



## **Discovery Labs Reports Progress in Responding to Surfaxin FDA Approvable Letter**

**Warrington, PA – August 6, 2008, -- Discovery Laboratories, Inc. (Nasdaq:DSCO)** announces that it has made significant progress in addressing key remaining requirements identified by the U.S. Food and Drug Administration (FDA) to gain marketing approval of Surfaxin<sup>®</sup> (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Over the upcoming weeks, Discovery Labs will continue to conduct and finalize activities necessary to submit a Complete Response to the May 1, 2008 FDA Approvable Letter. Discovery Labs anticipates submitting a Complete Response in September 2008 and believes the response may be designated by the FDA as a Class 1 resubmission with a target review period of 60 days.

The May 1, 2008 Approvable Letter did not require any additional clinical trials to gain Surfaxin approval. Prior to receiving that Approvable Letter, Discovery Labs and the FDA had agreed to a proposed Surfaxin package insert setting forth prescribing information. Also, the FDA had successfully conducted a pre-approval inspection (PAI) of Discovery Labs' manufacturing operations. On June 18, 2008, Discovery Labs met with the FDA to clarify and reach agreement on addressing the key remaining requirements necessary to gain Surfaxin approval. These key requirements are:

### Surfaxin Biological Activity Test

Based on discussions with the FDA several years ago, Discovery Labs qualified and validated a biological activity test in accordance with current Good Manufacturing Practices (cGMP) and successfully implemented this test for Surfaxin release and stability testing. In addition, as agreed to at a December 2006 Clarification Meeting with the FDA, Discovery Labs generated data in a well-characterized RDS animal model at a Surfaxin dose of 5.8 mL/kg (the 2007 Preclinical Study), which is the same dose that was used in the Phase 3 clinical studies of Surfaxin.

The 2007 Preclinical Study results, together with data generated from the biological activity test described above, support the comparability of Surfaxin drug product used in Discovery Labs Phase 3 clinical studies to the commercial manufacturing process for Surfaxin. In addition, these data were intended to establish final acceptance criteria for the biological activity test. The data from the biological activity test and the 2007 Preclinical Study were provided to and reviewed by the FDA during the Surfaxin review cycle that concluded with the May 1, 2008 Approvable Letter.

At the June 18, 2008 meeting, the FDA requested and Discovery Labs agreed to augment the previously-generated data by conducting additional Surfaxin biological activity tests at a dose of 5.8 mL/kg, which is different than the dose of 8.0 mL/kg historically employed for Surfaxin release and stability testing. In addition, Discovery Labs is contemporaneously conducting a

related preclinical study using the same RDS animal model and dose (5.8 mL/kg) as that used in the 2007 Preclinical Study.

The data generated from these additional studies will be used to determine the final acceptance criteria for the biological activity test and to further confirm the comparability of Surfaxin drug product used in Discovery Labs' Phase 3 clinical trials to the commercial manufacturing process for Surfaxin. These additional studies are ongoing and are being conducted at the same laboratories previously used by Discovery Labs. Although these activities must be successfully concluded, Discovery Labs believes that the preliminary results achieved to date are encouraging and are expected to support Surfaxin approval.

#### Specifications for Lipid-Related Impurities in Surfaxin Active Pharmaceutical Ingredients (APIs)

Surfaxin is comprised of four active pharmaceutical ingredients (APIs); a novel peptide, a fatty acid and two phospholipids. To gain final marketing authorization by the FDA, Discovery Labs must satisfy International Conference of Harmonization (ICH) guidelines for the proposed specifications for certain lipid-related impurities in the two phospholipids.

At the June 18 meeting with the FDA, Discovery Labs discussed its approach to justify the levels of certain of the lipid-related impurities given their presence in the human lung at levels equal to or greater than those that exist in Surfaxin. At that meeting, the FDA requested additional information about the levels of these lipid-related impurities specific to the neonatal lung. In addition to reviewing scientific literature to satisfy the requirement that lipid-related impurities in Surfaxin's two phospholipids meet ICH guidelines, Discovery Labs has consulted with lipid-experts and has been working closely with its phospholipid suppliers to reduce lipid-related impurity levels to the ICH threshold limit.

To date, notable progress has been made. Based on recent analyses, Discovery Labs believes that it can satisfy the FDA requirements by either accepting the ICH threshold limits for certain lipid-related impurities and/or working with its phospholipid suppliers to further reduce impurity levels to the ICH threshold limits. Discovery Labs and its phospholipid suppliers are focused on successfully completing this approach over the upcoming weeks and obtaining all information necessary to support a September submission of a Complete Response.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "I am extremely pleased with the results achieved to date and am confident that the upcoming Complete Response will satisfy the remaining FDA requirements to gain Surfaxin approval. We are positioning Surfaxin, the first peptide-containing, synthetic surfactant, to be the highest quality surfactant replacement therapy available. The state-of-the-art advancements made to our manufacturing operations, quality systems, analytical methods, and regulatory capabilities should favorably impact Surfaxin's acceptance by the medical community and meaningfully support the advancement of Discovery Labs' surfactant-based development pipeline."

Discovery Labs believes that it will be in a position to complete the activities related to satisfying all remaining FDA requirements and submit a Complete Response to this Approvable Letter in

the September 2008 timeframe. Based on its understanding of FDA guidelines, and in consultation with outside experts, Discovery Labs believes that the FDA may designate the Complete Response to this Approvable Letter as a Class 1 resubmission, which would result in a target review period of 60 days (whereas a Class 2 resubmission would result in a 6-month target review period). If Discovery Labs' understanding of the timeline is correct, the potential approval of Surfaxin is anticipated in 2008.

**DISCLOSURE NOTICE:** The information in this press release includes certain “forward-looking” statements relating to, among other things, the remaining steps necessary for FDA approval of Surfaxin for the prevention of RDS in premature infants and Discovery Labs' plans and expected timing to respond to the May 1, 2008 Approvable Letter. Although Discovery Labs believes that it has made significant progress towards gaining approval of Surfaxin, gaining approval of Surfaxin involves ongoing activities, the final results of which could vary materially from Discovery Labs' expectations and the results obtained to date. Discovery Labs currently believes that it will succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants within the timeline outlined above; however, these activities and the ultimate outcomes are subject to a variety of risks, including but not limited to risks that (i) even if Discovery Labs is able to generate the additional data requested by the FDA and file its Complete Response to the Approvable letter within the timeline indicated above, the FDA may not be satisfied with the new data and may require Discovery Labs to perform further studies or undertake other activities that are presently not contemplated by Discovery Labs, (ii) Discovery Labs may not succeed in adequately addressing other items identified in the Approvable Letter and be unable to gain approval of Surfaxin within the timeline indicated above, (iii) Discovery Labs, in the process of preparing its response to the Approvable Letter, may identify unforeseen problems that have not yet been discovered, and (iv) the FDA could impose additional requirements to gain approval of Surfaxin. Any failure to provide information requested by the FDA or to adequately address the items raised in the Approvable Letter in Discovery Labs' formal response to the Approvable Letter could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially prevent the approval of Discovery Labs' other products.

### **About Discovery Labs**

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' technology produces a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant. Discovery Labs believes that, with its proprietary technology, SRT has the potential, for the first time, to address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

SURFAXIN<sup>®</sup>, the Company's lead product from its SRT pipeline, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. SURFAXIN is also being developed for other neonatal and pediatric indications. AEROSURF<sup>™</sup>, Discovery Labs' aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to

significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

*To the extent that statements in this press release are not strictly historical, 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, including, without limitation, the risks that: Discovery Labs may be unable to respond, if at all, to the recent approvable letter for Surfaxin within the anticipated timeline and the response, when filed, may not satisfy the FDA; the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that Discovery Labs may file for its products, or may not approve any such applications or may limit marketing of such products to particular indications or impose unanticipated label limitations; changes in the national or international political and regulatory environment may make it more difficult for Discovery Labs to gain FDA or other regulatory approval of its products; Discovery Labs may be unable to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT); Discovery Labs' lengthy and costly research and development programs, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any of its products, including Surfaxin, may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs or its contract manufacturers or materials suppliers may be unable to successfully manufacture adequate supplies of its drug product or drug substances when needed or in amounts sufficient to meet demand; Discovery Labs may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs' drug products with innovative aerosolization technologies; Discovery Labs may be unable to profitably develop and market its products; Discovery Labs may be unable to maintain and protect the patents and licenses related to its SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further described in Discovery Labs 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.*

**Company Contact:**

Lisa Caperelli, Investor Relations  
215-488-9413