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

October 17, 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 October 17, 2008, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that it has submitted a Complete Response to the May 2008 Approvable Letter issued by the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Under the FDA guidelines, within 14 calendar days, the FDA will classify the submission and notify the Company of the statutory target date for potential approval of Surfaxin. The Company believes, based on its understanding of the FDA guidelines and advice of experts, that the FDA may designate the Complete Response as a Class 1 resubmission, which would result in a target review period of 60 days and potential approval of Surfaxin in 2008. However, the FDA has discretion to designate the submission as Class 2, which would result in a 6-month target review period.

The Company's Complete Response includes, among other things, (i) data and other information intended to demonstrate that the lipid-related impurities in the two phospholipid drug substances can be produced at levels that satisfy guidelines promulgated by the International Conference of Harmonization (ICH), and (ii) data from additional pre-clinical studies (conducted at a dose level requested by the FDA) using a Surfaxin biological activity test (a quality control and stability release test) and a well-characterized RDS animal model, which data the Company believes further confirms the comparability of Surfaxin drug product used in Discovery Labs' Phase 3 clinical trials to the product to be made using the commercial Surfaxin manufacturing process and further supports the determination of final acceptance criteria for the Surfaxin biological activity test. Prior to generating these additional data, on June 18, 2008, the Company held a teleconference with the FDA to clarify and reach agreement on these and other key requirements identified in the May 2008 Approvable Letter.

The May 2008 Approvable Letter did not require additional clinical trials. Prior to receiving the Approvable Letter, the Company had reached agreement with the FDA on the content of the Surfaxin package insert and the FDA had concluded a satisfactory pre-approval inspection of the Company's manufacturing operations. The press release, dated October 17, 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 October 17, 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: October 22, 2008

Discovery Labs Submits Complete Response to May 2008 FDA Approvable Letter for Surfaxin® for RDS

Warrington, PA — October 17, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today submitted its Complete Response to the May 2008 Approvable Letter issued by the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA's guidelines provide that by October 31, the FDA will determine the classification of the submission and notify Discovery Labs of its target date for potential approval of Surfaxin. 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 sixty-days and potential approval of Surfaxin in 2008.

The May 2008 Approvable Letter contains requirements that must be addressed to gain U.S. marketing approval for Surfaxin. All of these requirements have been addressed in the Complete Response. Discovery Labs met with the FDA on June 18, 2008 to clarify and reach agreement on addressing certain key requirements in the Approvable Letter, including the following:

- Discovery Labs must satisfy International Conference of Harmonization (ICH) guidelines for the proposed specifications for certain lipid-related impurities in two phospholipid drug substances that are contained in the Surfaxin drug product. The Complete Response includes data and other information to demonstrate that the lipid-related impurities in the two phospholipids can be produced at levels that satisfy ICH guidelines.

- Discovery Labs agreed to conduct additional Surfaxin preclinical studies, at a dose level requested by the FDA, using a Surfaxin biological activity test (a quality control and stability release test) and a well-characterized RDS animal model. The Complete Response includes data from these successfully concluded studies. Discovery Labs believes that the data obtained further confirms the comparability of Surfaxin drug product used in Discovery Labs' Phase 3 clinical trials to the commercial manufacturing process for Surfaxin and supports the determination of final acceptance criteria for the Surfaxin biological activity test.

The May 2008 Approvable Letter did not require any additional clinical trials. 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 content of the Surfaxin package insert and successfully concluding a pre-approval inspection of Discovery Labs' manufacturing operations.

Discovery Labs believes, based on its understanding of the FDA guidelines, that the FDA may designate this Complete Response as a Class 1 resubmission, which would result in a target review period of 60 days and potential approval of Surfaxin in 2008. However, the FDA has the discretion to designate any resubmission as Class 2, which would result in a 6-month target review period.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating, among other things, to the remaining steps necessary for FDA approval of Surfaxin for the prevention of RDS in premature infants and the timing of the anticipated FDA review period. 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) although Discovery Labs believes that the FDA will deem Discovery Labs’ formal response to be “complete” under the FDA guidelines, the FDA may nevertheless determine, for a reason not presently known to Discovery Labs, that the formal response filed by Discovery Labs is not “complete”, which determination would further delay the FDA review of the Surfaxin NDA and could result in Discovery Labs’ conducting additional activities to potentially gain Surfaxin approval, (ii) although Discovery Labs believes that the Complete Response may be designated a Class 1 resubmission, which would result in a target review period and potential approval of Surfaxin within 60 days after submission, under the FDA guidelines the FDA may for a variety of reasons, in its discretion, designate the Complete Response as a Class 2 submission, which would result in a target review period of up to 6 months, potentially delaying the potential approval of Surfaxin, (iii) although Discovery Labs believes that it has been successful in generating the additional data and other information requested by the FDA, the FDA may not be satisfied and may require Discovery Labs to perform further studies or undertake other activities that are presently not contemplated by Discovery Labs, (iv) although Discovery Labs believes that its suppliers can successfully and consistently reduce the lipid-related drug substance impurities in the two phospholipid drug substances comprising Surfaxin, its suppliers could encounter unanticipated manufacturing problems in the future, which could adversely affect Discovery Labs’ ability to manufacture its drug product, (v) 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, (vi) Discovery Labs may identify unforeseen problems that have not yet been discovered, and (vii) the FDA could impose additional requirements to gain approval of Surfaxin. Any failure to provide information requested by the FDA or to inadequately 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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