

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**

May 29, 2008

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

000-26422

(Commission File Number)

94-3171943

(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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On May 29, 2008, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that it has received from the U.S. Food and Drug Administration (FDA) written notification that a meeting between the FDA and the Company has been scheduled to occur by teleconference on June 18, 2008. On May 14, 2008, the Company submitted a formal request to the FDA to schedule such a meeting. The formal request was accompanied by an information package containing the Company's proposals to address a limited number of the remaining items identified in the Approvable Letter that the Company received on May 1, 2008 for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. If the June 18 meeting positively confirms the Company's approach to filing its formal response to the Approvable Letter, the Company plans to submit a formal response to the Approvable Letter in June 2008. The Company believes that the response may potentially be designated by the FDA as a Class 1 resubmission with a review target of 60 days. The overall timeline to gaining approval for Surfaxin may vary depending on the outcome of the meeting and other related factors. The press release, dated May 29, 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 May 29, 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: May 29, 2008

Discovery Labs and FDA to Meet on June 18, 2008 to Clarify Limited Items in SURFAXIN Approvable Letter

Warrington, PA - May 29, 2008, -- Discovery Laboratories, Inc. (Nasdaq:DSCO), announced that it has received written notification from the U.S. Food and Drug Administration (FDA) that a meeting has been scheduled for June 18, 2008 via teleconference. This meeting is intended to confirm with the FDA Discovery Labs' approach to address the limited key remaining items necessary to gain U.S. marketing approval of SURFAXIN[®] (lucinactant) for the prevention of RDS in premature infants. On May 1, 2008, Discovery Labs received an Approvable Letter from the FDA for SURFAXIN that reflected notable progress towards gaining FDA approval.

On May 14, Discovery Labs submitted a pre-meeting information package to the FDA which also served as a formal request to schedule the meeting. This information package discussed Discovery Labs' proposals for responding to select items identified in the Approvable Letter. The Company believes that the most important items involve justifying and finalizing one acceptance criterion for SURFAXIN's biological activity and limited acceptance criteria for lipid drug substance impurities. Discovery Labs believes it can satisfy these items with data that are already available and wants to confirm its approach with the FDA prior to filing a formal response to the Approvable Letter.

The recent Approvable Letter reflects key achievements towards gaining FDA approval for SURFAXIN including agreeing with the FDA on the SURFAXIN package insert and successfully concluding a pre-approval inspection of Discovery Labs' manufacturing operations. The Approvable Letter does not require any additional clinical trials to gain SURFAXIN approval. If the June 18 meeting with the FDA positively confirms Discovery Labs' approach to addressing the Approvable Letter items, Discovery Labs anticipates submitting a formal response to the Approvable Letter in June 2008. Discovery Labs continues to believe that this response may potentially be designated by the FDA as a Class 1 resubmission with a review target of 60 days. The overall timeline to gain SURFAXIN approval may be shortened or extended depending on the outcome of the meeting and other related factors.

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, including information related to Discovery Labs’ plans to meet with the FDA and 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 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 outcome are subject to a variety of risks, including but not limited to risks that (i) the FDA may not accept Discovery Labs’ proposals outlined in the information package, (ii) if Discovery Labs cannot reach agreement with the FDA on the acceptance criteria for SURFAXIN’s biological activity and lipid drug substance impurities, Discovery Labs may be unable to file a formal response to the Approvable Letter, if at all, within the timeline outlined in this press release, (iii) the FDA may require that Discovery Labs perform additional studies or undertake other activities that are presently not contemplated before Discovery Labs will be in a position to file a formal response to the Approvable Letter, which could significantly extend the anticipated timeline, (iv) Discovery Labs may not succeed in adequately responding to other items identified in the Approvable Letter, and (v) Discovery Labs, in the process of preparing its response to the Approvable Letter, may identify unforeseen problems that have not yet been discovered. 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 result in significant delays or additional requirements and could potentially prevent the approval of Surfaxin or other Discovery Labs’ 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 advance respiratory medicine and 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 timely respond, if at all, to the recent approvable letter for Surfaxin; Discovery Labs may not succeed in the FDA or other regulatory agency review process, including that such regulatory authority may not approve the marketing and sale of Surfaxin or any other drug product that Discovery Labs may develop, or such regulatory agency may further delay and/or limit marketing of Surfaxin or any of Discovery Labs' drug products by indication or impose other label limitations; Discovery Labs may not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT); 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 profitably develop and market its products; Discovery Labs' significant, time-consuming and costly research and development activities, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any of its products may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs may be unable to successfully manufacture or provide adequate supplies of drug substances on a timely basis; Discovery Labs may be unable to transfer its manufacturing technology to third-party contract manufacturers or its contract manufacturers or any of its materials suppliers may encounter problems manufacturing drug products or drug substances on a timely basis or manufacture in amounts sufficient to meet demand; Discovery Labs and its collaborators 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 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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