



## Discovery Labs Announces Preliminary Results of Phase 2 Clinical Trial in ARDS

**Warrington, PA — March 30, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO),** today announced preliminary results from its recently completed Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults using Discovery's precision-engineered surfactant delivered via bronchoscopic segmental lavage (Surfactant Lavage). **Discovery will hold a conference call on Friday, March 31, 2006 at 9:00 AM EST. The call in number is 866-332-5218.**

The ARDS Phase 2 clinical trial was an open-label, controlled, multi-center, international study of Surfactant Lavage for the treatment of ARDS in adults. Patients were randomized to receive either surfactant administered in high concentrations and large volumes via a bronchoscopic segmental lavage technique (lung wash), or the current standard of care (SOC), which is mechanical ventilation and other supportive therapies. Surfactant was delivered with a bronchoscope to each of the 19 segments of the lung and was intended to cleanse and remove inflammatory substances and debris from the lung, while leaving sufficient amounts of surfactant behind to help re-establish the lung's capacity to absorb oxygen. The trial was designed to enroll up to 160 patients and was structured in two parts. Total enrollment in the trial was 124 patients. Part A focused on dose escalation and safety and enrolled 22 patients. Part B, which focused on safety and efficacy, included 113 patients, 11 of which were from Part A.

The objective of the Surfactant Lavage was to restore functional surfactant levels in the patients' lungs, thereby improving oxygenation, as measured by an increase in the PaO<sub>2</sub>/FiO<sub>2</sub> (P/F ratio), in order to remove critically ill patients from mechanical ventilation sooner. The primary endpoint was the incidence rate of patients alive and off mechanical ventilation at Day 28. Secondary endpoints included all-cause mortality at Day 28, and safety and tolerability of surfactant and the bronchoscopic lavage procedure.

The key results of the trial showed:

- Surfactant Lavage exhibited a positive pharmacologic effect manifested as improved oxygenation. This was demonstrated by an acute increase in the P/F ratio after patients received Surfactant Lavage. Dose Group A (n=34) received up to two Surfactant Lavages totaling up to 57,000 mg of phospholipids per patient. Dose Group B (n=43) received up to two Surfactant Lavages and boluses totaling up to 61,000 mg of phospholipids per patient.

Clinically and statistically significant increases were observed in the P/F ratio at 24 hours after Surfactant Lavage, compared with SOC (59.7%, 53.4%, 22.5% for Dose Groups A and B, and SOC, respectively; p=0.004 and p=0.036, for Dose Groups A and B, respectively, versus SOC).

- All-cause mortality at Day 28 was 12% and 21% for patients in Dose Group A (n=34) and Dose Group B (n=43), respectively, and 17% for the combined Dose Groups (n=77) versus 14% for patients who received SOC (n=36).

For those patients who responded to the Surfactant Lavage (defined as patients who had an increase in their P/F ratio of greater than 50%; n=36 combined Dose Groups A and B), all-cause mortality at Day 28 was observed to be approximately 8%.

- The incidence of being alive and off mechanical ventilation at Day 28 was 71% and 72% for patients in Dose Group A (n=34) and Dose Group B (n=43), respectively, and 71% for the combined Dose Groups (n=77) versus 81% for patients who received SOC (n=36).
- There were no meaningful differences noted in the clinical outcomes in patients classified as having Direct or Indirect ARDS (explained below).

Robert Segal, MD, Senior Vice President and Chief Medical Officer of Discovery, commented, “A drug needs to be pharmacologically active to have an impact on clinical outcomes. The observed increase in P/F ratio in the Surfactant Lavage groups is evidence of pharmacological activity. In this trial, we observed no differences between the treatment groups and SOC in all-cause mortality and the incidence rate of being alive and off mechanical ventilation at Day 28. Of particular interest, we noted that in most patients who responded to Surfactant Lavage, defined as an acute increase in P/F ratio of greater than 50%, we observed a decrease in mortality compared to those patients who did not respond.”

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, stated, “Bronchoscopic segmental lavage with surfactant represents a novel approach in treating these critically ill patients suffering from ARDS. We believe our precision-engineered surfactant represents the future of surfactant replacement therapy and we are pleased to see this clinically and statistically significant improvement in P/F ratio in these very sick patients. What we’ve learned from this Phase 2 trial is that approximately half of the patients responded acutely to Surfactant Lavage and most of those patients were observed to have a better clinical outcome. We, alone or with potential partners, can apply scientific and clinical observations generated from this trial towards the design of future trials to address this serious respiratory syndrome. These trials may determine whether earlier intervention and or administration of surfactant throughout the patient’s clinical course may further improve clinical outcomes.”

Acute Respiratory Distress Syndrome (ARDS) is a life-threatening disorder for which no approved therapies exist anywhere in the world. There are estimated to be between 150,000 and 200,000 adults per year in the United States suffering from ARDS with similar numbers afflicted in Europe. Current medical literature indicates that the mortality rate is estimated to be between 30% - 35% for ARDS patients treated with the most effective SOC therapy. The syndrome is the result of various causes including pneumonia, gastric aspiration, near drowning, smoke inhalation, lung contusions (collectively known as Direct ARDS causes) and sepsis (a toxic condition caused by infection), pancreatitis, major surgery, trauma, and severe burns (collectively known as Indirect ARDS causes). ARDS is characterized by an excess of fluid in the lungs, destruction of surfactants naturally present in lung tissue, and decreased oxygen levels (measured by P/F ratio) in the patient.

P/F ratio is a measurement of the efficiency of oxygen exchange at the alveolar level, where P ( $\text{PaO}_2$ ) is the partial pressure of oxygen in arterial blood and F ( $\text{FiO}_2$ ) is the fraction of inspired oxygen, defining the amount of supplemental oxygen in excess of normal room air (21% oxygen). A healthy individual with normal lung function has a P/F ratio greater than 425, whereas an acutely ill patient with ARDS has a P/F ratio less than 200. In other words, a low P/F ratio indicates that a patient is very ill and requires very high supplemental oxygen concentrations in order to maintain adequate blood oxygenation ( $\text{PaO}_2$ ).

Comprehensive analysis of the data from this trial is ongoing. Continued assessment of safety and tolerability remains underway, as well as further sub-analysis of secondary endpoints, including ventilatory requirements, number of days in the intensive care unit, and number of days in the hospital. Following this analysis, Discovery plans to submit these data for publication in a peer review journal.

### **Conference Call Details**

Discovery Labs will hold a conference call on Friday, March 31 at 9:00 AM EST to further discuss in greater detail the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at <http://audioevent.mshow.com/294656/> and [www.discoverylabs.com](http://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. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 7124889.

### **About Discovery Labs**

Discovery Laboratories, Inc. is a biotechnology 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 Labs' technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that through its technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Discovery Labs' SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin<sup>®</sup>, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. Discovery Labs is preparing to conduct multiple Phase 2 pilot studies with Aerosurf<sup>™</sup>, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failure.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery Labs is developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

For more information, please visit our corporate website 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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 financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery'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 Discovery, 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 Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers and development partners to provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery's clinical studies, risks relating to drug manufacturing by Discovery, risks relating to the integration of manufacturing operations into Discovery's existing operations, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, risks relating to the ability of the Company and its collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements, 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 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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