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 6, 2011

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

Discovery Laboratories, Inc. issued a press release today announcing that it submitted its Complete Response to the 2009 Complete Response Letter issued by the U.S. Food and Drug Administration (FDA) for SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants. A copy of the release is attached hereto as Exhibit 99.1 and the text of such release is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

99.1 Press release dated September 6, 2011

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 Chief Executive Officer

Date: September 6, 2011

Exhibit 99.1

Discovery Labs Submits SURFAXIN® Complete Response to FDA

Company Seeks FDA Approval for Use of SURFAXIN for the Prevention of Respiratory Distress Syndrome in Premature Infants

Warrington, PA – September 6, 2011 – Discovery Labs, Inc. (Nasdaq:DSCO) today announced that, on September 2, 2011, it submitted its Complete Response to the 2009 Complete Response Letter issued by the U.S. Food and Drug Administration (FDA) for SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants. Discovery Labs believes that the FDA will designate the Complete Response as a Class 2 resubmission of the SURFAXIN New Drug Application (NDA), which would result in a target review period of six months and potential approval of SURFAXIN in the first quarter of 2012. If approved, SURFAXIN would represent the first synthetic, peptide-containing surfactant for use in neonatal medicine.

In April 2009, Discovery Labs received from the FDA a Complete Response Letter, which contains the requirements that must be addressed to gain U.S. marketing approval for SURFAXIN. The safety and efficacy of SURFAXIN for the prevention of RDS in premature infants has been previously demonstrated in a large, multinational Phase 3 clinical program. The Complete Response Letter did not question the quality of the clinical trial data or call for additional clinical trials to demonstrate the safety or efficacy of SURFAXIN. The Complete Response Letter focused primarily on certain aspects of an important quality control release and stability test for SURFAXIN, the fetal rabbit biological activity test (BAT). Discovery Labs believes that a key step to potentially gain FDA marketing approval for SURFAXIN is to satisfy the FDA's requirements for final validation of the BAT. Accordingly, Discovery Labs has completed a comprehensive preclinical program intended to meet the FDA's requirements and has included these data in its Complete Response.

"We have had several productive interactions with the FDA related to our SURFAXIN comprehensive preclinical program to support the Complete Response," said W. Thomas Amick, Chairman of the Board and Chief Executive Officer, Discovery Labs. "Based on these interactions, we believe we have addressed all requirements of the 2009 Complete Response Letter."

In accordance with FDA guidance, Discovery Labs expects that it will be notified within 14 days that the Complete Response is deemed "complete" and the classification of the submission, which, under the Prescription Drug User Fee Act, will determine the target action date (PDUFA date) for the FDA to complete its review of the SURFAXIN NDA. Upon receipt of this notification, Discovery Labs plans to hold an investor conference call to provide an overview of the comprehensive preclinical program and the SURFAXIN Complete Response.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements, including about the remaining steps to potentially gain FDA approval of Surfaxin for the prevention of RDS in premature infants and the timing of the anticipated FDA review period. The final results of these and other ongoing activities could vary materially from Discovery Labs' expectations and could adversely affect the chances for approval of Surfaxin for the prevention of RDS in premature infants. These activities and the ultimate outcomes are subject to a variety of risks and uncertainties, including but not limited to risks that (i) although Discovery Labs believes that the FDA will deem Discovery Labs' formal response to be "complete" under its guidelines, the FDA may determine that the Complete Response filed by Discovery Labs is not "complete", potentially requiring Discovery Labs to conduct additional activities before it can re-file, if at all, the Complete Response, (ii) although the FDA guidance indicates that (x) the FDA will determine the class of the Complete Response submission and the PDUFA date and notify Discovery Labs within 14 days after receipt of the submission, and (y) assuming that the FDA determines that the Complete Response is a Class 2 resubmission, the FDA will complete its review of the NDA within six months after receipt of the submission, the FDA may not complete its activities within the time frames included in the FDA guidance, (iii) although Discovery Labs believes that it has been successful in generating the additional data and other information requested by the FDA, the FDA may not be satisfied and may require Discovery Labs to perform further studies or undertake other activities that are presently not contemplated by Discovery Labs, (iv) the FDA may not be satisfied with (A) Discovery Labs' responses to other items identified in the 2009 Complete Response Letter, or (B) the results of anticipated pre-approval inspections of Discovery Labs' manufacturing and analytical facilities and the facilities of third party laboratories and manufacturers of active pharmaceutical ingredients (APIs) and other materials used in the manufacture of Surfaxin, and, as a result, Discovery Labs may be unable to gain approval of Surfaxin, if at all, within the time frame indicated above, (v) Discovery Labs may identify problems that have not yet been discovered, and (vi) the FDA could impose additional requirements to gain approval of Surfaxin. Any failure to satisfy the FDA's requirements could significantly delay, or preclude outright, approval of Surfaxin, which could potentially prevent the approval of Discovery Labs' other products.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to create life-saving products for patients with respiratory disease and improve the standard of care for pulmonary medicine. Discovery Labs' novel proprietary KL4 surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized and aerosol formulations. Discovery Labs is also developing its proprietary drug delivery technologies – capillary aerosol generator and novel patient interface adapters – to enable efficient, targeted upper respiratory or alveolar delivery of aerosolized KL4 surfactant. Discovery Labs believes that its proprietary technology 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.

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 set forth in the Disclosure Notice, above and 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.

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