

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**

**November 1, 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 November 1, 2010, Discovery Laboratories, Inc. (the “Company”) announced that the Office of Orphan Products Development of the United States Food and Drug Administration has granted orphan drug designation to Discovery’s KL4 surfactant for the treatment of cystic fibrosis.

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 and Exhibits.**

(d)       Exhibits

99.1      Press Release

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## 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/ John G. Cooper

Name: John G. Cooper

Title: President, Chief Financial Officer and  
Treasurer

Date: November 4, 2010

## Discovery Labs' KL<sub>4</sub> Surfactant Granted Orphan Drug Designation for the Treatment of Cystic Fibrosis

**Warrington, PA, November 1, 2010** — **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 KL<sub>4</sub> surfactant for the treatment of cystic fibrosis (CF). Orphan designation provides for up to seven years of U.S. market drug product exclusivity for the designated indication following marketing authorization.

Dr. Thomas F. Miller, Discovery Labs' Chief Operating Officer commented, "To date, Discovery Labs has successfully procured orphan designations for several respiratory disease targets in both the U.S. and Europe. We are pleased that the FDA's Office of Orphan Products Development has granted orphan designation for KL<sub>4</sub> surfactant for CF treatment."

CF is caused by a genetic mutation that leads to the production of thick, viscous mucus that is difficult to clear from the airways of the lung. The abnormal mucus allows for chronic airway infections that lead to airway destruction, decreased lung function, and ultimately, death. Dr. Miller continued, "Previous preclinical and exploratory clinical studies suggest that surfactant may improve mucociliary clearance, thereby potentially preventing further compromise of lung function. Our preclinical and recent clinical experience suggests that CF may be a viable therapeutic target for our aerosolized KL<sub>4</sub> surfactant technology."

Discovery recently announced the completion of a double-blind, randomized crossover Phase 2a study that evaluated the safety, tolerability and effectiveness of aerosolized KL<sub>4</sub> surfactant in a CF population. The trial was presented at the 2010 North American Cystic Fibrosis Conference, and the principle investigator concluded that aerosolized KL<sub>4</sub> surfactant delivery was feasible to CF patients, was generally safe and well tolerated, was not associated with serious adverse events (SAEs) and demonstrated evidence of pharmacologic response via improvement in mucociliary clearance (MCC) versus patient baseline. Previously, Discovery reported that KL<sub>4</sub> surfactant improved MCC in an established pre-clinical model designed to assess drug effect on mucociliary clearance.

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 receives marketing approval for the designated indication, orphan drug designation qualifies the sponsor for up to seven years of marketing exclusivity, tax credits related to clinical research, and exemption from the Prescription Drug User Fee Act filing fees. The Company is also in the process of applying for Orphan Designation for CF treatment in Europe.

### **About Cystic Fibrosis (CF)**

CF is a fatal genetic disease that causes life-threatening lung infections and premature death. It affects approximately 30,000 patients in the United States and nearly 70,000 worldwide. It is one of the most common genetic disorders in the United States. To date, treatment of pulmonary conditions in CF primarily includes antibiotics to address lung infection and airway clearance therapies to break down and remove mucus. Despite advances in research and medical therapies, the predicted median age of survival for patients with CF in the United States is currently 37 years.

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**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 and 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, including those related to Discovery Labs' pre-clinical and clinical research and development activities, are 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. Except as otherwise required by law, Discovery Labs undertakes no obligation to update or revise any forward-looking statements.*

**Contact Information:**

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