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 19, 2004
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)

350 Main Street, Suite 307
Doylestown, Pennsylvania 18901
(Address of principal executive offices)

(215) 340-4699
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Item 5. Other Events and Regulation FD Disclosure

On February 19, 2004, the Company will hold a conference call to provide an overview of the secondary endpoints and certain safety results from the Company's two Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants (RDS). In June 2003, the Company announced positive top-line results in its supportive non-inferiority Phase 3 RDS trial. In November 2003, the Company announced that it had achieved statistical significance in its coprimary endpoints in its pivotal superiority Phase 3 RDS trial. The secondary endpoint results from these two Phase 3 RDS trials are consistent with and supportive of the earlier positive pivotal and supportive top-line results. In addition, the Company intends to provide an update on selected other programs.

In October 2003, the Company and Laureate Pharma, L.P. ("Laureate"), entered into a Technology Transfer and Manufacturing Agreement providing for the installation and validation of the Company's Surfaxin(R) manufacturing and filling line at Laureate's facility for the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMP). The installation of this manufacturing and filling line has been completed. In addition, a key objective of producing two batches of Surfaxin for RDS, in order to provide stability data to support the anticipated NDA submission to the FDA, has been completed.

Validation of the Laureate Surfaxin manufacturing facility is ongoing, with the completion of process sterility assurance remaining as the final step. The Company originally anticipated that process sterility assurance would be completed and drug supply would be available in late fourth quarter of 2003. The Company now anticipates completing process sterility assurance and producing Surfaxin for the Company's ARDS Phase 2 trial in the first quarter of 2004. As a result, completion of the Company's ARDS Phase 2 trial is now anticipated for the second half of 2004.

The Company relies on outside manufacturers for its drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of its products. Presently, the Company has no validated clinical manufacturing facility to produce appropriate clinical grade material of its drug substance for use in the Company's ongoing clinical studies. Laureate may not be able to produce Surfaxin to appropriate standards for use in clinical studies or commercial requirements. This could delay, or impair the ability of the Company, to obtain regulatory approval for its products and possibly increase its costs substantially or deplete any profit margins.

On February 6, 2004, the Company issued a press release which is attached hereto as Exhibit 99.1, to announce that the U.S. Food and Drug Administration has selected Surfaxin, for the treatment of Acute Respiratory Distress Syndrome (ARDS), as the only applicant within the Division of Pulmonary and Allergy Drug Products to be included in the FDA's Continuous Marketing Application (CMA) Pilot 2 Program. The Pilot 2 program was established to study and document the benefits of more frequent FDA feedback and interactions as a company moves through the various phases of development, with the goal that such interactions will expedite the development of Fast Tracked products.

Item 7. Financial Statements, Pro Forma Financial Statements and Exhibits

(c) Exhibits: Press Release dated February 19, 2004.

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: February 19, 2004

Exhibit 99.1

[DISCOVERY LABORATORIES LOGO]

FDA Selects Discovery Laboratories' Surfaxin(R) ARDS Program
For Its New Continuous Marketing Application Pilot 2 Program

Doylestown, PA -- February 19, 2004 -- Discovery Laboratories, Inc. (Nasdaq: DSCO), a biopharmaceutical company developing its proprietary humanized surfactant technology as Surfactant Replacement Therapies for respiratory diseases, today announced that the U.S. Food and Drug Administration has selected Surfaxin(R) for the treatment of Acute Respiratory Distress Syndrome (ARDS), as the only applicant within the Division of Pulmonary and Allergy Drug Products to be included in its Continuous Marketing Application (CMA) Pilot 2 Program. Participation in this initiative is limited to one Fast Track product for each review division within the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) over the course of the program.

The Pilot 2 program was established to study and document the benefits of more frequent FDA feedback and interactions as a company moves through the various phases of development, with the goal that such interactions will expedite the development of Fast Track products.

"We are gratified to have been selected for this innovative program. Given the devastating effects of ARDS both in terms of mortality and disease-related complications, inclusion into this program is an opportunity to collaborate closely with the FDA in defining the scope of the development program and endpoints to capture the essence of surfactant replacement therapy for these patients," said Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery. "We look forward to an increased level of scientific exchange and interaction with the FDA to ensure a high quality ARDS program and agreed upon path toward approval."

The objective of the Pilot 2 program is to evaluate the costs and benefits of enhanced sponsor access to guidance and feedback from the FDA during the Investigational New Drug (IND) phase of new drug development of Fast Track products and determine whether such activity can improve the efficiency of the drug development and review process. Once selected, participants in the Pilot 2 program and the FDA define specific agreements on the nature and timing of feedback and interactions between the participants and the FDA. Eligibility is limited to drug and biological products that have Fast Track designation and have been subject to an end of phase 1 clinical trial or equivalent meeting. Criteria for selection included the FDA's assessment of the potential value of enhanced interaction with an emphasis on the health benefits likely to result from successful drug development. For more information on CMA Pilot 2, visit http://.fda.gov/cder/guidance/5740-fnl.pdf.

About Acute Respiratory Distress Syndrome

ARDS is a life-threatening respiratory disorder for which there are currently no approved therapies anywhere in the world. It is estimated that there are between 150,000 and 250,000 ARDS patients per year in each of the U.S. and Europe. The mortality rate can range from 35% to 50%. The current standard of care includes placing patients on mechanical ventilators in intensive care units at an average

estimated cost of approximately $8,500 per day typically for an average of 21 to 28 days. One prominent characteristic of ARDS is the destruction of the lung's natural surfactant that is essential to the ability to absorb oxygen. ARDS is also characterized by an excess of fluid, inflammatory cells and debris in the lungs that leads to decreased oxygen levels in the patient's blood. These conditions are caused by events such as pneumonia, aspiration of gastric contents, smoke inhalation, near drowning, industrial accidents, sepsis and other traumas.

About Discovery Laboratories

Discovery Laboratories, Inc., is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes in infants and adults, Acute Lung Injury, asthma, Chronic Obstructive Pulmonary Disease and upper airway disorders. Surfactants are compositions produced naturally in the lungs and essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to provide the

essential properties of 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 critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery recently completed two Phase 3 clinical trials of Surfaxin(R), the Company's lead product, for the treatment of Respiratory Distress Syndrome in premature infants and is preparing to file new drug applications with the Food and Drug Administration and other regulatory authorities in the rest of the world. Discovery's Surfactant Replacement Therapy is also in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, a Phase 3 and a Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants, and a Phase 1b clinical trial for asthma.

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 Company's product development, events conditioned on stockholder or other approval, 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 release 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 company's actual results and could cause results to differ from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, risks relating to the progress of the company's research and development, the risk that the Company will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies), risks relating to the progress of the Company's research and development, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with sufficient amounts of drug products for completion of any of the

Company's clinical studies, other risks relating to the lack of sufficient drug product for completion of any of the Company'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 the company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-KSB, 8-K, 10-Q and 10-QSB, and amendments thereto.

Company Contacts:
John G. Cooper, EVP, CFO
Kori Beer, IR & Communications
215-340-4699