**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**

**December 13, 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) |

**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 7.01.** **Regulation FD Disclosure.**

On December 13, 2004, Discovery Laboratories, Inc. (the "Company") issued a press release to announce that it had presented certain additional clinical data from its primary Phase 3 study, the SELECT trial, at the 2004 Annual Hot Topics in Neonatology meeting in Washington, DC on December 12, 2004. The full text of the press release is set forth in Exhibit 99.1 hereto.

**Item 9.01.** **Financial Statements and Exhibits.**

(c) Exhibits

99.1 Press Release dated December 13, 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: December 17, 2004

**Exhibit 99.1**

**Treatment with Surfaxin® Supports Improved Survival of Premature Babies**

***Data Presented at the 2004 Hot Topics in Neonatology Meeting***

***Analysis of Additional Phase 3 Data Supports Improved Outcomes Compared with Currently Available Surfactant Therapies***

***Surfaxin, an Investigational Drug, is Currently Under Review for Marketing Approval in Both the United States and European Union***

**Warrington, PA — December 13, 2004 —** Discovery Laboratories, Inc. (Nasdaq: DSCO) presented additional clinical data from their primary Phase 3 study, the SELECT trial at the 2004 Annual Hot Topics in Neonatology meeting in Washington, DC on Sunday, December 12. Top line data previously reported from Discovery's pivotal multinational SELECT study showed that prophylactic Surfaxin® (lucinactant) therapy increased survival of premature babies with Respiratory Distress Syndrome (RDS) compared with comparator surfactant replacement therapies. In addition, when treated with Surfaxin, more babies survived without developing debilitating chronic lung disease, also known as bronchopulmonary dysplasia (BPD), compared with those treated with Exosurf, a non-protein containing synthetic surfactant.

Additionally, new analyses based on the pooling of data from Discovery's two Phase 3 trials, SELECT and STAR (the latter was previously presented at the 2003 Hot Topics Meeting), support a significant survival advantage for premature babies treated with Surfaxin, as compared with the animal-derived comparator surfactant therapies (Survanta® and Curosurf®) used in these studies. Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant. Surfaxin represents a potential alternative for the animal-derived and the non-protein containing synthetic surfactants.

"The data from the pivotal study, and especially those from the pooled analysis are particularly important because they suggest that a new-generation surfactant therapy such as Surfaxin may save more babies' lives while improving their chances for a healthy future," said Fernando Moya, M.D., Chair of the SELECT study Steering Committee and Richard W. Mithoff Professor of Neonatal-Perinatal Medicine, Department of Pediatrics UT-Houston School of Medicine. "Premature infants are very high risk patients. Any additional benefits that we can achieve in increasing their odds for survival and reducing some of the long-term complications associated with prematurity such as BPD will be embraced by the medical community."

Nearly all premature infants born before 32 weeks gestation have not fully developed their natural lung surfactant, and are likely to be at risk for developing RDS, a life-threatening and costly breathing disorder. According to the American Lung Association, RDS strikes over 60% of babies born at less than 28 weeks' gestation and up to 30% of those born at 28 to 34 weeks gestation.

BPD is a costly syndrome that is associated with the prolonged use of mechanical ventilation and oxygen supplementation. Babies with BPD suffer from abnormal lung development and typically have a need for respiratory assistance - oftentimes, for many months, as well as comprehensive care spanning years. According to the 1998 Division of Lung Disease and Office of Prevention Education and Control, the overall cost of treating infants with BPD in the United States is approximately $2.4 billion. There are estimated to be between 10,000 to 25,000 babies that suffer from BPD per year in the United States alone, with the treatment of each patient costing up to $250,000.

“Any surfactant that can demonstrate a statistical benefit in reducing BPD compared to existing therapies would be meaningful to the medical community,” said Jay Greenspan, M.D., Professor & Vice Chairman of Pediatrics, Thomas Jefferson University, Philadelphia. “Chronic lung disease poses a serious threat for a growing number of premature infants around the world, and we are eager for an effective therapy that will help address this unmet need.”

**Study Results from SELECT Phase 3 Trial**

As previously reported, Discovery’s pivotal, multinational study, known as SELECT, demonstrated that Surfaxin, as compared with the non-protein synthetic surfactant, Exosurf, significantly ($p=0.002$) reduced the incidence of RDS at 24 hours and RDS associated mortality through the first 14 days of life (4.7% versus 9.6% respectively, $p=0.001$). Surfaxin also significantly ($p=0.001$) reduced RDS associated mortality compared with the animal-derived surfactant, Survanta (the active, protein-containing reference surfactant for the trial). Additionally, Surfaxin, significantly improved survival without the development of BPD, when compared with Exosurf (Moya et al. *Pediatr Res.* 2004; 55:466A).

**SELECT and STAR Phase 3 Pooled Analysis**

Also presented at the Hot Topics meeting were the pooled analyses from Discovery’s Phase 3 SELECT and STAR trials. The pooled analysis compared the combined Surfaxin data to the animal-derived surfactant comparators from the two Phase 3 studies. The pooled Surfaxin data showed significantly ($p<0.05$) improved survival compared to the combined data from the two animal-derived surfactants (Survanta and Curosurf). The incidence of all-cause mortality at day 28 was 17.8% for Surfaxin treated infants compared to 21.5% for the animal surfactant treated infants ($p<0.05$), with a sustained reduction in all-cause mortality favoring Surfaxin through 36 weeks post-menstrual age (20.3% versus 24.1% ($p<0.05$)).

“We believe these data strongly support the potential for Surfaxin to transform the treatment of respiratory diseases in the NICU. We are committed to the neonatology community by continuing to develop our Surfactant Replacement Therapies to address a broad range of diseases that affect neonates,” commented Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer of Discovery Laboratories.

**About Surfaxin**

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. The current standard of care for treating these patients is surfactant replacement therapy using animal-derived surfactants. Animal-derived products are prepared using a chemical extraction process from cow and pig lung washes or from the mincing of these animal lungs.

Discovery's Surfaxin is an engineered version of natural human lung surfactant and contains a peptide, sinapultide, which is designed to closely mimic the essential human lung surfactant protein B (SP-B). Surfaxin is capable of being produced in virtually unlimited quantities, in consistent pharmaceutical grade quality, and has no risk of potential transmission of animal-associated diseases.

Discovery has filed a New Drug Application with the United States FDA and a Marketing Authorization Application with the European Medicines Evaluation Agency for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of RDS in premature infants.

**About Discovery Laboratories**
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 is also conducting various clinical programs to address ARDS in adults, BPD (a form of chronic lung disease in infants), Neonatal Respiratory Failures in premature infants, severe asthma in adults, and 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 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 Surfactant Replacement Therapies), risk that the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that the Company's internal sales and marketing organization will not succeed in developing market awareness of the Company's products, risk that the Company'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 the Company, 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 the Company for any such drug product, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with adequate supplies of drug substance and drug products for completion of any of the Company's clinical studies, other risks relating to the lack of adequate supplies of drug substance and 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-Q and 8-K, and any amendments thereto.*

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