

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**

June 27, 2006

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 June 27, 2006, Discovery Laboratories, Inc. (the “Company”) issued a press release reporting progress on its ongoing investigation into and remediation efforts for the April 2006 process validation stability failure related to its Surfaxin[®] (lucinactant) New Drug Application. The press release, dated June 27, 2006, 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 June 27, 2006.

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

Date: June 27, 2006



Discovery Labs Reports Progress on its Surfactant Manufacturing Remediation

Warrington, PA — June 27, 2006— Discovery Laboratories, Inc. (Nasdaq: DSCO) today is reporting progress on its ongoing investigation into and remediation efforts for the April 2006 process validation stability failure related to its Surfaxin[®] (lucinactant) New Drug Application (NDA), including the attainment of some important investigative milestones. At this time, although the overall investigation is not complete, Discovery is optimistic that appropriate remedial actions can be successfully implemented, providing a path to potential approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants in the United States.

Manufacturing Investigative Milestones and Next Steps

The comprehensive investigation was implemented immediately following the April 2006 stability failure of Surfaxin process validation that supported Discovery's NDA. The investigation is being conducted in compliance with FDA current good manufacturing practices (cGMP) requirements and covers analysis of manufacturing processes; equipment and process validation; manufacturing components, drug substances and excipient manufacturers; review and assessment of out-of-specification and deviation reports; analytical methods and method validation; and change control documentation. The investigation will culminate in a comprehensive investigation report and a corrective and preventative action (CAPA) plan.

The investigation is ongoing and, at this time, it is not possible to anticipate or predict with certainty the timing or results of the investigation. Discovery reports the following progress to date:

- Discovery recently manufactured two investigation batches of Surfaxin that have passed all of the critical release specification assays, with the remaining release analytical procedures and stability monitoring ongoing. These investigation batches are intended to assess the impact of the investigative observations and will provide significant supportive data to the investigation report and the CAPA plan. These investigation batches are not designated as process validation batches.
 - Discovery's data and information gathering phase of the investigation is nearly complete. These data will support the investigation report and the CAPA plan. After a CAPA plan has been implemented, Discovery will meet with the FDA to clarify the issues identified in the second Approvable Letter and discuss Discovery's plan to manufacture new process validation batches. It is Discovery's goal to meet with the FDA and manufacture new process validation batches in the fourth quarter of 2006.
 - Discovery has been able, through the investigative process, to simultaneously address certain issues associated with the second Approvable Letter received from the FDA. Discovery believes that resolution of the manufacturing issues and implementation of a CAPA plan will also resolve a number of issues previously raised by the FDA in the second Approvable Letter.
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In April 2006, Discovery received a second Approvable Letter from the FDA relating to its NDA for Surfaxin for RDS in premature infants. Issues contained in the second Approvable Letter primarily focused on the Chemistry, Manufacturing and Controls section of the NDA and product labeling. Most notably, the FDA did not require any additional clinical trials.

Over the years, Discovery has successfully manufactured numerous batches of Surfaxin, representing thousands of vials that achieved the desired stability profile. These batches included those used in Discovery's highly successful Phase 3 clinical studies which demonstrate that Surfaxin was significantly more effective in the prevention of RDS and also improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. Discovery is conducting its investigation, in part, with reference to the manufacturing procedures that were used to produce those Surfaxin batches.

The investigation is led by Charles F. Katzer, Senior Vice President of Manufacturing Operations, and Gerald J. Orehostky, Vice President of Quality Operations. Mr. Katzer joined Discovery in January 2006 to oversee Discovery's newly-purchased manufacturing facility in Totowa, NJ. Mr. Katzer has more than 30 years of broad functional experience in all aspects of manufacturing operations with major pharmaceutical and biopharmaceutical companies. He has extensive expertise in the sterile manufacture of liquids, injectables and aerosol dosage forms, product and process development, and process validation. Mr. Orehostky has approximately 20 years of diverse quality assurance and regulatory compliance experience with global pharmaceutical, biopharmaceutical and medical device companies.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements relating to the potential results of Discovery's ongoing manufacturing investigation and remediation and FDA approval of its NDA for Surfaxin. Although Discovery is encouraged by the preliminary findings of its investigation, the investigation is ongoing, more work remains to be done and the final results could vary materially from the preliminary indications obtained to date. Discovery currently believes that it will succeed in implementing a CAPA plan and submitting its complete response to the second Approvable Letter, subject to the risks that the final investigation report may identify unforeseen problems that have not yet been discovered. The reader of this release should understand that the failure to satisfactorily investigate and remediate Discovery's manufacturing issues could result in significant delays and prevent the approval of Surfaxin or other Discovery products.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing proprietary Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that its proprietary pulmonary surfactant platform has the potential to address a variety of respiratory diseases where there are few or no approved therapies available.

Discovery's lead product, Surfaxin, has received two Approvable Letters from the FDA for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In addition, Discovery recently concluded patient enrollment for its Phase 2 clinical trial of Surfaxin for premature infants for the prevention and treatment of Bronchopulmonary Dysplasia (BPD).

Discovery is also developing Aerosurf, its proprietary SRT administered in aerosolized form, for the treatment of premature infants with multiple respiratory disorders. Discovery is preparing to initiate Phase 2 clinical studies with Aerosurf administered through nasal continuous positive airway pressure (nCPAP), potentially obviating the need for intubation and conventional mechanical ventilation. Discovery is also developing its SRT to potentially address Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), cystic fibrosis and other respiratory conditions.

To the extent that statements in this press release 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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. Among the factors which could affect Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all risk that approval by the FDA or other health regulatory authorities of any applications filed by Discovery may be withheld, delayed and/or limited by indications or other label limitations, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by Discovery for any such drug product, risks that Discovery's CMC will not satisfy the FDA, risk in the FDA or other regulatory agency review process generally, risks relating to the ability of Discovery or Discovery's third party contract manufacturers and development partners to manufacture or provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery's clinical studies, risks relating to drug manufacturing by Discovery, risks relating to the integration of manufacturing operations into Discovery's existing operations, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, risks relating to the ability of Discovery and its collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements, and risks relating to the development of competing therapies and/or technologies by other companies. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated risks and others are further described in Discovery'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.

For more information, please visit our corporate website at www.Discoverylabs.com.

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