

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**

**January 26, 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 January 26, 2006, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that the United States Food and Drug Administration has granted Fast Track designation to the Company's lead product, Surfaxin®, for the prevention and treatment of Bronchopulmonary Dysplasia ("BPD") in premature infants. Under the FDA Modernization Act of 1997, designation as a Fast Track product for a new drug means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The Company is currently conducting a Phase 2 clinical trial to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD. Results from this study are expected in 2006. The press release, dated January 26, 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 January 26, 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

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

Date: January 30, 2006



## FDA Grants Discovery Labs' Surfaxin® Fast Track Designation for Prevention and Treatment of Bronchopulmonary Dysplasia

**Warrington, PA — January 26, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO)** announced that the United States Food and Drug Administration (FDA) has granted Fast Track designation to Discovery's lead product, Surfaxin®, for the prevention and treatment of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants.

Under the FDA Modernization Act of 1997, designation as a Fast Track product for a new drug means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product.

BPD is a costly syndrome affecting premature infants. It is associated with surfactant deficiency and the prolonged use of mechanical ventilation and oxygen supplementation. Some 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 Respiratory Distress Syndrome (RDS). To treat RDS, babies require a surfactant usually within one hour of birth as well as mechanical ventilation to support the babies' respiration. The lack of surfactant and use of mechanical ventilation may cause chronic injury and scarring of the lungs - resulting in BPD.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery commented, "The FDA's decision to grant Fast Track designation to Surfaxin for BPD is important for the neonatal medical community. Presently there are no approved drugs for the treatment of BPD. These babies suffer from abnormal lung development and typically have a need for respiratory assistance spanning from many months to years. It is estimated that the cost of treating an infant with BPD in the United States can approach \$250,000."

Surfaxin has already received an Approvable Letter from the FDA for the prevention of RDS in premature infants and anticipates potential approval in April 2006. To further develop Surfaxin for neonatal respiratory diseases, Discovery is currently conducting a Phase 2 clinical trial to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD. The BPD study design provides that premature infants receive a treatment regime of up to 5 Surfaxin doses beginning within the first 3-10 days of life that are in addition to the surfactant they received on day 1 of life for RDS. The purpose of this study is to determine whether such treatment can decrease the proportion of infants on mechanical ventilation or oxygen supplementation or decrease the incidence of death or BPD. Results from this trial are expected in 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. Surfactant treatment options available today are limited to FDA approved animal-derived or non-protein containing synthetic products and are only approved for RDS. Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant. In clinical trials comparing Surfaxin to the currently available products, Surfaxin demonstrated a significant survival advantage for RDS babies. If approved by the FDA, Surfaxin represents a potential alternative to the current surfactant treatment options for RDS.

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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 Labs' technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs 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 Labs' 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 prevention and treatment of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. Discovery Labs is preparing to conduct multiple Phase 2 pilot studies with Aerosurf<sup>™</sup>, 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 Labs 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).

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*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 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 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:**

Lisa Caperelli, Manager, Investor Relations  
215-488-9413

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