



Discovery Labs and FDA to Meet on June 2, 2009 to Discuss SURFAXIN Complete Response Letter

Warrington, PA – May 11, 2009 -- Discovery Laboratories, Inc. (Nasdaq:DSCO) has received written notification from the U.S. Food and Drug Administration (FDA) that an end-of-review meeting has been scheduled for June 2, 2009 at the FDA offices in Rockville, Maryland. The purpose of this meeting is to determine the resolution of the remaining primary issue necessary for Discovery Labs to gain U.S. marketing approval of Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants.

On April 17, 2009, Discovery Labs received a Complete Response letter from the FDA for Surfaxin for RDS. In its letter, the FDA focused primarily on certain aspects of a Surfaxin biological activity test (BAT, a quality control stability and release test) that must be addressed before Surfaxin can be approved. The FDA questioned whether the BAT can adequately distinguish change in Surfaxin drug product over time and whether Discovery Labs has adequately validated the BAT and determined its final acceptance criteria. Discovery Labs intends to rely on data already submitted to the FDA, as well as limited existing data, to support the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product and demonstrate that the BAT can adequately distinguish change in Surfaxin over time and is an appropriate test for monitoring Surfaxin biological activity throughout shelf-life.

Following the meeting and receipt of formal written minutes from the FDA, Discovery Labs intends to provide an update regarding the outcome and anticipated timeline to potential approval of Surfaxin.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating, among other things, to Discovery Labs’ understanding of the approach and timing required to address the remaining questions identified in the Complete Response letter dated April 17, 2009 to gain FDA approval of Surfaxin for the prevention of RDS in premature infants and the timing of the anticipated FDA review period. Although Discovery Labs currently is hopeful 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, these activities and the ultimate outcomes are subject to a variety of risks and uncertainties that could cause actual results to be materially different. These risks and uncertainties include, but are not limited to, risks that (i) although Discovery Labs is hopeful that it will be able to reach agreement with the FDA with respect to the validation of the BAT, finalization of acceptance criteria for the BAT and use of the BAT to establish the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product, Discovery Labs and the FDA may not reach agreement with respect any or all of these issues; if Discovery Labs and the FDA do not reach agreement, the FDA will likely require Discovery Labs to perform further studies or undertake other activities, which potentially could include additional preclinical studies and/or , if the FDA determines that Discovery Labs has failed to establish to the FDA’s satisfaction the comparability of Surfaxin drug product used in the clinical trials to the commercial Surfaxin drug product, new clinical trials, which are presently not contemplated by Discovery Labs, and Discovery Labs may be unable to gain approval of Surfaxin, if at all, within the timeline indicated above; (iii) even if Discovery Labs were to agree to and did complete additional activities required by the FDA, the FDA may in the future require other activities as a condition to

gaining Surfaxin approval, or may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; (iv) although Discovery Labs thinks it unlikely, the FDA may not be satisfied with Discovery Labs' responses to other items identified in the Complete Response letter and Discovery Labs may be unable to gain approval of Surfaxin, if at all, within the timeline indicated above; (v) Discovery Labs may identify unforeseen problems that have not yet been discovered; and (vi) the FDA could impose additional requirements to gain approval of Surfaxin. Any failure to satisfy the issues raised by the FDA in the Complete Response letter could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially delay or prevent the approval of Discovery Labs' other products.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' novel proprietary KL₄ Surfactant Technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol or lyophilized formulations. In addition, Discovery Labs' proprietary Capillary Aerosolization Technology produces a dense aerosol, with a defined particle size that is capable of potentially delivering aerosolized KL₄ surfactant to the deep lung without the complications currently associated with liquid surfactant administration.

Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. Discovery Labs is focused initially on developing its KL₄ surfactant pipeline to build a pediatric franchise that will potentially address several respiratory conditions affecting neonates and young children. For more information, please visit our website at www.Discoverylabs.com.

Forward Looking Statements

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. Examples of such risks and uncertainties are: risks relating to the rigorous regulatory requirements required for approval of any drug or drug-device combination products that Discovery Labs may develop, including that: (i) Discovery Labs and the U.S. Food and Drug Administration (FDA) will not be able to agree on the matters raised by the FDA in its Complete Response letter dated April 17, 2009, or the FDA may require Discovery Labs to conduct significant additional activities to potentially gain approval of Surfaxin, if ever, (ii) the FDA or other regulatory authorities may not accept or may withhold or delay consideration of any of Discovery Labs' applications, or may not approve or may limit approval of Discovery Labs' products to particular indications or impose unanticipated label limitations, and (iii) changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval; risks relating to Discovery Labs' research and development activities, including time-consuming and expensive pre-clinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or fail; risks relating to Discovery Labs' ability to develop and manufacture drug products and capillary aerosolization systems for clinical studies, and, if approved, for commercialization of drug and combination drug-device products, including risks of technology transfers to contract manufacturers and problems or delays encountered by Discovery Labs, its contract manufacturers or suppliers in manufacturing drug products, drug substances and capillary aerosolization systems on a timely basis or in an amount sufficient to support Discovery Labs'

development efforts and, if approved, commercialization; risks that (a) market conditions, the competitive landscape or otherwise, may make it difficult to launch and profitably sell products, (b) Discovery Labs may be unable to identify potential strategic partners or collaborators to market its products, if approved, in a timely manner, if at all, and (c) Discovery Labs' products will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community; the risk that Discovery Labs or its strategic partners or collaborators will not be able to attract or maintain qualified personnel; the risk that Discovery Labs will not be able in a changing financial market to raise additional capital or enter into strategic alliances or collaboration agreements, or that the ongoing credit crisis will adversely affect the ability of Discovery Labs to fund its activities, or that additional financings could result in substantial equity dilution; the risk that Discovery Labs will not be able to access credit from its committed equity financing facilities, or that the share price at which Discovery Labs may access the facilities from time to time will not enable Discovery Labs to access the full dollar amount potentially available under the facilities; the risk that Discovery Labs will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of Discovery Labs' common stock to decline; the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten Discovery Labs' ability to continue as a going concern; the risks that Discovery Labs may be unable to maintain and protect the patents and licenses related to its products, or other companies may develop competing therapies and/or technologies, or health care reform may adversely affect Discovery Labs; risks of legal proceedings, including securities actions and product liability claims; risks relating to reimbursement and health care reform; and other risks and uncertainties 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.

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