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

February 14, 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:

[ ] 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))

Item 8.01. Other Events

On February 14, 2005, Discovery Laboratories, Inc., a Delaware corporation (the "Company") announced the receipt of an Approvable Letter from the U.S. Food and Drug Administration (FDA) for Surfaxin® for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The Approvable Letter is an official notification that the FDA is prepared to approve the Surfaxin New Drug Application and contains conditions that the applicant must meet prior to obtaining final U.S. marketing approval. The conditions that Discovery must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues. Most notably, the FDA is not requiring additional preclinical or clinical trials for final approval. Based on the nature of the observations contained in the Approvable Letter, the Company currently anticipates that it will respond to the FDA with a "Class 2" response. A "Class 2" response allows the FDA up to six months following the completion of the labeling and manufacturing issues outlined in the PDUFA letter. However, the Company believes that soon after the FDA receives the Company's response to the PDUFA letter, an opportunity will exist for the FDA to permit the Company to address the outstanding issues at the same time as the FDA's review of the Company's NDA for Surfaxin. In such case, the Company believes that the potential approval of Surfaxin for the prevention of RDS in premature infants could take place in the fourth quarter of 2005. There can be no assurance, however, that the FDA will agree to a parallel review and remediation approach, in which event the commercial launch of Surfaxin, if approved, could be delayed until at least the first quarter of 2006. The Company issued a press release providing this update on February 14, 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 February 14, 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.

Date: February 14, 2005

By: /s/ Robert J. Capetola

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

Discovery Labs Receives Approvable Letter from FDA for Surfaxin® for Respiratory Distress Syndrome in Premature Infants

Conference Call Today at 10:00 AM EST

Warrington, PA — February 14, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO) announces receipt of an Approvable Letter from the U.S. Food and Drug Administration (FDA) for Surfaxin® for the prevention of Respiratory Distress Syndrome (RDS) in premature infants.

The Approvable Letter is an official notification that the FDA is prepared to approve the Surfaxin New Drug Application and contains conditions that the applicant must meet prior to obtaining final U.S. marketing approval. The conditions that Discovery must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues. Most notably, the FDA is not requiring additional preclinical or clinical trials for final approval. The Company anticipates potential approval and commercial launch of Surfaxin to occur in the fourth quarter of 2005 or first quarter of 2006.

Surfaxin is the first precision-engineered lung Surfactant Replacement Therapy (SRT). Surfaxin contains a peptide, sinapultide, which is designed to closely mimic the essential properties of human lung surfactant protein B (SP-B). 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.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "This is a momentous occasion for Discovery Labs and its prospective patients. We are extremely pleased with the approvable designation, which reflects positively on the results achieved in our Phase 3 clinical program. We are indebted to Charlie Cochrane, M.D., Professor and Co-Founder of The Scripps Research Institute, who is the inventor of the Surfaxin technology and continues to be our most influential scientific advisor.

"Surfaxin is the cornerstone of our Surfactant Replacement Therapy pipeline and potentially sets a new standard for the prevention of RDS. Our mission is to advance to market precision-engineered Surfactant Replacement Therapies with the promise to revolutionize the treatment of respiratory diseases prevalent in the neonatal intensive care unit, critical care, and hospital settings."

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 will be published in a leading medical journal in the second quarter of 2005.

Discovery will hold a conference call today at 10:00 AM EST. The call in number is 800-665-0669. The international call in number is 706-643-0254. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at http://www.irconnect.com/primecast/dsco/487/ 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 issues previously raised by earlier FDA inspections of the Totowa, NJ facility of Laureate Pharma, L.P. (Laureate), Discovery's contract manufacturer for Surfaxin. Such assumptions also include timely correction of the manufacturing deficiencies for follow-up facility reinspections by the FDA, and that the FDA permits Discovery to address the

current Good Manufacturing Practice (cGMP) Action Plan submitted by Laureate and Discovery to the FDA on January 31, 2005, generally at the same time that the FDA reviews Discovery's Surfaxin NDA. If the FDA does not permit a parallel review and remediation approach, approval and launch could be delayed, possibly until at least the first quarter of 2006. Although Discovery believes that the manufacturing issues raised by the FDA are highly correctable, such issues are subject to substantial risks and uncertainties. Many factors could cause the resolution of those issues to differ materially from Discovery's forward-looking statements, including that the timing, scope and duration of a resolution of the cGMP issues will depend on the ability of Discovery and Laureate to assure the FDA of the quality and reliability of its basic quality controls, process assurances and documentation requirements that support the commercial production manufacturing process under applicable cGMPs. The reader of this release should understand that the failure to reach resolution of the cGMP issues could result in delays in ultimate approval of Discovery's potential products.

About Discovery Labs

Discovery Laboratories, Inc. is a biopharmaceutical 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 precisely 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 the 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 the 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.

Contacts:

Company Contacts:
John G. Cooper, EVP and CFO
215-488-9490

Lisa Caperelli, Investor Relations
215-488-9413

Media Contacts:

MCS, Inc.
Kathleen Breslin or Sarah Morgan
908-234-9900