

UNITED STATES
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

April 12, 2006

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of Company 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 18976-3622

(Address of principal executive offices)

(215) 488-9300

(Company'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 Company 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))
-

Item 8.01. Other Events.

On April 12, 2006, Discovery Laboratories, Inc. (the “Company”) held a conference call to provide a regulatory update on its lead product, Surfaxin[®] for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, focusing on its U.S. New Drug Application. The update also provided information with respect to the outcomes of two recently completed regulatory authority inspections of the Company’s manufacturing facility, and provided guidance regarding the Company’s response to such inspections.

European Medicines Evaluation Agency (EMA) Inspection Update

In February 2006, the Medicines and Health Products Regulatory Agency (MHRA) conducted an on-site inspection of the Company’s manufacturing facility on behalf of the EMA. Such on-site inspection is required by the EMA before the grant of a Marketing Authorization. EMA regulatory guidelines provide that manufacturing facility inspectional observations are classified into three categories: “critical,” “major” and “other.” The February 2006 inspectional observations report contained observations categorized only as “other.”

The Company responded in writing to all of the EMA inspectional observations within 14 days of the conclusion of the inspection. The Company has not received any objections, comments or questions from the EMA to its responses to date. Since the timeline, per EMA guidance, for providing any such comments has expired, the Company considers the EMA site inspection process satisfactorily completed.

Food and Drug Administration (FDA) Inspection Update

The FDA concluded a three-week re-inspection of the Company’s manufacturing facility on April 7, 2006. The FDA had previously conducted a pre-approval inspection of the facility in January 2005, at which time the FDA had certain observations concerning the facility’s compliance with current Good Manufacturing Practices (cGMPs). The inspection observations at that time were associated primarily with basic quality controls, process assurances and documentation requirements to support the commercial production process, to which the Company responded by implementing an extensive cGMP corrective action plan, which also included the revalidation of the media and process validation runs.

The focus of the FDA re-inspection centered on the corrective actions to the Form FDA-483 issued in January 2005, as well as related manufacturing and quality operations, systems and controls. The FDA issued an inspectional observations report (Form FDA-483) citing certain observations related predominantly to the clarification of procedures, documentation and preventative maintenance. The report did not note a requirement of re-inspection of the facility. The Company expects to submit its response to a majority of the Form FDA-483 items within the next two weeks.

One item noted on the inspection report relates to certain drug product specification issues cited in the second Approvable Letter the Company received on April 5, 2006. The Company plans on responding to this inspectional item in its complete response to the second Approvable Letter. The Company believes that its satisfactory response to all of the observations contained in the re-inspection report will preclude the need for re-inspection of the manufacturing facility by the FDA prior to approval. However, in accordance with FDA practice, the agency may re-inspect the facility at any time.

Second Approvable Letter

The Company's conference call also outlined proposed further steps towards gaining clarity with respect to issues cited by the FDA in its second Approvable Letter and to the course of events leading to a potential approval of Surfaxin for the prevention of RDS in premature infants. In accordance with FDA procedural guidelines, the Company must submit a formal written request for a meeting with the FDA to which the agency must respond within 14 days of receipt of such request, and the meeting must occur within 75 days of the written request. The Company expects the meeting to be classified as a Type C Meeting whose purpose is to clarify the issues outlined in the Approvable Letter and allow the Company to file a complete response to the noted items.

The Company is in the process of preparing a detailed informational package which will establish the agenda for the meeting, and will be submitted to the FDA in advance of such meeting. The Company is positioning its activities to prepare and submit such informational package and the written meeting request in sufficient time for the meeting to potentially occur in mid- to late June of this year.

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 Company 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, Ph.D.

Robert J. Capetola, Ph.D.
President and Chief Executive Officer

Date: April 18, 2006