in Toronto, Canada. Also presented at PAS were data regarding Discovery's novel aerosolized KL-4 surfactant, Aerosurf[™] (lucinaactant for inhalation). The *Pediatric Academic Societies* annual meeting is internationally recognized as the largest, most relevant medical meeting dedicated to pediatric critical care research. These data were presented for the first time to the medical community.

Phase 2 Clinical Trial of Surfaxin[®] for the Prevention and Treatment of BPD

Carl Bose, MD, Director of Neonatology and Professor of Pediatrics at University of North Carolina and Chairman of the Discovery BPD Clinical Study Steering Committee, presented an overview of key trial data. These data suggest that Surfaxin, when administered beyond the standard acute Respiratory Distress Syndrome (RDS) treatment period, may represent a novel therapeutic option for infants at risk for developing BPD. BPD is a chronic, debilitating lung disease affecting premature infants who survive treatment for RDS. Presently, there are no approved pharmaceutical therapies for BPD.

Surfaxin was shown to be generally safe and well-tolerated. Top-line results demonstrated that infants treated with up to five incremental standard doses of Surfaxin experienced:

- a lower incidence of death or BPD,
- a higher survival rate through 36 weeks post-menstrual age (PMA), and
- fewer days on mechanical ventilation.

Dr. Bose commented, "The data from this Phase 2 estimation trial are encouraging. These data support the continued evaluation of Surfaxin as a therapeutic option for the prevention of BPD."

Discovery's Phase 2 clinical trial enrolled 136 premature infants. In addition to standard of care, patients were randomized to receive either Surfaxin standard dose (175 mg/kg), Surfaxin low dose (90 mg/kg), or sham air as a control. The trial was designed as an estimation study to evaluate the safety and potential efficacy of Surfaxin in infants at risk for BPD, and was not powered to determine statistically significant differences in outcomes. The Surfaxin standard dose (175 mg/kg) is the dose that was administered in Discovery's RDS Phase 3 clinical trials. No meaningful conclusions could be

drawn from the Surfaxin low dose (90 mg/kg) treatment group, as infants randomized to this arm had more pre-existing medical risk factors compared with the Surfaxin standard dose (175 mg/kg) group and the control group.

Aerosurf™ (aerosolized KL-4 surfactant) delivered via the Chrysalis Technologies novel capillary aerosol generator device

Data from previously conducted pre-clinical studies using aerosolized KL-4 surfactant were also presented to the medical community for the first time. In these studies, KL-4 surfactant was aerosolized to compare Chrysalis' novel, investigational capillary aerosol generator technology to commercially available aerosol generator devices. The studies demonstrated that Aerosurf maintains its chemical structure and essential functional activity post-aerosolization. In addition, the Chrysalis investigational capillary aerosol generator technology generated a nearly 10-fold higher aerosol output rate than the other study devices.

Discovery Labs, in collaboration with Chrysalis, is developing an integrated drug device system that combines precision-engineered KL-4 surfactant technology with the capillary aerosol generator technology. This integrated drug device system potentially can be uniquely customized to address specific respiratory diseases in a broad range of patient populations. Discovery's lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nasal continuous positive airway pressure (nCPAP) to treat premature infants in the Neonatal Intensive Care Unit (NICU) with RDS. Discovery plans to initiate multiple Phase 2 clinical studies of Aerosurf utilizing the Chrysalis aerosolization technology in 2007.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "The ability to effectively deliver a less-invasive aerosolized surfactant could potentially redefine respiratory critical care medicine. Historical attempts to achieve this ambitious goal have been constrained by current technological limitations. These data support our approach in collaboration with our partners at Chrysalis to address these historical limitations."

DISCLAIMER: The Aerosurf pre-clinical study results discussed above cannot be interpreted to reflect whether the investigational integrated drug device system will be safe or effective in humans.

About BPD

BPD is associated with surfactant deficiency and is diagnosed when premature infants require mechanical ventilation or supplemental oxygen either at the 28th day of life or 36 weeks PMA. Premature babies are often born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen, resulting in RDS. These infants often require endotracheal intubation to administer one of the currently available animal-derived surfactants (usually within the first hours of birth), and to provide respiratory support via mechanical ventilation. Unfortunately, many infants relapse following initial therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen, which increases their risk of developing BPD. Discovery believes that after an initial RDS treatment, BPD may be successfully treated with repeated doses of a non-immunogenic, precision-engineered synthetic surfactant (Surfaxin) to improve the clinical outcome of these infants.

Discovery's Proprietary KL-4 Surfactant Technology: Product Candidates Surfaxin® and Aerosurf™

Discovery's surfactant product candidates, including Surfaxin and Aerosurf, are engineered versions of natural human lung surfactant and contain the precision-engineered KL-4 peptide. KL-4 is a 21 amino acid protein-like substance that is designed to closely mimic the essential attributes of human

surfactant protein B (SP-B), the surfactant protein most important for the proper functioning of the respiratory system. KL-4 surfactant has the potential to be precisely formulated, either as a liquid instillate, aerosolized liquid or dry powder, to address various respiratory diseases affecting premature infants, children and adults.

Surfaxin, a precision-engineered Surfactant Replacement Therapy (SRT) administered as a liquid-instillate, represents a potential alternative to animal-derived surfactants. Surfaxin's precision-engineered and non-immunogenic nature allows it to be further developed as a therapeutic to address other pulmonary conditions in neonatal and pediatric medicine. Data from Discovery's pivotal, multinational SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and results in improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. The SELECT and STAR (a supportive Phase 3 study) trials, as well as a pooled Phase 3 analysis, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*.

Aerosurf is a precision-engineered, aerosolized SRT administered via nasal continuous positive airway pressure (nCPAP) intended to treat premature infants at risk for respiratory failure. Premature infants at risk for Respiratory Distress Syndrome (RDS) benefit from both nCPAP and intratracheal instillation of lung surfactants. Administration of aerosolized lung surfactants via nCPAP, may avoid the need for endotracheal intubation. The potential utility of a less-invasive method of delivering lung surfactants to treat premature infants suffering from an array of respiratory disorders has been recognized by the neonatal medical community.

Chrysalis Technologies Aerosol Generation Technology

The Chrysalis Technologies aerosol generation technology is designed to produce high-quality, low velocity aerosols for possible deep lung aerosol delivery. Aerosols are created by pumping the drug formulation through a small, heated capillary, yielding a dense aerosol with a defined particle size. The defined particle size can be readily controlled and adjusted through device modifications. Discovery has a strategic alliance with Chrysalis Technologies (a division of Philip Morris USA) to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Through this alliance, Discovery gained exclusive rights to Chrysalis' novel aerosol generating technology for use with pulmonary surfactants for all respiratory diseases.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery's lead product candidate, Surfaxin[®], is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. Surfaxin is also being developed for other neonatal and pediatric indications. Aerosurf[™], Discovery's aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at www.Discoverylabs.com.

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements 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 Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that Discovery may not profitably develop and market its products, the risk that financial market conditions may change, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements, the risk that Discovery will not be able to attract or retain qualified personnel or timely provide for a successful sales and marketing organization, risks relating to the progress of Discovery's research and development, risks in the FDA or other regulatory agency review process generally, including that such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application or that approval by such regulatory agency may be withheld, delayed and/or limited by indications or other label limitations, risks that the Chemical, Manufacturing and Controls section of Discovery's New Drug Application will not satisfy the FDA, risks relating to the ability of Discovery or Discovery's third party manufacturers and development partners to manufacture or provide Discovery with adequate supplies of drug substances and expertise for completion of any of Discovery's clinical studies, risks related to the ability of Discovery and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery's drug products with innovative aerosolization technologies, risks relating to drug manufacturing by Discovery, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval process for any products that Discovery may develop independently or with Discovery's collaboration arrangements, risks relating to the development by other companies of competing therapies and/or technologies, risks relating to reimbursement and health care reform, and risks relating to securities, product liability and other litigation. 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 Discovery'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.

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