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 24, 2008
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 24, 2008, Discovery Laboratories, Inc. (the "Company") announced that it has achieved technical success in addressing key remaining requirements identified by the U.S. Food and Drug Administration (FDA) to gain marketing approval of Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The Company is completing the remaining activities and expects to file a Complete Response to the Approvable Letter that it received from the FDA on May 1, 2008 within the next four weeks.

The Company has concluded additional Surfaxin preclinical studies at the dose level requested by the FDA in both the Surfaxin biological activity test and a well-characterized RDS animal model. The Company believes that the data generated by these studies further confirms the comparability of the Surfaxin drug product used in the Company's Phase 3 clinical trials to the commercial manufacturing process for Surfaxin and will support the determination of final acceptance criteria for the Surfaxin biological activity test. In addition, in collaboration with its suppliers, the Company has now determined that the two phospholipid drug substances that are contained in Surfaxin drug product can be produced with lipid-related impurities at levels that satisfy guidelines promulgated by the International Conference of Harmonization (ICH). The Company and its phospholipid suppliers expect to complete the remaining activities and finalize the information necessary to support the Complete Response in the next few weeks.

The Company continues to believe that the FDA may designate the Complete Response as a Class 1 resubmission, which would result in a target review period of 60 days (whereas a Class 2 resubmission would result in a 6-month target review period). If the Company's belief regarding the timeline is correct, it expects that the potential approval of Surfaxin may be received in 2008.

The press release, dated September 24, 2008, is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated September 24, 2008

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/ Robert J. Capetola
Name: Robert J. Capetola, Ph.D.
Title: President and Chief Executive Officer

Date: September 24, 2008

Discovery Labs Reports Technical Achievements Towards Gaining FDA Approval of Surfaxin

Warrington, PA - September 24, 2008, -- Discovery Laboratories, Inc. (Nasdaq: DSCO) announces that it has achieved technical success in addressing the key remaining requirements identified by the U.S. Food and Drug Administration (FDA) to gain marketing approval of Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Discovery Labs is completing the remaining activities and finalizing the information for its Complete Response to the May 2008 FDA Approvable Letter (Approvable Letter) and now expects to submit its Complete Response within the next four weeks. Discovery Labs continues to believe that the FDA may designate its Complete Response as a Class 1 resubmission, with a target review period of 60 days and potential approval of Surfaxin in 2008.

With respect to the key remaining items identified in the Approvable Letter and further clarified at a June 18 meeting with the FDA, the following achievements are expected to support Surfaxin approval:

- Discovery Labs has successfully concluded additional Surfaxin preclinical studies at a dose level requested by the FDA in both the Surfaxin biological activity test and a well-characterized RDS animal model. Discovery Labs believes that the data further confirms the comparability of Surfaxin drug product used in Discovery Labs' Phase 3 clinical trials to the commercial manufacturing process for Surfaxin and will support the determination of final acceptance criteria for the Surfaxin biological activity test.

- Through a close scientific collaboration with its phospholipid suppliers, Discovery Labs has now determined that the two phospholipid drug substances that are contained in Surfaxin drug product can be produced with lipid-related impurities at levels that satisfy International Conference of Harmonization (ICH) guidelines. In the next few weeks, Discovery Labs and its phospholipid suppliers expect to complete the remaining activities and finalize the information necessary to support the Complete Response.

The information necessary to address the balance of the items outlined in the Approvable Letter, as previously disclosed, is ready for inclusion in the Complete Response.

Prior to receiving the Approvable Letter, Discovery Labs had made notable progress towards gaining FDA approval of Surfaxin, including agreeing with the FDA on the form of the Surfaxin package insert and successfully concluding a pre-approval inspection of Discovery Labs' manufacturing operations. The Approvable Letter did not require any additional clinical trials to gain Surfaxin approval.

Based on its understanding of FDA guidelines, and in consultation with outside experts, Discovery Labs believes that the FDA may designate the Complete Response as a Class 1 resubmission, which would result in a target review period of 60 days (whereas a Class 2 resubmission would result in a 6-month target review period). If Discovery Labs' understanding of the timeline is correct, the potential approval of Surfaxin is anticipated in 2008.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating to, among other things, the remaining steps necessary for FDA approval of Surfaxin for the prevention of RDS in premature infants and Discovery Labs’ plans and expected timing to respond to the May 1, 2008 Approvable Letter. Although Discovery Labs believes that it has made significant progress towards gaining approval of Surfaxin, gaining approval of Surfaxin involves ongoing activities, the final results of which could vary materially from Discovery Labs’ expectations and the results obtained to date. Discovery Labs currently believes that it will succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants within the timeline outlined above; however, these activities and the ultimate outcomes are subject to a variety of risks, including but not limited to risks that (i) even if Discovery Labs is able to generate the additional data requested by the FDA and file its Complete Response to the Approvable letter within the timeline indicated above, the FDA may not be satisfied with the additional data and may require Discovery Labs to perform further studies or undertake other activities that are presently not contemplated by Discovery Labs, (ii) Discovery Labs and its suppliers may encounter unanticipated problems in reducing the lipid-related drug substance impurities and such problems could delay Discovery Labs’ submission of its Complete Response; (iii) the FDA may not be satisfied with Discovery Labs’ responses to other items identified in the Approvable Letter and Discovery Labs may be unable to gain approval of Surfaxin within the timeline indicated above, (iv) Discovery Labs, in the process of preparing its response to the Approvable Letter, may identify unforeseen problems that have not yet been discovered, and (v) the FDA could impose additional requirements to gain approval of Surfaxin. Any failure to provide information requested by the FDA or to adequately address the items raised in the Approvable Letter in Discovery Labs’ formal response to the Approvable Letter could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially prevent the approval of Discovery Labs’ other products.

About Discovery Labs
Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs’ technology produces a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant. Discovery Labs believes that, with its proprietary technology, SRT has the potential, for the first time, to address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

SURFAXIN®, the Company’s lead product from its SRT pipeline, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. SURFAXIN is also being developed for other neonatal and pediatric indications. AEROSURF™, Discovery Labs’ aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at www.Discoverylabs.com.

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, including, without limitation, the risks that: Discovery Labs may be unable to respond, if at all, to the recent Approvable Letter for Surfaxin within the anticipated timeline and the response, when filed, may not satisfy the FDA; the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that Discovery Labs may file for its products, or may not approve any such applications or may limit marketing of such products to particular indications or impose unanticipated label limitations; changes in the national or international political and regulatory environment may make it more difficult for Discovery Labs to gain FDA or other regulatory approval of its products; Discovery Labs may be unable to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT); Discovery Labs’ lengthy and costly research and development programs, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any of its products, including Surfaxin, may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs or its contract manufacturers or materials suppliers may be unable to successfully manufacture adequate supplies of its drug product or drug substances when needed or in amounts sufficient to meet demand; Discovery Labs may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs’ drug products with innovative aerosolization technologies; Discovery Labs may be unable to profitably develop and market its products; Discovery Labs may be unable to maintain and protect the patents and licenses related to its SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further 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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