SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

September 29, 2009
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 September 30, 2009, Discovery Laboratories, Inc. (the "Company") issued a press release announcing the results of its September 29, 2009 teleconference with the U.S. Food and Drug Administration (FDA). The meeting was convened to discuss an approach, which had been suggested by the FDA at an earlier meeting held on June 2, 2009 as a way for the Company to increase the likelihood of gaining U.S. marketing approval of Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The meeting focused on the Company's plans regarding optimization and final method validation of its fetal rabbit Biological Activity Test (BAT, a quality control and stability release test) and a proposed limited Surfaxin clinical trial design, which would simultaneously employ the newly-optimized BAT.

At the meeting, Discovery Labs sought clarification with respect to its plans to further optimize and validate the BAT. As a result of the meeting, the Company believes that it has reached an understanding with the FDA and is confident that it will be able to optimize the BAT to the satisfaction of the FDA. The Company intends to employ the optimized BAT in conjunction with all of its KL_4 surfactant pipeline programs, including the potential limited Surfaxin clinical trial. In addition, the Company received guidance from the FDA on its proposed limited clinical trial design. The trial design is intended to primarily assess a pharmacodynamic (PD) response following Surfaxin administration in preterm infants with RDS. This design was selected to address the FDA's requirements for Surfaxin approval while attempting to limit trial expense and duration. The FDA indicated that a PD-based approach is consistent with their expectation for a limited clinical trial and also provided direction regarding trial design specifics. The final clinical trial design will be subject to FDA review following submission of a formal protocol. Discovery Labs expects to finalize a protocol and anticipates submitting it to the FDA in mid-fourth quarter of 2009.

The Company's top priority is to secure strategic alliance partners and access capital to advance its KL_4 surfactant pipeline, including Surfaxin, Surfaxin LS™ and Aerosurf®, which have the potential to greatly improve the management of RDS and to potentially redefine the RDS market. Following its anticipated further interaction with the FDA with respect to the BAT optimization and the proposed formal protocols, the Company plans to make a strategic assessment, together with existing and potential new partners, to determine the appropriate level and timing of future Surfaxin investments and to maximize the value of its KL_4 pipeline for the management of RDS.

The press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated September 30, 2009

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 Interim Chief Executive Officer

Date: September 30, 2009

Discovery Labs and FDA Establish Path for Potential SURFAXIN Approval

FDA Supports Proposed BAT Optimization and Approach for Limited Clinical Trial

Warrington, PA – September 30, 2009 - -- Discovery Laboratories, Inc. (Nasdaq:DSCO) held a teleconference on September 29, 2009 with the U.S. Food and Drug Administration (FDA). The meeting established an approach to potentially resolve the remaining primary issue that Discovery Labs must address to gain U.S. marketing approval of Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The meeting focused on Discovery Labs' plans regarding optimization and final method validation of its fetal rabbit Biological Activity Test (BAT, a quality control and stability release test) and a proposed limited Surfaxin clinical trial design, which would simultaneously employ the newly-optimized BAT.

At the meeting, the FDA indicated that Discovery Labs' proposed program to optimize and validate the BAT is reasonable. The program is intended, among other things, to confirm that the BAT can adequately distinguish change in Surfaxin biological activity over time. As a result of the meeting, Discovery Labs believes that it has reached an understanding with the FDA and is confident that it will be able to optimize the BAT to the satisfaction of the FDA. Discovery Labs intends to employ the optimized BAT in conjunction with all of Discovery Labs' KL_4 surfactant pipeline programs, including the potential limited Surfaxin clinical trial.

In addition, Discovery Labs received guidance from the FDA on its proposed limited clinical trial design. The trial design is intended to primarily assess a pharmacodynamic (PD) response following Surfaxin administration in preterm infants with RDS. This design was selected to address FDA requirements for Surfaxin approval while limiting trial expense and duration. The FDA indicated that a PD-based approach is consistent with their expectation for a limited clinical trial and also provided direction regarding trial design specifics. The final clinical trial design will be subject to FDA review following submission of a formal protocol. Discovery Labs expects to finalize a protocol and anticipates submitting it to the FDA in mid-fourth quarter of 2009.

W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs, commented, "We are pleased with the guidance received and outcomes obtained from our interaction with the FDA. This guidance provides a viable option for Surfaxin and meaningfully supports advancing our pipeline initiatives to potentially address a broad range of respiratory diseases such as RDS, Acute Respiratory Failure, Acute Lung Injury and Cystic Fibrosis. We look forward to continued productive dialogue with the FDA.

Our most advanced programs from our KL_4 surfactant pipeline, Surfaxin, Surfaxin LS™ and Aerosurf®, have the potential to greatly improve the management of RDS and to redefine the RDS market. Our top priority is to secure strategic alliance partners and access capital to advance our pipeline and build shareholder value. As we move forward, we will take into account further interaction with the FDA and make strategic assessment, together with existing and potential new partners to determine the appropriate level and timing of Surfaxin investment and to maximize the value of our KL_4 pipeline for RDS."

Background

On April 17, 2009, Discovery Labs received a Complete Response letter from the FDA for Surfaxin for RDS and on June 2, 2009, conducted a related meeting focusing primarily on certain aspects of the BAT, specifically whether preclinical data generated using both the BAT and a well-established preterm lamb model of RDS adequately supports the comparability of Surfaxin clinical drug product to the to-be-manufactured Surfaxin, and whether the BAT can adequately distinguish change in Surfaxin biological activity over time.

During the conduct of Phase 3 clinical trials for Surfaxin, Discovery Labs employed an array of quality control tests, but did not employ the BAT to evaluate biological activity of the Surfaxin clinical drug product. After completing the Phase 3 clinical trials, in accordance with discussions with the FDA, Discovery Labs validated and implemented the BAT as a recurring quality control test to confirm biological activity for Surfaxin release and stability testing. Based on guidance received from the FDA in meetings with the FDA in 2006 and 2008, Discovery Labs conducted a series of preclinical experiments to establish comparability between Surfaxin drug product used in Phase 3 clinical trials and the Surfaxin drug product intended to be manufactured for commercial use. Accordingly, Discovery Labs initiated a series of side-by-side studies employing both the preterm lamb model of RDS and the BAT and believes that the correlated results demonstrate comparability and support approval of Surfaxin.

At the June 2 meeting with the FDA, Discovery Labs presented data from the preterm lamb model and BAT studies, together with a comprehensive statistical evaluation of such data, intended to establish the comparability of clinical drug product to Surfaxin drug product to be manufactured for commercial use. The comprehensive statistical evaluation was a comparative regression analysis using an accepted FDA statistical method. Discovery Labs believes that the data and related statistical evaluation are highly supportive of the comparability of clinical drug product to commercial Surfaxin.

However, the FDA stated at the June 2 meeting that data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Based on this standard, Discovery Labs believes that establishment of comparability in this manner would be an extremely high hurdle and that, from the FDA's perspective, the data analysis provided by Discovery Labs did not meet that standard.

In addition, the FDA suggested that the comparability studies in the preterm lamb model and the BAT would not be necessary if the BAT had been implemented to assess Surfaxin drug product used in the Phase 3 clinical trials. The FDA also suggested that, to increase the likelihood of gaining Surfaxin approval and as an alternative to demonstrating comparability using the preterm lamb model and BAT, Discovery Labs could consider conducting a limited clinical trial, while simultaneously employing the BAT, as a path forward to Surfaxin approval.

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 a teleconference held with the FDA on September 29, 2009. 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) although Discovery Labs is hopeful that it will be able to optimize and validate the BAT method to the FDA's satisfaction, and finalize acceptance criteria for the BAT, as a precursor to potentially using the BAT in a limited Surfaxin clinical trial,, the FDA may not be satisfied with the results of Discovery Labs optimization and validation activities and Discovery Labs and the FDA may not reach agreement with respect to any or all of these issues; (ii) if Discovery Labs and the FDA do not reach agreement on the details of a formal protocol for a limited clinical trial, Discovery Labs may be unable to gain approval of Surfaxin; (iii) even if Discovery Labs and the FDA reach agreement on the matters discussed above and Discovery Labs does complete the additional activities to the FDA's satisfaction, the FDA 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 April 17, 2009 Complete Response letter and Discovery Labs may be unable to gain approval of Surfaxin; (v) Discovery Labs may identify unforeseen problems that have not yet been discovered; and (vi) 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 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_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, including without limitation, any relating to the second half of the Company's fiscal year, 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; 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.*

Contact Information:

Lisa Caperelli, Investor Relations
215-488-9413