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 28, 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.

On September 28, 2011, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has deemed "complete" the Company's Complete Response for SURFAXIN® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA classified the review of the Complete Response as a Class 2 review and established March 6, 2012 as the target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for SURFAXIN. 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 28, 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 28, 2011

Exhibit 99.1

Discovery Labs Notified of PDUFA Date for SURFAXIN®

Conference call today at 3:00 PM EDT

Warrington, PA – September 28, 2011 - Discovery Laboratories, Inc. (Nasdaq: DSCO) announced today that the U.S. Food and Drug Administration (FDA) has deemed "complete" the company's Complete Response for SURFAXIN® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA classified the review of the Complete Response as a Class 2 review and established March 6, 2012 as the target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for SURFAXIN.

If approved, SURFAXIN would represent the first synthetic, peptide-containing surfactant for use in neonatal medicine and provide healthcare practitioners with a potential alternative to the currently approved, animal-derived surfactants that today are the standard of care to manage RDS in premature infants.

Discovery Labs will hold a conference call today at 3:00 PM EDT to provide an overview of the SURFAXIN Complete Response filed with the FDA.

Conference Call Details
A live webcast of the conference call, including a slide presentation, is available at https://us.reg.meeting-stream.com/surfaxin-update and www.discoverylabs.com. An archive of the webcast will be available on Discovery Labs Investor Relations web site for approximately 45 days.

For both "listen-only" participants and those who wish to take part in the question and answer portion of the call, the dial-in numbers are (866) 332-5218 (U.S.) or (706) 679-3237 (international). The passcode for the call is 11540927.

An audio replay of the conference call will be available two hours after the call's completion. The dial-in numbers for the replay are (855) 859-2056 or (404) 537-3406. The passcode for the replay is 11540927.

About RDS and SURFAXIN
RDS is a condition in which premature infants are born with an insufficient amount of their own natural pulmonary surfactant, a substance produced naturally in the lungs and essential for breathing. This condition often requires that infants receive surfactant replacement therapy (currently animal-derived surfactants) along with mechanical ventilation to survive. Approximately 90,000 premature infants in the United States are treated annually with the currently available animal-derived surfactants.

SURFAXIN is an investigational drug for the prevention of RDS in premature infants. A New Drug Application for SURFAXIN is under review by the U.S. FDA with a target date of March 6, 2012 for potential US marketing approval. If approved, SURFAXIN would represent the first synthetic, peptide-containing surfactant for use in neonatal medicine and provide healthcare practitioners with a potential alternative to the currently approved, animal-derived surfactants that today are the standard of care to manage RDS in premature infants.

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. In April 2009, the FDA issued to Discovery Labs a Complete Response Letter, which contained the requirements that must be addressed to gain U.S. marketing approval for SURFAXIN. The FDA 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. Rather, it 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. With the benefit of several interactions with the FDA, Discovery Labs completed a comprehensive preclinical program intended to meet the FDA's requirements. Data from the comprehensive preclinical program was included in Discovery Labs' Complete Response for SURFAXIN filed with the FDA on September 2, 2011.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements, including statements 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 related 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 the FDA guidance indicates that 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 this time frame, (ii) 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, (iii) 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 (iv) 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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