

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**

**December 3, 2007**

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 December 3, 2007, Discovery Laboratories, Inc. issued a press release to announce that data from pre-clinical studies using Aerosurf™ in preterm lambs were recently presented at the 2007 annual Hot Topics in Neonatology meeting in Washington, D.C. The studies were conducted using a well-established pre-clinical model of respiratory distress syndrome (RDS) and key observations demonstrate that Aerosurf improves both lung function and reduces inflammation associated with lung injury and chronic lung disease. The press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Aerosurf is an aerosolized formulation of the Company's novel KL4 surfactant technology that is delivered non-invasively via novel aerosol generating technology and employs nasal continuous positive airway pressure (nCPAP). Aerosurf, like Discovery's lead product Surfaxin®, is a precision-engineered synthetic, peptide-containing surfactant which is designed to closely mimic the essential attributes of human lung surfactant. In clinical trials, Surfaxin has demonstrated mortality and morbidity benefits versus currently available animal-derived surfactants. Surfaxin for the treatment of RDS in premature infants is currently under review by the U.S. Food and Drug Administration (FDA) with a May 1, 2008 target date for potential approval under the Prescription Drug User Fee Act (PDUFA).

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

(d) Exhibits

99.1 Press release, dated December 3, 2007.

**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: December 4, 2007



## Discovery Labs' Aerosurf™ Improves Lung Function and Reduces Inflammation in a Model of Respiratory Distress Syndrome

**Warrington, PA, December 3, 2007**— Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that data from pre-clinical studies using Aerosurf™ in preterm lambs were presented at the 2007 Annual *Hot Topics in Neonatology* meeting in Washington, DC. The studies were conducted using a well-established pre-clinical model of respiratory distress syndrome (RDS) and key observations demonstrate that Aerosurf improves both lung function and reduces inflammation associated with lung injury and chronic lung disease.

Aerosurf is an aerosolized formulation of Discovery Lab's novel KL4 surfactant technology that is delivered non-invasively via novel aerosol generating technology and employs nasal continuous positive airway pressure (nCPAP). Aerosurf, like Discovery's lead product Surfaxin®, is a precision-engineered synthetic, peptide-containing surfactant which is designed to closely mimic the essential attributes of human lung surfactant. In clinical trials, Surfaxin has demonstrated mortality and morbidity benefits versus currently available animal-derived surfactants. Surfaxin is currently under review by the FDA with a May 1, 2008 PDUFA date for potential approval.

The study was conducted at Temple University School of Medicine in Philadelphia, PA. The pre-term RDS lamb model was selected because it closely resembles the development, structure, and function of human lungs and is the most relevant system to study the pathophysiology and treatment of RDS. Key observations from the study comparing lambs receiving Aerosurf plus CPAP with those receiving CPAP alone include:

- Treatment with Aerosurf resulted in significant reductions in key markers of inflammation, including interleukin-6 and 8 compared with CPAP alone ( $p < 0.05$ )
- Treatment with Aerosurf preserved structural integrity of the lung by preserving the tissue structure of the lung to a greater degree compared with CPAP alone ( $p < 0.05$ )
- Improvement in lung function trended higher in the Aerosurf-treated group
- Aerosurf was well tolerated and interfaced effectively with CPAP respiratory support

Dr. Marla R. Wolfson, Associate Professor, Departments of Pediatrics and Physiology at the Temple University School of Medicine, commented, "This novel approach allows for a non-invasive administration of surfactant to improve lung function. In addition we observed a significant reduction in pulmonary inflammation and preservation of lung integrity. Historical attempts to achieve this ambitious objective have been constrained by technological limitations that are overcome by the Discovery Labs technology platform. The benefits of Aerosurf in reducing lung inflammation and in preserving the lung integrity are especially promising as we consider clinical therapeutic applications."

In order to avoid endotracheal intubation and the risk of lung damage, nCPAP is increasingly being employed to support preterm infants with respiratory insufficiency. Unfortunately, many infants relapse following initial attempts at therapy with nCPAP alone and require intubation and mechanical ventilation, each with their attendant risks, as well as the increased risk for these infants subsequently developing chronic lung disease. The neonatal, pediatric, and adult critical care medical communities recognize the potential for an aerosolized lung surfactant, delivered non-invasively, to address a wide array of respiratory disorders.

---

Robert Segal, M.D., Senior Vice President and Chief Medical Officer of Discovery Labs, commented, “The current treatment approach for premature babies with RDS requires delivery of animal-derived surfactants via an endotracheal tube. Aerosurf, a synthetic aerosolized surfactant that is delivered non-invasively, has the potential to revolutionize the approach to treating preterm babies who are at great risk, not only for RDS, but also subsequent chronic lung disease, such as bronchopulmonary dysplasia (BPD). Aerosurf also has the potential to expand therapeutic options for a broad range of patients with respiratory diseases. The potential benefits of reducing inflammation and preserving structural lung integrity further support our excitement about our Aerosurf development program. We are looking forward to advancing Aerosurf into Phase 2 clinical trials in 2008.”

Data from previous pre-clinical and clinical studies using Aerosurf were presented at the *Pediatric Academic Societies (PAS) 2006 and 2007 Annual Meetings*. In these studies, Aerosurf maintained its chemical structure and essential functional activity post-aerosolization. In addition, Aerosurf was observed to be safe and well tolerated in human preterm infants.

Both Surfaxin and Aerosurf are investigational drugs that have 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 Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs’ technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery Labs’ lead product candidate, Surfaxin<sup>®</sup>, 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 other neonatal and pediatric indications. Aerosurf<sup>™</sup>, Discovery Labs’ aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

---

*To the extent that statements in this press release are not strictly historical, 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 risk factors which could affect Discovery Labs actual results and could cause results to differ from those contained in these forward-looking statements are the risks that: Discovery Labs may be unable to profitably develop and market its products; financial market conditions may change; Discovery Labs may not be able to raise additional capital or enter into additional collaboration agreements; Discovery Labs may not be able to attract or retain qualified personnel or timely provide for successful sales and marketing activities; Discovery Labs' research and development efforts may not progress; Discovery Labs may not be successful in the FDA or other regulatory agency review process generally, including that such regulatory authority will not approve the marketing and sale of a drug product even after accepting an application or may withhold, delay and/or limit marketing a drug product by indication or impose other label limitations; Discovery Labs' recently-submitted response to the Approvable Letter may not satisfy the FDA; Discovery Labs or its third party manufacturers and development partners may be unable to manufacture or provide adequate supplies of drug substances and expertise to allow for completion of any of Discovery Labs clinical studies; Discovery Labs and its collaborators may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs drug products with innovative aerosolization technologies; Discovery Labs may not be able to successfully manufacture its drug product candidates; Discovery Labs' significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and efforts to gain regulatory approval for any products that it may develop (independently or in connection with collaboration arrangements) may not succeed; other companies may develop competing therapies and/or technologies; reimbursement and health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further described in Discovery Labs 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 Contact:**

Lisa Caperelli, Investor Relations  
215-488-9413

---