

UNITED STATES  
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

April 24, 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 24, 2006, Discovery Laboratories, Inc. issued a press release, the full text of which is set forth in Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01.      Financial Statements and Exhibits**

(d)      Exhibits:

99.1      Press Release dated April 24, 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.**

Date: April 26, 2006

By: /s/ Robert J. Capetola, Ph.D.

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



## Discovery Labs Reports Surfaxin Manufacturing Issue

**Warrington, PA — April 24, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today is announcing that analysis of ongoing stability data from Surfaxin<sup>®</sup> process validation batches indicates that certain stability parameters have not been achieved and, therefore, additional process validation batches will likely have to be produced. These process validation batches were previously manufactured as a requirement for Discovery's U.S. NDA regulatory approval and have been undergoing periodic stability testing. Discovery anticipates a potentially significant delay in the U.S. regulatory approval process for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. At this time, it is not known whether this issue will have any impact on the Surfaxin European regulatory approval process.

Discovery will be hosting a conference call on Tuesday, April 25 at 10:00 AM EDT. Details are provided below.

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. This recent development does not call into question the established pharmacology and highly statistically significant clinical outcomes demonstrated in the Company's Surfaxin Phase 3 clinical program. Data from Discovery's pivotal multinational SELECT Study demonstrates 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 previously reported the results of two recently completed pre-approval site inspections, conducted separately by the FDA and the EMEA, of the Company's drug product sterile manufacturing facility. The Surfaxin clinical drug product that is currently in use in Discovery's ongoing Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia in premature infants is unaffected.

The major focus of Discovery's development programs are aerosolized Surfactant Replacement Therapies to address serious respiratory conditions such as Neonatal Respiratory Disorders and Acute Lung Injury. Discovery's lead aerosol product candidate is Aerosurf<sup>™</sup> for Neonatal Respiratory Disorders. The development of an aerosolized surfactant administered via nasal continuous positive airway pressure (nCPAP) has the potential to revolutionize neonatal medicine for the treatment of infants with a wide array of respiratory disorders that typically would require mechanical ventilation. This recent development currently does not affect the aerosolized drug product supply for its Phase 2 Aerosurf clinical development program.

Discovery is analyzing all aspects of its business with an immediate intention to conserve cash. The establishment of a commercial infrastructure is no longer in Discovery's near-term plans. The Company's focus will be on remediating these manufacturing issues, developing its Surfactant Replacement Therapy pipeline and potentially entering into strategic partnerships.

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### **Conference Call Details**

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/296693/> and [www.discoverylabs.com](http://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 8158896.

### **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 focused on significant respiratory conditions prevalent in the neonatal intensive care unit, critical care and other hospital settings. Discovery'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 is preparing to conduct Phase 2 pilot studies with Aerosurf, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory disorders. 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), cystic fibrosis 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 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.*

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