

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 1, 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 2, 2008, Discovery Laboratories, Inc. (the "Company") announced the receipt of an Approvable Letter from the U.S. Food and Drug Administration (FDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. This official notification sets forth the remaining conditions that must be satisfied to gain U.S. marketing approval for Surfaxin. The Approvable Letter was received in the evening of May 1, 2008, the PDUFA date that had been established for Surfaxin. Prior to receiving this Approvable Letter, Discovery Labs had finalized Surfaxin labeling discussions with the FDA. In addition, the FDA had completed its pre-approval inspection of Discovery Labs' manufacturing facility in Totowa, NJ. Within the next few days, Discovery Labs will contact the FDA to discuss required actions and timing to gain Surfaxin approval. Next week, Discovery Labs expects to be in a position to provide guidance regarding its actions in response to the Approvable Letter. The press release, dated May 2, 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 2, 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 2, 2008



Discovery Labs Receives an Approvable Letter from FDA for Surfaxin[®] for RDS

Warrington, PA — May 2, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced that it has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. This official notification sets forth the remaining conditions that must be satisfied to gain U.S. marketing approval for Surfaxin.

The Approvable Letter was received in the evening of May 1, 2008, the PDUFA date that had been established for Surfaxin. Prior to receiving this Approvable Letter, Discovery Labs had finalized Surfaxin labeling discussions with the FDA. In addition, the FDA had completed its pre-approval inspection of Discovery Labs' manufacturing facility in Totowa, NJ and recently issued an Establishment Inspection Report (EIR) reflecting a successful inspection.

Discovery Labs is assessing the Approvable Letter and will contact the FDA within the next few days to discuss required actions and timing to gain Surfaxin approval. Discovery Labs expects to be in a position early next week to provide guidance regarding its plans and timeline considerations to address the Approvable Letter.

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 designed to closely mimic the essential properties of natural human lung 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.

Discovery Labs' lead product candidate, Surfaxin[®], 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; 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 a drug product or may withhold, delay and/or limit marketing of a drug product 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 to gain FDA or other regulatory approval of drug 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 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.

Company Contact:

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