

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 5, 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 18976-3622

(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 April 5, 2006, Discovery Laboratories, Inc. (the "Company") announced the receipt of a second Approvable Letter from the U.S. Food and Drug Administration (FDA) for the Company's lead product candidate, Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The Approvable Letter is an official notification from the FDA and contains conditions that must be satisfied by the Company prior to obtaining final U.S. marketing approval. Specifically, the FDA is requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the New Drug Application (NDA). Consistent with its previous review, the FDA does not have any clinical or statistical comments. The Company is in the process of arranging a meeting with the FDA regarding conditions for final approval. The Company anticipates that this meeting will clarify timelines with respect to its response to the FDA. This is the second Approvable Letter received by the Company from the FDA since the Company's NDA for Surfaxin was filed in April 2004. The Company's previously submitted responses to the first Approvable Letter were accepted by the FDA as a complete response in October 2005. The full text of the press release is set forth in Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements, Pro Forma Financial Statements and Exhibits

(d) Exhibits:

99.1 Press Release dated April 5, 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
Name: Robert J. Capetola, Ph.D.
Title: President and Chief Executive Officer

Date: April 5, 2006



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

Warrington, PA — April 5, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced that it has received a second Approvable Letter from the U.S. Food and Drug Administration (FDA) for Discovery's lead product candidate, Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative to animal-derived surfactants. **Discovery will hold a conference call today at 8:45 AM EDT. The call in number is 866-332-5218.**

The Approvable Letter is an official notification from the FDA and contains conditions that must be satisfied by Discovery prior to obtaining final U.S. marketing approval. Specifically, the FDA is requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous review, the FDA does not have any clinical or statistical comments. Discovery is in the process of arranging a meeting with the FDA regarding conditions for final approval. The Company anticipates that this meeting will clarify timelines with respect to its response to the FDA.

This is the second Approvable Letter received by the Company from the FDA since the Company's NDA for Surfaxin was filed in April 2004. Our previously submitted responses to the first Approvable Letter were accepted by the FDA as a complete response in October 2005.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "Our top priority is to satisfy the FDA's requests as soon as possible, so that we can obtain final approval for this important life-saving therapy and make it available to the neonatal community. In light of today's news, we are analyzing all aspects of our business with an intention to conserve cash while remaining focused on developing our NICU franchise of Surfaxin and Aerosurf[™]."

RDS is a life-threatening and costly breathing disorder that strikes tens of thousands of premature infants in the United States each year, with a global at-risk population in excess of 500,000 infants. Approximately 75,000 infants are treated with surfactants in the United States annually. Current surfactant treatment options are limited to animal-derived surfactants harvested from bovine (cow) and porcine (pig) sources.

Data from Discovery's pivotal, multinational SELECT study demonstrates that Surfaxin was significantly more effective in the prevention of RDS and improved survival and other outcomes versus comparator surfactants. The SELECT and STAR (a supportive Phase 3 study) trials, as well as a pooled Phase 3 analysis, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*.

Discovery will hold a conference call today at 8:45 AM EDT to further discuss in greater detail the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at <http://audioevent.mshow.com/295458/> and www.discoverylabs.com. It is recommended that participants log onto one of these sites at least 15 minutes prior to the call. The Internet broadcast will be available for up to 30 days after the call at both website addresses. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 7560777.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing its proprietary surfactant technology as 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 through its technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Discovery's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. Discovery's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. Discovery is preparing to conduct multiple Phase 2 pilot studies with Aerosurf, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failure.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery has completed a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

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

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 a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery's internal sales and marketing organization will not be able to attract or maintain qualified personnel, 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 review process generally, risks relating to the ability of Discovery's third party contract manufacturers and development partners to 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 the Company 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.

Company Contacts:

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