

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**

**October 21, 2005**

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 October 21, 2005, Discovery Laboratories, Inc. (the “Company”) issued a press release to announce that the U.S. Food and Drug Administration (“FDA”) has accepted the Company’s Response Letter, amended by a letter submitted to the FDA on October 5, 2005, as a complete response to the Approvable Letter for Surfaxin<sup>0</sup> for the prevention of Respiratory Distress Syndrome in premature infants. The FDA has established April 2006 as its target to complete its review of the Surfaxin New Drug Application. 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 October 21, 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.

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**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.**

Date: October 21, 2005

By: /s/ Robert J. Capetola

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Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

FDA Accepts Discovery Labs' Complete Response to  
Approvable Letter for Surfaxin<sup>®</sup>

Warrington, PA, October 21, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), has been informed today by the U.S. Food and Drug Administration (FDA) that the FDA has accepted Discovery's resubmission of October 5, 2005 as a complete response to the Approvable Letter for Surfaxin<sup>®</sup>, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established April 2006 as its target to complete its review of the Surfaxin New Drug Application (NDA).

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "With the acceptance of our response to the Surfaxin Approvable Letter, the FDA six month review process has begun as of October 5, 2005, the date of our resubmission. Discovery will work diligently with the FDA during this review, which will include the reinspection of our Surfaxin contract manufacturing facility, Laureate Pharma in Totowa, New Jersey. We anticipate that Surfaxin, the first precision-engineered Surfactant Replacement Therapy, will be available to the neonatal medical community in the second quarter of 2006."

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 received an Approvable Letter from the FDA for the prevention of RDS in premature infants and is pending approval. 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.

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., Discovery's contract manufacturer for Surfaxin.

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## 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. The Company's lead product, Surfaxin<sup>®</sup>, 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 treatment of Chronic Lung Disease (CLD) in premature infants. Aerosurf<sup>™</sup>, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), is in development to address neonatal respiratory failures.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also 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](http://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.*

## Company Contacts:

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