



**Discovery Labs Announces Encouraging Preliminary Data from
ARDS Phase 2 Clinical Trial**

Expands trial to strengthen endpoint signal prior to designing potential Phase 3 trial

Warrington, PA — December 7, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO), announced encouraging preliminary data from its Surfaxin[®] Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults. **Discovery will hold a conference call today at 11:00 AM EST. The call in number is 800-665-0669.**

The ARDS Phase 2 trial is comprised of two parts; a dose-escalation/safety phase and an efficacy/safety phase. As of November 15, 2004, a total of 89 patients were enrolled in the trial and completed the 28-day study. The table below shows results from 78 evaluable patients. These evaluable patients received either one of two dosing regimens chosen for the efficacy/safety phase, or Standard of Care.

| <u>Endpoint</u> | <u>Surfaxin Dose Group A</u> ⁽¹⁾ (N=29) | <u>Surfaxin Dose Group B</u> ⁽²⁾ (N=29) | <u>Standard of Care Group</u> (N=20) | Relative Difference in Favor of Group B vs. Standard of Care |
|--|---|---|---|---|
| All cause Mortality @ Day 28 | 13.8% | 13.8% | 20.0% | 31.0% |
| Incidence of being Alive & off MV @ Day 28 | 69.0% | 82.8% | 75.0% | 10.4% |

⁽¹⁾ **Dose Group A:** Two Surfaxin lavages totaling up to 57,000 mg of phospholipid

⁽²⁾ **Dose Group B:** Two Surfaxin lavages and boluses totaling up to 61,000 mg phospholipid

Both Surfaxin dose groups showed a 31% relative improvement in overall mortality assessed at Day 28 versus Standard of Care. With respect to the primary endpoint of the incidence rate of being alive and off mechanical ventilation at Day 28, 69% of Dose Group A patients, 82.8% of Dose Group B patients, and 75% of the Standard of Care patients, were alive and off mechanical ventilation. With respect to overall safety, no differences were apparent between the two Surfaxin treatment groups.

Antonio Anzueto, M.D., Professor of Medicine at the University of Texas Health Science Center at San Antonio, commented, "Following my review of the preliminary data, I am impressed with these observations. The separation between Surfaxin and Standard of Care, especially with regard to all cause mortality is impressive even with the uncharacteristically low rate of mortality in the Standard of Care group in this trial."

Based on these data and in consultation with the Company's clinical advisors, the current ARDS Phase 2 protocol has been modified to better establish the endpoint signal in key clinical outcomes in order to properly power and design a potential Phase 3 clinical trial. The modified protocol allows for increased enrollment of up to 160 patients. The remainder of the trial will be comprised of Surfaxin Dose Group B (lavage with bolus) and Standard of Care. The Phase 2 trial is expected to be completed by the fourth quarter of 2005.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, stated, "These data, especially with regard to all cause mortality, support our belief that our Surfactant Replacement Therapy (SRT) lavage, or lung wash, is the most scientifically sound approach to the treatment of ARDS. We remain committed to advancing this trial with the scientific rigor necessary to bring this potentially life-saving therapy to patients, and believe that expanding the trial to 160 patients will better allow us to understand the appropriate patient population and primary endpoints for a potential Phase 3 clinical trial."

R. Duncan Hite, M.D., Director of Medical Intensive Care and Critical Care Research, Wake Forest University Health Sciences, commented, "These data are encouraging. Other ARDS trials utilizing surfactants have failed to show a mortality benefit. These data support the premise that the use of high dose Surfaxin, a precisely-engineered surfactant, in combination with the bronchoscopic segmental lavage procedure could prove to be the optimal therapy for ARDS patients. I believe the expansion of Discovery's Phase 2 clinical trial is a logical approach. It is smart to strengthen the signal in the Phase 2 trial to more accurately design and power the Phase 3 clinical program."

The Phase 2 trial is an open-label, controlled, randomized, dose-ranging, multicenter trial comparing the safety and efficacy of Surfaxin to Standard of Care in up to 160 ARDS patients. Patients on mechanical ventilation are randomized to receive Surfaxin or to continue to be managed on mechanical ventilation alone, which is the current standard of care for this patient population. The objective is to restore functional surfactant levels in the lung, in order to keep these critically ill patients alive and get them off costly mechanical ventilation as soon as possible. The primary endpoint of this trial is the incidence rate of patients being alive and off mechanical ventilation at Day 28. Key secondary endpoints include mortality at the end of Day 28, and safety and tolerability of Surfaxin and the bronchoscopic lavage procedure.

Surfaxin is administered via a proprietary sequential bronchopulmonary segmental lavage technique (a "lung wash" where Surfaxin is delivered through a tube, called a bronchoscope, to each of the 19 to 20 segments of the lung), which is intended to cleanse and remove inflammatory substances from the lungs, while approximately one-half of the Surfaxin remains to help re-establish the lung's capacity to absorb oxygen.

Acute Respiratory Distress Syndrome

ARDS is a life-threatening respiratory disorder for which there are currently no approved therapies anywhere in the world. It is estimated that there are between 150,000 and 250,000 ARDS patients per

year in each of the U.S. and Europe. The mortality rate for ARDS patients can range from 30% to 50%. The current standard of care includes placing patients on mechanical ventilators in intensive care units at an average estimated cost of approximately \$8,500 per day. ARDS is characterized by an excess of fluid, inflammatory cells and debris in the lungs that leads to decreased oxygen levels in the patient's blood. One prominent characteristic is the destruction of the lung's natural surfactant that is essential to the ability to absorb oxygen. These conditions are caused by events such as pneumonia, aspiration of gastric contents, smoke inhalation, near drowning, industrial accidents, sepsis and other traumas.

Conference Call Details

Discovery will hold a conference call today at 11:00 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/474/> 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.

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 surfactant that is designed to closely mimic the essential properties of natural 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 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 United States FDA and a Marketing Authorization Application with the European Medicines Evaluation Agency for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of RDS in premature infants. Discovery is also conducting various clinical programs to address ARDS in adults, BPD (a form of chronic lung disease in infants), Neonatal Respiratory Failures in premature infants, severe asthma in adults, and MAS 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 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.

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