



## **DISCOVERY LABORATORIES, INC.**

### **Discovery Laboratories Successfully Completes Phase 1b Asthma Clinical Trial**

#### **Expects to Initiate United States Phase 2 Clinical Trial in Second Half of 2004**

**Doylestown, PA — March 9, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases, announced the successful completion of a Phase 1b clinical trial to evaluate the tolerability and lung deposition of its humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104), to treat patients with asthma.

This masked, placebo-controlled, randomized, Phase 1b dose-escalation study included 6 healthy subjects and 8 mild-persistent asthmatic patients. Results demonstrated that DSC-104 was safe and well tolerated, did not induce bronchospasm, and was deposited to both the central and peripheral regions of the lungs in the mild-persistent asthmatic group and the healthy volunteers. The study was conducted at a leading pulmonary research facility in the United Kingdom.

Robert J. Capetola, Ph.D., Discovery's President and Chief Executive Officer commented, "These results are extremely encouraging and demonstrate early proof of concept for DSC-104. Several scientific studies have demonstrated that during an asthmatic episode, surfactant damage and dysfunction occurs in the airways of the deep lung and those airways become obstructed. Patients who suffer from severe asthmatic attacks often end up in the emergency room, with limited alternatives to help relieve their symptoms and open up their airways. We are now preparing our Phase 2 dose escalation study to be conducted at several leading asthma clinics in the United States and should initiate this in the second half of this year."

#### **The Impact of Asthma**

The American Lung Association reports that in 2001 asthma afflicted approximately 20.3 million people in the United States and its prevalence continues to increase. Asthma ranks within the top 10 activity-limiting health conditions costing \$14 billion in United States healthcare costs annually.

Asthma may require life-long therapy. Ten percent of patients are considered severe asthmatics and require moderate to high dosages of drugs. Currently available asthma medications include inhaled and oral steroids, bronchodilators and leucotrine antagonists. Bronchodilators have limited effect during severe episodes and do not control chronic, severe asthma. Oral steroids can cause serious side effects when used for prolonged periods and are typically limited to severe asthmatic episodes and chronic, severe asthma. Discovery believes that supplying surfactant as an inhaled aerosol may relieve airway

obstruction in the deep lung and lead to a more rapid improvement in asthmatic symptoms.

### **About Discovery Laboratories**

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases. Surfactants are compositions produced naturally in the lungs and essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung 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 critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery recently completed two Phase 3 clinical trials of Surfaxin<sup>®</sup>, the Company's lead product, for the treatment of Respiratory Distress Syndrome in premature infants and is preparing to file new drug applications with the United States Food and Drug Administration and other regulatory authorities in the rest of the world. Discovery's Surfactant Replacement Therapy is also in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, a Phase 3 and a Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants, and is preparing a Phase 2 clinical trial for severe asthma.

More information about Discovery Laboratories is available on the Company's Web site at [www.discoverylabs.com](http://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), risks relating to the progress of the Company's research and development, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with sufficient amounts of drug products for completion of any of the Company's clinical studies, other risks relating to the lack of sufficient 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-KSB, 8-K, 10-Q and 10-QSB, and amendments thereto.*

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