

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**June 8, 2010**

Date of Report (Date of earliest event reported)

**Discovery Laboratories, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**000-26422**

(Commission File Number)

**94-3171943**

(IRS Employer  
Identification Number)

**2600 Kelly Road, Suite 100  
Warrington, Pennsylvania 18976**  
(Address of principal executive offices)

**(215) 488-9300**

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01.            Other Events.**

On June 8, 2010, Discovery Laboratories, Inc. (the “Company”) announced the receipt of FDA guidance regarding its preclinical program to gain Surfaxin® approval. The full text of the press release is set forth in Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01.            Financial Statements and Exhibits.**

(d)       Exhibits

99.1      Press Release dated June 8, 2010.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### **Discovery Laboratories, Inc.**

By: /s/ W. Thomas Amick

Name: W. Thomas Amick

Title: Chairman of the Board and interim Chief Executive Officer

Date: June 8, 2010



## **Discovery Labs Receives FDA Guidance Regarding Preclinical Program to Gain SURFAXIN<sup>®</sup> Approval**

*On-Track for Q1 2011 SURFAXIN Complete Response Filing*

**Warrington, PA – June 8, 2010** — **Discovery Laboratories, Inc. (Nasdaq:DSCO)** announces today that it has received written guidance from the U.S. Food and Drug Administration (FDA) that is consistent with its ongoing, comprehensive preclinical program to resolve the sole remaining chemistry, manufacturing & control (CMC) issue necessary to potentially gain FDA marketing approval for Surfaxin<sup>®</sup> (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The safety and efficacy of Surfaxin for neonatal RDS has been previously demonstrated in a Phase 3 clinical program. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine. Discovery Labs believes it remains on track to complete the preclinical program and submit its Complete Response to the FDA in the first quarter of 2011.

Discovery Labs is now conducting a series of prospectively-designed, side-by-side preclinical studies employing both the newly-optimized and revalidated fetal rabbit Biological Activity Test (BAT, an important quality control release and stability test) and the well-established preterm lamb model of RDS. Discovery Labs plans to complete the preclinical program and submit a Complete Response taking into account the recently-received FDA comments. Multiple Surfaxin batches will be employed in the side-by-side preclinical studies to assess the short-term physiologic response following Surfaxin administration (via measurement of respiratory compliance) in both the preterm lamb model and the optimized BAT.

The resulting data will be examined to evaluate the relative changes in biologic activity of Surfaxin at several different time points over intended shelf life to determine the degree of comparability between the optimized BAT and the preterm lamb model. The FDA has indicated that, to satisfactorily establish comparability between the optimized BAT and the preterm lamb model, these data must demonstrate the same relative changes in respiratory compliance between both models over time. These studies are intended to also satisfy the FDA regarding the ability of the BAT to adequately discriminate biologically active from inactive Surfaxin drug product and establish the Surfaxin drug product's final acceptance criteria (with respect to biologic activity as assessed by the BAT) for release and ongoing stability.

Dr. Russell Clayton, Vice President, Research and Development, Preclinical and Regulatory Affairs commented, "Discovery's plan for the potential approval of Surfaxin continues to benefit from the FDA's direction and their recent suggestions have been incorporated into our plan. Another positive aspect of the most recent communication is the FDA's indicated willingness to continue to interact on our approach to gain potential Surfaxin approval."

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In May 2010, Discovery Labs completed a key component of the comprehensive preclinical program, the optimization and revalidation of the BAT, having met all pre-specified acceptance criteria. Prior to optimizing and revalidating the BAT, Discovery Labs had several interactions with the FDA and submitted a proposed revalidation protocol, which also included pre-specified acceptance criteria. Within the next few weeks, Discovery Labs anticipates submitting to the FDA data and analysis from the recently completed optimization and revalidation of the BAT. This information, together with results from the ongoing side-by-side preclinical studies, is expected to be used by the FDA in its review of the planned Complete Response and its ultimate determination on whether to grant marketing approval for Surfaxin.

Discovery Labs believes that it is advantageously positioned to successfully complete the comprehensive preclinical program taking into consideration (i) the revalidation of its optimized BAT (meeting all pre-specified acceptance criteria), (ii) Discovery Labs' experience and relationships with well-recognized academic centers of excellence who routinely measure respiratory compliance in both the BAT and preterm lamb model, and (iii) the FDA's willingness to date to provide continued guidance regarding the Company's plans to resolve the remaining CMC matter.

Surfaxin is an investigational drug candidate that has not been approved by the FDA or any other world health regulatory authority.

**DISCLOSURE NOTICE:** The information in this press release includes certain "forward-looking" statements relating, among other things, to Discovery Labs' understanding of the remaining questions identified in the April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin and the outcomes of the June 2, 2009 end-of-review meeting, the September 29, 2009 teleconference held with the FDA, and the recently-received written guidance from the FDA. Although Discovery Labs currently believes that it is on track to submit the Complete Response in the first quarter of 2011 and may still succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants, 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; and (ii) 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. 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.

#### **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 KL<sub>4</sub> 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 KL<sub>4</sub> 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](http://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: (a) Discovery Labs and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on the matters raised during regulatory reviews, or Discovery Labs may be required to conduct significant additional activities to potentially gain approval of its product candidates, if ever; (b) 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 (c) 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 (i) 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, and (ii) the need for sophisticated and extensive analytical methodologies, including an acceptable biological activity test, if required, as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities; 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; the risk that Discovery Labs may be unable to identify potential strategic partners or collaborators to develop and commercialize its products, if approved, in a timely manner, if at all; 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 (CEFFs), or that the minimum share price at which Discovery Labs may access the CEFFs from time to time will prevent Discovery Labs from accessing the full dollar amount potentially available under the CEFFs; the risk that Discovery Labs or its strategic partners or collaborators will not be able to retain, or attract, qualified personnel; the risk that Discovery Labs will be unable to regain compliance with The Nasdaq Capital Market listing requirements prior to the expiration of the additional grace period currently in effect, which could cause 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 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.

**Contact Information:**

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