



Discovery Labs Provides Update Regarding its Program for Surfaxin[®] U.S. Marketing Authorization

Warrington, PA — January 10, 2011 — Discovery Laboratories, Inc. (Nasdaq: DSCOD), a biotechnology company developing its novel, synthetic, peptide-containing surfactant, is providing an update regarding its efforts to file a Complete Response intended to gain U.S. Food and Drug Administration (FDA) marketing authorization of Surfaxin[®] for the prevention of respiratory distress syndrome (RDS) in premature infants. Discovery Labs has had multiple interactions with the FDA regarding various aspects of the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit biological activity test (BAT). In response to a proposal submitted by Discovery Labs, the FDA has recently provided detailed, written direction regarding the verification of certain parameters related to final BAT validation. The FDA indicated that several aspects of Discovery Labs' proposed approach to the BAT validation are reasonable; however, with respect to certain parameters, the FDA is requesting additional data to further support ultimate determination of BAT validation.

W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs commented, "We have made considerable progress towards the filing of a Surfaxin Complete Response. The work that we originally proposed to the FDA relating to the comprehensive preclinical program has been completed. We have generated data that demonstrate a meaningful reduction in variability in the optimized BAT and have conducted supportive side-by-side studies with the well-established pre-term lamb model of RDS. We appreciate the FDA's willingness to provide guidance and, based on our preliminary assessment, believe that we could generate the additional data and be in a position to file a Surfaxin Complete Response by early third quarter 2011."

Discovery Labs has conducted a comprehensive pre-clinical program employing an optimized BAT in a series of prospectively-designed, side-by-side preclinical studies with the well-established preterm lamb model of RDS. Discovery Labs engaged in several interactions with the FDA intended to ensure that the comprehensive preclinical program would satisfy the FDA. At the FDA's suggestion, Discovery Labs submitted a proposal seeking clarification regarding specific and detailed aspects of final BAT validation. To address certain technical criteria relating to final BAT validation, the FDA's recent correspondence advises Discovery Labs to increase the sample size of a specific data set by testing additional Surfaxin batches. Discovery Labs currently has data from batches that have already been manufactured and, to be responsive to the FDA's advice, anticipates manufacturing additional batches in January and February of this year.

Later this month, Discovery Labs expects to provide to the public a detailed overview of its program and anticipates holding a conference call.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements relating, among other things, to Discovery Labs' understanding of the recently-received written guidance from the FDA and the remaining questions identified in the FDA's April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin. Although Discovery Labs currently believes that it may still succeed in submitting a Complete Response and gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants, anticipated activities will require that Discovery Labs raise significant amounts of additional capital. Discovery Labs has initiated activities relating to this most recent FDA communication and anticipates potential

further interactions with the FDA in advance of filing a Complete Response. Such potential interactions with the FDA could affect the ultimate timing, conduct and outcomes of remaining steps necessary to gain Surfaxin approval, including the potential filing of the Complete Response. In addition, these activities and the ultimate outcomes remain 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) the FDA may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; (ii) Discovery Labs may be unable to complete the manufacture of additional Surfaxin batches within the time frame set forth above, (iii) Discovery Labs may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin; and (iv) Discovery Labs may be unable to raise sufficient additional capital, through financings, strategic collaborations, or otherwise. Any failure to satisfy the issues raised by the FDA, in the Complete Response letter or in related discussions, could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially delay or prevent the approval of Discovery Labs' other products.

Surfaxin is an investigational drug product and is not approved by the FDA or any other world health regulatory authority for use in humans. If approved, Surfaxin would become the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine.

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 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. 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, including those related to the Company's comprehensive non-clinical program, development and manufacturing activities and related regulatory efforts, are 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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