

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

June 15, 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

(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 June 15, 2006, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that the Office of Orphan Products Development of the United States Food and Drug Administration has granted orphan drug designation to the Company's lead product, Surfaxin®, for the prevention of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. The U.S. Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. Surfaxin, a precision-engineered lung surfactant replacement therapy, has previously received orphan drug designation for the treatment of BPD, as well as fast track designation for both the prevention and treatment of BPD. The Company recently concluded its Phase 2 double-blind, placebo-controlled trial enrolling very low birth weight premature infants born at risk for developing BPD, and plans to report results in the fourth quarter of 2006. The press release, dated June 15, 2006, is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release, dated June 15, 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.

By: /s/ Robert J. Capetola

Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

Date: June 16, 2006



Discovery Labs' Surfaxin[®] Granted Orphan Drug Designation for the Prevention of Bronchopulmonary Dysplasia

Warrington, PA, June 15, 2006 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announced that the Office of Orphan Products Development of the United States Food and Drug Administration (FDA) has granted orphan drug designation to Discovery's lead product, Surfaxin[®], for the prevention of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. Surfaxin, a precision-engineered lung surfactant replacement therapy, has previously received orphan drug designation for the treatment of BPD, as well as fast track designation for both the prevention and treatment of BPD.

BPD is a costly syndrome affecting premature infants. It is associated with surfactant deficiency and the prolonged use of mechanical ventilation and oxygen supplementation. Some 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 Respiratory Distress Syndrome (RDS). To prevent and treat RDS, babies require a surfactant usually within the first hours of birth, and mechanical ventilation to support their respiration. The lack of surfactant and use of mechanical ventilation may cause chronic injury and scarring of the lungs - resulting in BPD.

The U.S. Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. Orphan drug designation in the United States is awarded to compounds that offer potential therapeutic value in the treatment of rare diseases, defined as those affecting fewer than 200,000 Americans. If the company complies with certain FDA specifications and should the drug receive marketing approval, orphan drug designation qualifies the sponsor for seven years of marketing exclusivity, exemption from the Prescription Drug User Fee Act filing fees, and tax credits related to clinical research.

Robert J. Capetola, Ph.D. President and Chief Executive Officer of Discovery commented, "Market exclusivity under this designation would mean that Surfaxin, as a precision-engineered surfactant, has the potential to become the dominant surfactant in the neonatal intensive care unit for the next decade. If Surfaxin is the first product to receive marketing authorization in the United States for the treatment of Bronchopulmonary Dysplasia, orphan status would block any similar synthetic surfactant products for this indication throughout the United States market for a significant period of time."

Discovery recently concluded its Phase 2 double-blind, placebo-controlled trial early, enrolling approximately 130 very low birth weight premature infants born at risk for developing BPD. The purpose of the trial was to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD. Premature infants in this study received a treatment regime of up to 5 Surfaxin doses beginning within the first 3-10 days of life, in addition to the surfactant they received on day 1 of life for RDS. Discovery plans to report the top-line results in the fourth quarter of 2006.

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant. Discovery's Surfaxin has received two Approvable Letters from the FDA for the prevention of RDS in premature infants. 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.

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 lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received two Approvable Letters from the FDA.

Discovery's proprietary SRT is also being developed in an aerosolized form under the name Aerosurf[™], for the treatment of neonatal respiratory disorders. Discovery is preparing to conduct Phase 2 pilot studies with Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP). In addition, also for premature infants, Discovery recently concluded early a Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), also known as Chronic Lung Disease. Discovery recently completed and announced preliminary results of a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to potentially address Acute Lung Injury (ALI), cystic fibrosis and other respiratory conditions.

For more information, please visit our corporate website 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 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 or otherwise provide for a successful sales and marketing organization in a timely manner, if at all, 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 or other regulatory agency review process generally, risks relating to the ability of Discovery or Discovery's third party contract manufacturers and development partners to manufacture or 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.

Company Contacts:

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