



DISCOVERY LABORATORIES, INC.

DISCOVERY DEVELOPS ITS SURFACTANT AS AN INHALABLE AEROSOL THAT RETAINS CRITICAL THERAPEUTIC PROPERTIES

Engineered Lung Surfactants Now Positioned for Clinical Development for a Broad Range of Respiratory Diseases

Severe Asthma and Acute Lung Injury Targeted as Lead Indications

Doylestown, PA – April 23, 2003 – Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that its proprietary lung surfactant technology was successfully prepared as an inhalable aerosol formulation that retained critical therapeutic properties. Surfactant therapy for respiratory medicine has now evolved to where aerosol formulations of engineered lung surfactant have the potential to be developed to treat a broad range of respiratory diseases such as Respiratory Distress Syndromes, Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disease (COPD), and upper airway disorders including sinusitis and sleep apnea.

Discovery is the only company with a surfactant technology platform engineered to mimic the essential attributes of natural human lung surfactant. Discovery has exploited this proprietary platform to move its lead liquid instillate product, Surfaxin[®], into five late-stage clinical trials for critical care patients suffering from Respiratory Distress Syndromes. Discovery's product pipeline has expanded to now include aerosol surfactant formulations as Surfactant Replacement Therapies with the potential to treat an abundance of new respiratory disease targets or to prevent respiratory conditions from becoming severe, even life-threatening, events.

Discovery's proprietary lung surfactant compound was aerosolized as a liquid formulation that exhibited the following critical therapeutic properties:

- Retention of the essential pharmacological properties of a functioning surfactant, including the surface-tension lowering abilities necessary to restore lung function and keep the airways open and expanded;
- A particle size and distribution suitable for deposition in the lungs;
- Delivery rates to achieve therapeutic dosing in an appropriate time period; and
- Reproducible aerosol output and minimal waste of surfactant dose.

Specific details will be presented in full at the International Society for Aerosols in Medicine in Baltimore, MD, on June 14-18, 2003.

Robert J. Capetola, Ph.D, President and Chief Executive Officer of Discovery Laboratories, Inc., stated, “In early 2002, we launched our Redwood City, California operations, focused on preclinical development and aerosol activities, to capitalize on the breadth of our surfactant technology platform. In one year, a potential aerosol surfactant product is positioned to enter Phase 1b/2a clinical trials. This accomplishment is attributed to our superb scientific team, our collaborators, and a proprietary surfactant platform that facilitates rapid development.

There is a wealth of clinical literature and scientific evidence supporting the therapeutic benefits of Surfactant Replacement Therapy. We believe our technology is the only one presently available with the potential to provide Surfactant Replacement Therapy for respiratory diseases. A significant number of patients have been treated in our clinical trials and Surfaxin has been well tolerated. I am extremely pleased that our engineered surfactant can now be developed as an inhalable aerosol to potentially treat a broad range of respiratory diseases that have so far been unable to benefit from Surfactant Replacement Therapy.”

Discovery’s lead development programs for its liquid aerosol Surfactant Replacement Therapy will focus on treating hospital or emergency room patients suffering from severe asthma and Acute Lung Injury. Each condition is associated with an inflammatory event that causes surfactant dysfunction and each represents a potential billion-dollar market.

John G. Cooper, Senior Vice President and Chief Financial Officer stated, “We now have the opportunity to build one of the most extensive respiratory pipelines available. Of course, we have to prioritize the number and timing of our projects. Given our existing resources and taking into account the current financing environment, our business model calls for initiating our lead aerosol clinical programs once the results are available from our pivotal Phase 3 trial of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and our Phase 2b trial of Surfaxin for the treatment of Acute Respiratory Distress Syndrome. An “aerosol surfactant” product pipeline strengthens our potential to attract strong strategic pharmaceutical partners that can support the significant potential of our Surfactant Replacement Therapy technologies and allow us to begin development even earlier.”

Acute Lung Injury

Acute Lung Injury is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs’ natural surfactant layer. The most serious manifestation of Acute Lung Injury is Acute Respiratory Distress Syndrome (ARDS). ARDS may arise from a variety of disorders including sepsis, burn trauma and severe pneumonia, as well as Severe Acute Respiratory Syndrome (SARS). There is an estimated one million hospitalized patients a year at risk in the United States for Acute Lung Injury and there are no currently-approved therapies. An aerosolized Surfactant Replacement Therapy may be effective as a preventive measure for patients at risk for Acute Lung Injury by providing a functioning surfactant to act as an anti-inflammatory and to maintain proper lung function.

Asthma

Asthma is a common disease characterized by sudden, recurrent constriction of the airways and chronic inflammation of the lungs. Several studies have shown that surfactant damage and dysfunction is a significant component of asthma -- airway obstruction occurs when there is a

surfactant dysfunction in the airways of the deep lung of the type that develops during an asthma attack. Surfactant Replacement Therapy has the potential to relieve the obstruction in the airways associated with asthma. In the United States alone, there are roughly one million hospital outpatient visits and 1.8 million emergency room visits each year due to asthma.

Lung Surfactants

Surfactants are protein/lipid compositions that are produced naturally in the lungs and are critical to the lungs' ability to absorb oxygen. They cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the alveoli. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli. In the absence of sufficient surfactant or should the surfactant degrade, these air sacs tend to collapse, and, as a result, the lungs do not absorb sufficient oxygen. Surfactants also lower the surface tension of the conducting airways and keep the airway open and expanded.

About Discovery Laboratories

Discovery Laboratories, Inc. is a specialty pharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes, Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disease (COPD), and upper airway disorders. Discovery's surfactant technology produces an engineered version of natural human lung surfactant that is designed to precisely mimic the essential properties of human lung surfactant. Discovery believes that through its surfactant technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for hospitalized and ambulatory patients. Surfaxin, Discovery's lead product, is in three Phase 3 and two Phase 2 clinical trials for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Discovery's first aerosol surfactant product is positioned to enter clinical trials for hospital patients with severe asthma or acute lung injury. Discovery has a commercialization alliance with Quintiles Transnational Corp. and a strategic alliance with Laboratorios del Dr. Esteve S.A.

Interested parties can receive corporate updates by sending their email addresses to [**dsco@focuspartners.com**](mailto:dsco@focuspartners.com). 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 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 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. 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-QSB and 10-Q, and amendments thereto.

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