**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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# FORM 8-K

## CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

**July 29, 2005**
Date of Report (Date of earliest event reported)

**Discovery Laboratories, Inc.**
(Exact name of Registrant as specified in its charter)

| **Delaware** | **000-26422** | **94-3171943** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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 July 29, 2005, Discovery Laboratories, Inc., a Delaware corporation (the "Company") announced that it has submitted a response to the Approvable Letter received from the U.S. Food and Drug Administration ("FDA") for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome ("RDS") in premature infants. The FDA issued the Approvable Letter in February 2005 noting certain previously reported manufacturing issues from inspections of the Company's contract manufacturer Laureate Pharma, Inc. The Company issued a press release providing this update on July 29, 2005. The full text of the press release is set forth in Exhibit 99.1.

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

(c) Exhibits:

99.1 Press Release dated July 29, 2005.

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: July 29, 2005

**Exhibit 99.1**

Discovery Labs Submits Response to FDA Approvable Letter for Surfaxin® for RDS in Premature Infants

Warrington, PA, July 29, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that it has submitted its response to the Approvable Letter received from the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The Company believes that the response addresses the comments noted in the Approvable Letter by providing the FDA with the information necessary to complete its review of the Surfaxin New Drug Application (NDA) within six months.

In February 2005, the FDA issued an Approvable Letter indicating that it is prepared to approve the NDA when issues noted in the letter are adequately addressed. Most importantly, the FDA is not requiring additional preclinical or clinical studies. The Approvable Letter addressed certain labeling, chemistry, and manufacturing issues. With respect to Discovery's contract manufacturer, Laureate Pharma, Inc. (Laureate), the FDA previously issued a Form 483, citing inspectional observations related to compliance with current Good Manufacturing Practices (cGMPs) and other processes to be used for commercial production of the product. The general theme of the observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process.

Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer of Discovery commented, "Discovery and Laureate have worked aggressively to implement improved quality systems and documentation controls. We believe these efforts support our response to the FDA Approvable Letter and prepare us for the FDA's reinspection of Laureate's Totowa facility. We are confident that these actions bring Surfaxin, the first precision-engineered Surfactant Replacement Therapy, closer to the neonatal community as we anticipate approval and commercial launch in the first quarter of 2006."

Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. Premature babies are born with a lack of natural surfactant in their lungs. Without surfactant, the air sacs in the lungs collapse and are unable to absorb sufficient oxygen resulting in RDS. 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 for the animal-derived and non-protein containing synthetic surfactants. Discovery's Surfaxin has recently received an Approvable Letter from the FDA for the prevention of RDS in premature infants and is pending approval.

Discovery will hold a conference call on Tuesday, August 2, 2005 at 10:00 AM EDT. 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/247473 or 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.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating to the timing of FDA approval of Discovery’s NDA for Surfaxin for RDS, which assume that all of the conditions in the Approvable Letter are timely satisfied. These conditions include, without limitation, issues previously raised by earlier FDA inspections of the Totowa, NJ facility of Laureate Pharma, Inc. (Laureate), Discovery’s contract manufacturer for Surfaxin.

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 be developed into a series of respiratory therapies for patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has received an Approvable Letter from the FDA for Surfaxin, the Company’s lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and has filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome (MAS) in full-term infants.

More information about Discovery is available on the Company's Web site 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 our 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 of delay in the FDA's or other health regulatory authorities' approval of any applications filed by Discovery, 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 relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, 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.*

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