

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

October 11, 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))
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Item 8.01. Other Events.

On October 11, 2006, Discovery Laboratories, Inc. issued a press release to announce top-line results of its Phase 2 clinical trial of Surfaxin[®] (lucinactant) for the prevention and treatment of Bronchopulmonary Dysplasia. The press release 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 October 11, 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

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

Date: October 11, 2006



Discovery Labs Announces Topline Results of Surfaxin[®] Phase 2 Clinical Trial for the Prevention and Treatment of BPD

Improved outcomes observed with Surfaxin including increased survival without BPD

Warrington, PA — October 11, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced encouraging results from its recently completed Phase 2 clinical trial of Surfaxin[®] (lucinactant) for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered Respiratory Distress Syndrome (RDS). The results suggest that Surfaxin, administered up to five times, may represent a novel therapeutic option for infants at risk for BPD. Presently there are no approved therapies for this disease. Surfaxin has received an Approvable Letter from the United States FDA for the prevention of RDS and has Orphan Drug Status and Fast Track designation from the FDA for the prevention and treatment of BPD.

Discovery will hold a conference call on Thursday, October 12th at 9:00 AM EST. The call in number is 866-332-5218. The audio webcast is available at <http://audioevent.mshow.com/310493>.

In Discovery's Phase 2 clinical trial, 136 premature infants were enrolled and received either Surfaxin standard dose (175 mg/kg), Surfaxin low dose (90 mg/kg), or sham air as a control. This clinical trial was designed as an estimation study to evaluate the safety and potential efficacy of Surfaxin in infants at risk for BPD, and was not powered to determine statistically significant differences in outcomes. The Surfaxin standard dose (175 mg/kg) is the dose that was administered in Discovery's successful RDS Phase 3 clinical trials. The key preliminary findings observed in this Phase 2 BPD trial were:

- A positive acute pharmacological response to Surfaxin therapy evidenced by a reduction in supplemental oxygen and ventilatory support.
- A lower incidence of death or BPD in patients receiving the standard 175 mg/kg Surfaxin dosing compared with controls (57.8% vs. 65.9%, respectively).
- A higher survival rate through 36 weeks post-menstrual age (PMA) in patients receiving the standard 175 mg/kg Surfaxin dosing compared with controls (88.9% vs. 84.1%, respectively).
- A reduction in duration of mechanical ventilation (approximately four less days) and need for supplemental oxygen in patients receiving the standard 175 mg/kg Surfaxin dosing compared with controls.
- Surfaxin therapy was generally safe and well tolerated with generally no differences between the Surfaxin treatment groups and the control group in common complications of prematurity. There were no differences noted in tolerability of drug between the Surfaxin standard dose of 175 mg/kg (given at a volume of 5.8 ml/kg) and the Surfaxin low dose of 90 mg/kg (given at a volume of 3.0 ml/kg).

By chance, infants assigned to the Surfaxin low dose (90 mg/kg) treatment group were significantly sicker with more pre-existing medical risk factors, that typically adversely affect clinical outcomes, compared with the Surfaxin standard dose (175 mg/kg) group or the control group. Therefore, the data from the Surfaxin low dose treatment group cannot be easily interpreted and no meaningful conclusions can be drawn.

Comprehensive analysis of the data from this trial is ongoing. Following this analysis, Discovery in collaboration with its Steering Committee and Investigators, will present the study results to the medical community and submit these data for publication in a peer review journal.

Robert Segal, MD, Chief Medical Officer and Senior Vice President of Discovery, commented, “These data are very exciting and support the further development of Surfaxin as a potential therapy for BPD. Surfactant dysfunction is associated with many respiratory disorders prevalent in neonatal, pediatric and adult patients. These data, consistent with those from our RDS and ARDS clinical programs, continue to validate the pharmacology of our technology. There are many unmet medical needs in pulmonary medicine. Discovery’s unique pipeline of precision-engineered Surfactant Replacement Therapies is potentially capable of transforming the treatment of numerous pulmonary diseases.”

Carl Bose, MD, Chairman of the BPD Clinical Study Steering Committee and Professor of Pediatrics at University of North Carolina, commented, “The data from this Phase 2 estimation trial are encouraging. The medical community would embrace a medical therapy such as a surfactant treatment if it were proven to increase the odds for survival while improving the chances for a healthy future. These data support the continued evaluation of Surfaxin as a therapeutic option for the prevention of BPD.”

BPD is associated with surfactant deficiency and is diagnosed when premature infants require mechanical ventilation or supplemental oxygen either at the 28th day of life or 36 weeks PMA. Premature babies are often born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen, resulting in RDS. These infants often require endotracheal intubation to administer one of the currently available animal derived surfactants (usually within the first hours of birth), and to provide respiratory support via mechanical ventilation. Unfortunately, many infants relapse following initial therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen which increases their risk of developing BPD. Discovery believes that BPD may be treated with repeated doses, beyond the initial RDS treatment, of a non-immunogenic, precision-engineered synthetic surfactant (Surfaxin) to improve the clinical outcome of these infants.

Judy Aschner, MD, Professor of Pediatrics at the Vanderbilt University Medical Center and a member of the BPD Clinical Study Steering Committee, commented, “BPD represents one of the most challenging clinical problems we face in neonatology. All extremely low birth weight infants that require mechanical ventilation are at risk for this debilitating disorder and, unfortunately, there are no approved therapies that effectively prevent or treat this significant medical problem.”

Discovery's Phase 2 BPD study was a randomized, double-blind, placebo-controlled trial that enrolled 136 extremely low birth weight (600-900 grams) premature infants 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. All enrolled infants were initially supported by mechanical ventilation and most had received a currently available animal derived surfactant on the first day of life for treatment of RDS. Subsequently, per protocol, infants treated with Surfaxin received up to five doses, with the initial dose being administered between the third and tenth day of life.

Bronchopulmonary Dysplasia (BPD)

BPD is a costly complication of prematurity that affects approximately 30-40% of infants who survive RDS and require prolonged use of mechanical ventilation and oxygen supplementation. Presently there are no approved therapies for the treatment or prevention of BPD. Infants diagnosed with BPD have abnormal lung function and typically need respiratory support, often requiring comprehensive care for several years. Infants with BPD also have longer hospital stays and higher rates of other complications of prematurity, including cerebral palsy. More than 50,000 infants develop BPD in the United States and Europe, combined, each year. The cost of treating an infant with BPD in the United States can exceed \$250,000.

Surfaxin®

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative to animal-derived surfactants. Surfaxin's precision-engineered and non-immunogenic nature allows it to be further developed as a therapeutic addressing other pulmonary conditions in neonatal and pediatric medicine. Data from Discovery's pivotal, multinational SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and improved survival (continuing through at least one year of life) 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 the results from the two studies were published in *Pediatrics*.

Conference Call Details

Discovery Labs will hold a conference call on Thursday, October 12th at 9:00 AM EST to further discuss in greater detail the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at <http://audioevent.mshow.com/310493> and 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. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 8268400.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing 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 its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting premature infants, children and adults.

Discovery's lead product candidate, Surfaxin, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. Surfaxin® is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia in premature infants. Aerosurf™, Discovery's aerosolized SRT, is being developed initially to treat premature infants suffering from respiratory disorders and is intended to obviate the need for intubation and conventional mechanical ventilation. Discovery's SRT pipeline also includes programs addressing Acute Lung Injury, Acute Respiratory Failure, Cystic Fibrosis, Acute Respiratory Distress Syndrome, 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), the 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, the 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, the risk 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 the Chemistry, Manufacturing and Controls (CMC) section of Discovery's New Drug Application 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 Discovery and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery's 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 Discovery's 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.

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