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

November 17, 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 November 17, 2009, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that it has submitted to the U.S. Food and Drug Administration (FDA) its proposed protocol for a Surfaxin® (lucinactant) limited clinical trial. Discovery Labs proposed this trial in response to a comment by the FDA that a limited clinical trial could potentially resolve the key remaining issue for approval of Surfaxin for the prevention of RDS in premature infants.

The protocol incorporates a clinical trial design that is primarily intended to assess a pharmacodynamic (PD) response following Surfaxin administration in preterm infants with Respiratory Distress Syndrome (RDS). Typically, PD-based clinical trials primarily assess short-term, physiologic responses to therapy and, therefore, are generally less expensive and of shorter duration than trials that have clinical outcomes as a primary endpoint. On September 29, 2009, Discovery Labs held a teleconference with the FDA to discuss, among other things, whether a PD approach would satisfy the FDA's requirement for a limited clinical trial. The FDA indicated that Discovery Labs' proposed concept of a PD trial design is acceptable and also provided direction regarding certain trial design specifics.

The final protocol and clinical trial design is subject to FDA review and comment. In accordance with the FDA's guidance, Discovery Labs expects to receive the FDA comments early in the first quarter 2010. At that time, Discovery Labs will be in a position to estimate the expected costs and duration of the trial and make a strategic assessment, with existing and potential new partners, regarding any investment in a potential limited clinical trial for Surfaxin for 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 November 17, 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: November 18, 2009

Exhibit 99.1

Discovery Labs Submits SURFAXIN Pharmacodynamic Trial Protocol to FDA

Potential Resolution of Key Remaining Issue for Approval

Warrington, PA – November 17, 2009 -- Discovery Laboratories, Inc. (Nasdaq:DSCO) announced today that it has submitted to the U.S. Food and Drug Administration (FDA) its proposed protocol for a Surfaxin® (lucinactant) limited clinical trial. The protocol incorporates a clinical trial design that is primarily intended to assess a pharmacodynamic (PD) response following Surfaxin administration in preterm infants with Respiratory Distress Syndrome (RDS). Discovery Labs proposed this trial design in response to a comment by the FDA that a limited clinical trial could potentially resolve the key remaining issue for approval of Surfaxin for the prevention of RDS in premature infants.

Discovery Labs received a Complete Response Letter for Surfaxin in April 2009. At an end-of-review meeting with the FDA on June 2, 2009, the FDA suggested that, to increase the likelihood of gaining Surfaxin approval, Discovery Labs could consider conducting a limited clinical trial. On September 29, 2009, Discovery Labs held a teleconference with the FDA to discuss, among other things, whether a PD approach would satisfy the FDA's requirement for a limited clinical trial. Typically, PD-based clinical trials primarily assess short-term, physiologic responses to therapy and, therefore, are generally less expensive and of shorter duration than trials that have clinical outcomes as a primary endpoint. The FDA indicated that Discovery Labs' proposed concept of a PD trial design is acceptable and also provided direction regarding certain trial design specifics.

Employing the FDA's guidance, Discovery Labs worked closely with leading academic neonatologists to design the PD protocol. The final protocol and clinical trial design is subject to FDA review and comment. In accordance with the FDA's guidance, Discovery Labs expects to receive the FDA comments early in the first quarter 2010. At that time, Discovery Labs will be in a position to estimate the expected costs and duration of the trial and make a strategic assessment, with existing and potential new partners, regarding any investment in a potential limited clinical trial for Surfaxin for RDS.

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) 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; (ii) even if Discovery Labs and the FDA reach agreement on the matters discussed above and Discovery Labs does complete the limited clinical trial 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; (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. 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_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 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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