**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**

**May 19, 2010**
Date of Report (Date of earliest event reported)

**Discovery Laboratories, Inc.**
(Exact name of registrant as specified in its charter)

| **Delaware** | **000-26422** | **94-3171943** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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:

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

**Item 8.01. Other Events.**

On May 19, 2010, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that the revalidation of its optimized fetal rabbit Biological Activity Test (an important quality control release and stability test) has been completed. The optimization and successful revalidation of the BAT is a key milestone in the Company's plans to resolve the sole remaining Chemistry, Manufacturing & Control issue necessary to potentially gain U.S. Food and Drug Administration ("FDA") marketing approval for Surfaxin® (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 comprehensive Phase 3 clinical program. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine.

The information in this Form 8-K includes certain "forward-looking" statements relating, among other things, to the Company's understanding of the remaining questions that must be addressed to gain FDA approval of Surfaxin. Although the Company currently believes that it may still succeed in gaining approval of its New Drug Application 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) the Company 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 secure FDA approval or further delay associated with the FDA's review process could potentially delay or prevent the approval of Surfaxin or the Company's other products and would have a material adverse effect on the Company's business.

The press release is attached as Exhibit 99.1 hereto.

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

(d) Exhibits

99.1 Press release dated May 19, 2010

**Cautionary Note Regarding Forward-looking Statements:**

To the extent that statements in this Current Report on Form 8-K 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 the Company's product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company'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.

**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 Chief Executive Officer

Date: May 21, 2010

# Discovery Labs Achieves Key Milestone Towards Potential Surfaxin® Approval

***Biological Activity Test (BAT) optimization and revalidation completed with all pre-specified acceptance criteria met***

**Warrington, PA – May 19, 2010 — Discovery Laboratories, Inc. (Nasdaq: DSCO),** announces today that the revalidation of its optimized fetal rabbit Biological Activity Test (BAT, an important quality control release and stability test) has been completed, having met all pre-specified acceptance criteria. The optimization and successful revalidation of the BAT is a key milestone in Discovery Labs' plans to resolve the sole remaining Chemistry, Manufacturing & Control (CMC) issue necessary to potentially gain U.S. Food and Drug Administration (FDA) marketing approval for Surfaxin® (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 comprehensive Phase 3 clinical program. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine.

The successful optimization and revalidation of the BAT represents a key component of the comprehensive preclinical program that Discovery Labs is now conducting to potentially address the sole remaining issue to gain FDA approval of Surfaxin. 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. The BAT optimization and recently completed revalidation has taken into account FDA suggestions and comments.

To complete the comprehensive preclinical program, Discovery Labs will now employ the optimized BAT in a series of prospectively-designed, side-by-side preclinical studies with the well-established preterm lamb model of RDS. Multiple Surfaxin batches will be employed 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 at various time points. The resulting data will be examined to evaluate the relative changes, over time, in biological activity upon Surfaxin administration to determine the degree of comparability between the optimized BAT and the preterm lamb model. These studies are intended to satisfy the FDA as to the BAT's ability to adequately discriminate biologically active from inactive Surfaxin drug product and establish the Surfaxin drug product's final acceptance criteria (with respect to biological activity as assessed by the BAT) for release and ongoing stability.

Jerry Orehostky, Senior Vice President, Quality Operations commented, "We believe that optimizing and revalidating the BAT has improved its performance and increased the likelihood that the results of our preclinical program will demonstrate, to the FDA's satisfaction, a level of comparability between data generated using the BAT and the preterm lamb model."

Discovery Labs has also been communicating with the FDA regarding other important aspects of the comprehensive preclinical program and submitted for FDA review and comment a protocol outlining a proposed study design and success criteria for the side-by-side preclinical studies. Recent communications with the FDA indicate that its written feedback to the protocol should be anticipated in June 2010. Subject to satisfactory FDA feedback, 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.

W. Thomas Amick, Chairman and interim Chief Executive Officer, commented, “We have worked productively with the FDA to improve the performance of the BAT, an important milestone for Surfaxin and our $KL_4$ surfactant pipeline. We will continue to avail ourselves of the FDA’s willingness to provide guidance towards potential Surfaxin approval and advancing our other $KL_4$ surfactant pipeline programs.”

**The BAT as a Quality Control Drug Product Release Assay**

The BAT has been validated as a quality control test in accordance with current Good Manufacturing Practices (GMP) and International Conference on Harmonization (ICH) guidelines. The BAT is one of numerous methods that Discovery Labs employs in an extensive quality surveillance program to assess drug product quality and stability. These highly sophisticated release tests monitor drug product quality throughout shelf-life and represent very sensitive methods for detecting changes in quality over time.

Discovery Labs intends to employ the BAT for drug product release and stability testing for Surfaxin and its other pipeline programs, including Surfaxin LS™ and Aerosurf® (each in development for RDS), Surfaxin for Acute Respiratory Failure (enrollment recently completed in a Phase 2 clinical trial), and aerosolized $KL_4$ surfactant for Cystic Fibrosis (currently being evaluated in an investigator-initiated Phase 2 clinical trial with enrollment currently 70% complete).

Surfaxin, Surfaxin LS and Aerosurf are investigational drug candidates that have 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 issues that must be addressed to gain FDA approval of Surfaxin. Although Discovery Labs currently believes that it 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 April 2009 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 $KL_4$ surfactant therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs’ novel proprietary $KL_4$ 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 $KL_4$ 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. 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: (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 Global Market listing requirements prior to the expiration of the 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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