

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

September 8, 2005

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 September 8, 2005, Discovery Laboratories, Inc., a Delaware corporation (the “Company”) announced that it has completed a pilot Phase 2 feasibility study of Aerosurf™, the Company’s precision-engineered aerosolized Surfactant Replacement Therapy (SRT) administered via nasal continuous positive airway pressure (nCPAP) intended to treat premature infants at risk for respiratory distress syndrome (RDS). This initial pilot trial was not designed to demonstrate efficacy outcomes. The Company issued a press release providing this information on September 8, 2005. The full text of the press release is set forth in Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements, Pro Forma Financial Statements and Exhibits

(c) Exhibits:

99.1 Press Release dated September 8, 2005.

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: September 9, 2005

Discovery Labs Completes Pilot Phase 2 Study of Investigational Drug Aerosurf™, its Aerosolized Surfactant Delivered via Nasal CPAP

Warrington, PA - September 8, 2005 - Discovery Laboratories, Inc. (Nasdaq: DSCO) has completed its first pilot Phase 2 feasibility study of Aerosurf™, the Company's precision-engineered aerosolized Surfactant Replacement Therapy (SRT) administered via nasal continuous positive airway pressure (nCPAP) intended to treat premature infants at risk for respiratory distress syndrome (RDS). This pilot clinical trial serves as the first step in the development of a revolutionary technology that has the potential to treat infants with a wide array of respiratory failures who typically would require mechanical ventilation. **Discovery will hold a conference call today at 10:00 AM EDT. The call in number is 866-332-5218.**

The pilot Phase 2 clinical trial was an open label, multicenter study to evaluate the feasibility, safety and tolerability of Aerosurf delivered via nCPAP for the prevention of RDS in premature infants. The trial was conducted at four centers in the United States and enrolled 17 infants with a gestational age ranging between 28-32 weeks and a mean birth weight of 1460 grams. Aerosurf was administered to infants within 30 minutes of birth for a three hour duration. Retreatments were allowed if infants met certain medical criteria.

The study showed that it is feasible to deliver Aerosurf via nCPAP and the treatment was generally safe and well tolerated. This initial pilot trial was not designed to demonstrate efficacy outcomes. Key observations included:

- All infants survived; none had lung airleaks or developed necrotizing enterocolitis (an inflammatory gastrointestinal disease) and one developed a low-grade intraventricular hemorrhage.
- Fifteen of the seventeen infants had no evidence of bronchopulmonary dysplasia (commonly known as BPD, a chronic lung disease) at Day 28.
- Four infants had evidence of RDS at 24 hours with three requiring intubation with mechanical ventilation due to complications of their clinical course. Two additional infants required intubation with mechanical ventilation without evidence of RDS at 24 hours.
- Peri-dosing events included apnea and desaturation but without clinically important sequelae.

"We are very encouraged with the outcomes of our first pilot study with Aerosurf. The insights gained will allow us to prepare for our next clinical trial," commented Robert Segal MD, Senior Vice President and Chief Medical Officer. "Neonatologists have limited pharmacologic options to treat serious respiratory diseases outside of RDS; many of these infants suffer significant morbidity and require costly treatments with prolonged hospital stays. No currently available surfactants have addressed these unmet needs. Aerosurf represents a novel therapeutic approach for the potential treatment of infants with various respiratory diseases."

Neonatal Respiratory Failures

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in Neonatal Intensive Care Units. There are approximately 1.5 million premature infants born annually worldwide at risk for respiratory problems associated with surfactant dysfunction. The majority of these infants are usually at a birth weight greater than 1250 grams, and neonatologists generally try to avoid mechanically ventilating these patients because doing so requires intubation (the invasive process of inserting a breathing tube down the trachea). This reluctance is due to the risks associated with intubation and the need for paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits clearly outweigh the risks. The neonatal medical community recognizes the potential utility of a non-invasive method of delivering SRT to treat premature infants suffering from respiratory disorders including RDS, BPD, bronchiolitis, acute hypoxia, pneumonia, and transient tachypnea.

Discovery will hold a conference call today at 10:00 AM EDT 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/252908> 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 9329269.

Aerosurf is an investigational drug that has not been approved by the U.S. FDA or any other world health regulatory authorities.

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 SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. In addition, the Company is developing Surfaxin for the treatment of Bronchopulmonary Dysplasia (BPD) in premature infants and Aerosurf, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for neonatal respiratory failures.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, 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 our aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery'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 Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery'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 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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