

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 23, 2001
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)
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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)

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Item 5. Other Events

On February 23, 2001, the Registrant issued a press release addressing the Registrant's proposed plans to conduct a Phase 3 clinical trial of Surfaxin(R) in Latin America for the treatment of idiopathic respiratory distress syndrome (IRDS) in premature newborns.

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

(c) Exhibits:

99.1 Press Release dated February 23, 2001.

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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.

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

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

Date: March 2, 2001

IMMEDIATE RELEASE:

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DISCOVERY LABORATORIES, INC.
 ADDRESSES PLANS TO CONDUCT A SURFAXIN(R) TRIAL IN LATIN AMERICA

Doylestown, PA, -- February 23, 2001 -- Discovery Laboratories, Inc. (NASDAQ: DSCO) today commented regarding its proposed plans to conduct a Phase 3 clinical trial of Surfaxin(R) in Latin America for the treatment of idiopathic respiratory distress syndrome (IRDS) in premature newborns.

The Phase 3 trial was designed by Discovery's clinical staff and outside advisors, which include prominent neonatologists in the U.S. and Latin America, bioethicists, registered nurses, respiratory therapists, as well as input from the FDA, to evaluate the safety and efficacy of Discovery's humanized surfactant, when compared to the standard of care in those regions in Latin America where the trial will be conducted. One aspect of the trial, designed to serve as a reference, will include the use of a commercially available replacement surfactant that is derived from cow lungs. This animal derived product is the leading surfactant sold for treatment of premature babies in the United States and is currently not generally available in the regions in Latin America where the trial will be conducted.

Every year approximately 2 million babies worldwide are born premature. Of these it is estimated that only about 150,000 are treated adequately with surfactant therapy. The mortality rate for these untreated infants ranges from 40-70 percent. The limited availability of surfactant treatment is due in part to the high cost of existing products and limitations in producing quantities of this scale from animal source materials.

Discovery has provided and plans to continue extensive clinical training at anticipated sites in Latin America as well as a comprehensive and ongoing assessment of each site's clinical needs. In addition, clinical supplies such as antibiotics, and equipment including mechanical ventilators and monitors, are being donated by the Company in an effort to raise the long-term level of care in these regions. The Company has also committed to provide Surfaxin(R) to these areas at a reduced cost for a substantial time period.

In designing the trial, Discovery and its advisors considered carefully the ongoing worldwide debate concerning the conduct of clinical studies in the developing world. It is believed that all patients in the study would benefit from either Surfaxin(R), the animal-derived surfactant or the enhanced standard of supportive care. The Company believes that without this study the majority of patients in these regions will continue to go largely untreated with attendant high mortality and morbidity.

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The trial is a collaborative effort between the Company and thought leaders in Latin America to bring this novel product to the region as quickly and safely as possible. Alternative designs were viewed as likely to increase the length of the study by as much as two years, resulting in thousands of additional deaths and debilitating lung conditions within this infant patient group.

A well recognized world leader in neonatology for Latin America and clinical advisor for Discovery, Fernando Moya, M.D., commented "As a result of our education campaign, equipment donations, and commitment to provide this humanized, non-animal derived, potentially highly efficacious and cost effective surfactant to these regions, it is reasonable to expect that we will have a major impact on significantly lowering mortality rates among premature newborns in these areas. The ethical thing to do is to conduct this trial as quickly as possible. "

Discovery is a Pennsylvania-based bio-pharmaceutical company with approximately 30 full-time employees whose mission is to develop and commercialize medically novel therapeutics for critical care. Presently, Discovery has two other clinical trials of Surfaxin(R) underway in the United States. Surfaxin(R) is also the subject of a pivotal Phase 3 clinical trial in meconium aspiration

syndrome (MAS) in full term newborns for which no approved drug treatment presently exists. In addition, the Company is involved in a Phase 2 clinical trial in acute respiratory distress syndrome (ARDS) in adults and is developing a second product, SuperVent(TM), to treat cystic fibrosis. The Company has been awarded an Orphan Products Development Grant and has received Fast Track designation for Surfaxin(R) from the FDA for MAS. The Company has previously been granted Orphan Drug Status for Surfaxin(R) from the FDA for MAS, RDS and ARDS. [omitted].

To the extent that statements in this press release are not strictly historical, including statements as to the Company's business strategy, outlook, objectives, 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 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, the risk that the Company will not be able to raise additional capital or enter into additional collaboration agreements, risks relating to the progress of the Company's research and development and the development of competing therapies and/or technologies by other companies. Those associated risks and others are further described in the Company's periodic filings with the Securities and Exchange Commission including the most recent reports on Form 10-KSB, 8-K and 10-QSB, and amendments thereto.

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