

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**

**June 9, 2010**

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 June 9, 2010, Discovery Laboratories, Inc. (the “Company”) announced the release of preliminary top line results in the Phase 2 clinical trial to determine whether Surfaxin® (lucinactant) improves lung function and reduces the duration and related risk exposure of mechanical ventilation in children up to two years of age diagnosed with Acute Respiratory Failure. The full text of the press release is set forth in Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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

(d)       Exhibits

99.1      Press Release dated June 9, 2010.

## 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/ W. Thomas Amick  
Name: W. Thomas Amick  
Title: Chairman of the Board and interim Chief  
Executive Officer

Date: June 9, 2010

## Discovery Labs Reports Preliminary Results from Phase 2 Clinical Trial of Surfaxin in Pediatric Acute Respiratory Failure

**Warrington, PA – June 9, 2010** — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, reports preliminary results from its Phase 2 clinical trial of Surfaxin<sup>®</sup> in children with Acute Respiratory Failure (ARF), a critical condition often caused in children by severe respiratory infections. The objective of the study was to evaluate the safety and tolerability of intratracheal administration of Surfaxin and to assess whether Surfaxin treatment could decrease the duration of mechanical ventilation in children with ARF.

The Phase 2 trial was a multicenter, randomized, masked, placebo-controlled estimation trial that enrolled 165 children under the age of two with ARF and compared Surfaxin treatment to standard of care alone, masked with sham air control. All children enrolled received standard of care and were randomized to receive either Surfaxin at 5.8 mL/kg of body weight or sham air. The trial enrolled patients at 24 sites located in the northern and southern hemispheres.

Key preliminary observations in this Phase 2 trial are:

- Relative to the control treatment group, Surfaxin treatment reduced time on mechanical ventilation by approximately 10%, although this observation was not statistically significantly different. Duration on mechanical ventilation was 3.8 days for the Surfaxin treatment group versus 4.1 days for the control treatment group, expressed as the geometric mean (primary analysis per protocol).
- Surfaxin treatment appeared generally safe and well tolerated in this trial. Statistically significant differences in the incidence of bradycardia and desaturation were observed in the Surfaxin treatment group during the dosing period versus the control treatment group. Generally, such peri-dosing events are transient and expected with intratracheal surfactant administration.

Comprehensive analysis of the data from this trial is ongoing. Further assessment of safety and tolerability, as well as in-depth analysis of additional efficacy endpoints and patient sub-populations, is expected to be completed in the third quarter of 2010. Following this analysis, Discovery Labs in collaboration with the ARF Steering Committee plans to present the comprehensive results at relevant medical congresses and submit these data for publication in a peer review journal.

Robert Segal, MD, Chief Medical Officer and Senior Vice President of Discovery Labs, commented, “Pediatric Acute Respiratory Failure represents a significant medical challenge and, unfortunately, there are no approved medical therapies that effectively treat this disorder today. Pulmonary surfactant is critical for normal respiration and may become impaired following patient exposure to a pathogen such as influenza or respiratory syncytial virus. The comprehensive data set from this Phase 2 trial is being further analyzed with the study Steering Committee as we evaluate next steps. These data are important as we are assessing, for the first time, the safety, tolerability and efficacy of intratracheally administered Surfaxin in the ARF patient population.”

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Surfaxin is an investigational drug candidate that has not been approved by the FDA or any other world health regulatory authority.

#### **About Acute Respiratory Failure**

ARF in young children occurs primarily after they have been exposed to serious respiratory infections, such as influenza (including the type A serotype referred to as H1N1) or respiratory syncytial virus (RSV), and leads to an impairment in lung function and the need for endotracheal intubation and mechanical ventilation (the current standard of care). Children with ARF usually suffer surfactant inactivation as part of the disease process. When there is insufficient functional surfactant in the lung, the alveoli (air sacs) collapse and are unable to support sufficient oxygenation. ARF affects approximately 15,000 children under two years of age in the United States with an estimated 30,000 – 40,000 children afflicted in developed countries each year, depending on severity of the viral season. Presently there are no approved drugs for the treatment of ARF.

#### **About Discovery Labs**

Discovery Laboratories, Inc. is a biotechnology company developing KL<sub>4</sub> surfactant therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' novel proprietary KL<sub>4</sub> surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol or lyophilized formulations. In addition, Discovery Labs' proprietary capillary aerosolization technology produces a dense aerosol, with a defined particle size that is capable of potentially delivering aerosolized KL<sub>4</sub> surfactant to the deep lung without the complications currently associated with liquid surfactant administration. Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

**Forward-Looking Statements**

*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. Examples of such risks and uncertainties are: risks relating to the rigorous regulatory requirements required for approval of any drug or drug-device combination products that Discovery Labs may develop, including that: (a) Discovery Labs and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on the matters raised during regulatory reviews, or Discovery Labs may be required to conduct significant additional activities to potentially gain approval of its product candidates, if ever; (b) the FDA or other regulatory authorities may not accept or may withhold or delay consideration of any of Discovery Labs' applications, or may not approve or may limit approval of Discovery Labs' products to particular indications or impose unanticipated label limitations, and (c) changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval; risks relating to Discovery Labs' research and development activities, including (i) time-consuming and expensive pre-clinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or fail, and (ii) the need for sophisticated and extensive analytical methodologies, including an acceptable biological activity test, if required, as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities; risks relating to Discovery Labs' ability to develop and manufacture drug products and capillary aerosolization systems for clinical studies, and, if approved, for commercialization of drug and combination drug-device products, including risks of technology transfers to contract manufacturers and problems or delays encountered by Discovery Labs, its contract manufacturers or suppliers in manufacturing drug products, drug substances and capillary aerosolization systems on a timely basis or in an amount sufficient to support Discovery Labs' development efforts and, if approved, commercialization; the risk that Discovery Labs may be unable to identify potential strategic partners or collaborators to develop and commercialize its products, if approved, in a timely manner, if at all; the risk that Discovery Labs will not be able in a changing financial market to raise additional capital or enter into strategic alliances or collaboration agreements, or that the ongoing credit crisis will adversely affect the ability of Discovery Labs to fund its activities, or that additional financings could result in substantial equity dilution; the risk that Discovery Labs will not be able to access credit from its committed equity financing facilities (CEFFs), or that the minimum share price at which Discovery Labs may access the CEFFs from time to time will prevent Discovery Labs from accessing the full dollar amount potentially available under the CEFFs; the risk that Discovery Labs or its strategic partners or collaborators will not be able to retain, or attract, qualified personnel; the risk that Discovery Labs will be unable to regain compliance with The Nasdaq Capital Market listing requirements prior to the expiration of the additional grace period currently in effect, which could cause the price of Discovery Labs' common stock to decline; the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten Discovery Labs' ability to continue as a going concern; the risks that Discovery Labs may be unable to maintain and protect the patents and licenses related to its products, or other companies may develop competing therapies and/or technologies, or health care reform may adversely affect Discovery Labs; risks of legal proceedings, including securities actions and product liability claims; risks relating to health care reform; and other risks and uncertainties 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.*

**Contact Information:**

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