



## **New Health Economic Data Shows Cost Benefit in using Surfaxin<sup>®</sup> in RDS Babies**

**Warrington, PA – September 1, 2005** — Discovery Laboratories, Inc. (Nasdaq: DSCO) announces the results from a comparative pharmacoeconomic analysis of Surfaxin<sup>®</sup> (lucinactant) versus leading animal-derived surfactants (Survanta<sup>®</sup> and Curosurf<sup>®</sup>) in the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The data was presented at the 46<sup>th</sup> Annual Meeting (August 31 – September 3) of the European Society for Paediatric Research (ESPR) in Siena, Italy.

Conclusions from the comparative pharmacoeconomic analysis are:

- Survival represents the largest component of aggregate cost of care and a significant increase in survival was observed with Surfaxin versus the animal-derived surfactants (mortality rates at 36 weeks post-menstrual age, 20.3% vs 24.1%, P=0.04, respectively).
- Surviving premature infants treated with Surfaxin had 4.09 fewer days in the Neonatal Intensive Care Unit (NICU), compared to the surviving premature infants treated with animal-derived surfactants.
- The average inpatient costs were \$130,280 for infants treated with Surfaxin compared to \$136,150 to infants treated with animal-derived surfactants, a cost savings of \$5,870 per surviving premature infant.

Robert Segal, MD, Chief Medical Officer of Discovery Laboratories commented, “This is a very extensive comparative pharmacoeconomic analysis of surfactants in the prevention of Respiratory Distress Syndrome in premature infants. As previously reported, Surfaxin has shown a significant survival advantage over the animal-derived surfactants based upon a pooled analysis of Discovery’s SELECT and STAR clinical trials. Not only does Surfaxin save babies’ lives, but what is most impressive about these pharmacoeconomic outcomes is that Surfaxin reduces the cost associated with the care of these surviving babies. Surfaxin has the potential to transform the treatment of Respiratory Distress Syndrome in the NICU.”

The objectives of this research were to estimate the clinical consequences and economic impact of Surfaxin versus the combined animal-derived surfactants in the prevention of RDS among surviving premature infants. A decision-analytic model was constructed using a hospital perspective to assess the pharmacoeconomics of surfactant replacement therapy. Data sources included, premature infant epidemiologic data from the U.S. National Centers for Health Statistics and the Vermont Oxford Network, the combined clinical outcomes from Discovery’s two clinical trials (SELECT and STAR, published in *Pediatrics*, April 2005), and cost data derived from an assessment from current daily NICU costs for pre-term infants with severe RDS including the cost of mechanical ventilation.

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative for the animal-derived and non-protein containing synthetic surfactants. Discovery's Surfaxin is pending approval and has recently received an Approvable Letter from the United States Food and Drug Administration (FDA) for the prevention of RDS in premature infants.

### **About European Society Paediatric Research (ESPR)**

European Society Paediatric Research was founded in 1953, and is one of the oldest European societies. ESPR initially started as a club for Pediatricians especially interested in research in children, which then evolved to become the ESPR. ESPR is comprised of about 500 members, mostly doctors caring for children oriented towards research, which may improve child health. The ESPR in collaboration with the SPR (Society for Paediatric Research) owns the journal Pediatric Research that now, is ranked as the second most important Pediatric journal based on the impact factor.

### **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's technology produces a precision-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 address respiratory diseases where there are few or no approved therapies available.

Discovery's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin, 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. In addition, the Company is conducting several Phase 2 clinical trials including Surfaxin for the treatment of Bronchopulmonary Dysplasia (BPD) in premature infants and aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP) for neonatal respiratory failures.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also 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 our 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 to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery'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 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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