**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**

**June 10, 2013**

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 June 10, 2013, Discovery Laboratories, Inc. (the "Company"), announced that on June 7, 2013, it submitted its response to the U.S. Food and Drug Administration's (FDA) recent correspondence relating to the Company's recently updated product specifications for SURFAXIN®. The Company expects that the FDA may take up to four months to review the information provided. If its plan is successful and the FDA agrees with the response, the Company expects to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013. A copy of the press release is attached hereto as Exhibit 99.1 and the text of such release is incorporated by reference herein.

The updated change in SURFAXIN product specifications is expected to have no impact on the Company's development programs, including AEROSURF®. The AEROSURF program currently remains on track for the initiation of phase 2 clinical program in the fourth quarter of 2013.

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

(d) Exhibits

| | |
|---|---|
| 99.1 | Press release dated June 10, 2013 |

**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 our product development, our plans regarding the anticipated commercial introduction of SURFAXIN and AEROSURF, the anticipated strategic alliance for the development and commercialization of SURFAXIN LS and AEROSURF 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/ John G. Cooper
Name: John G. Cooper
Title: President and Chief Executive Officer

Date: June 10, 2013

**Exhibit 99.1**

**Discovery Labs Responds to FDA Request for Clarification of Recently Submitted SURFAXIN® (lucinactant) Updated Product Specifications**

**Warrington, PA — June 10, 2013** — Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today announced that on June 7, 2013 it submitted a response to the U.S. Food and Drug Administration's (FDA) recent correspondence relating to Discovery Labs' recently updated product specifications for SURFAXIN®. Discovery Labs expects that the FDA may take up to four months to review the information provided. If its plan is successful and the FDA agrees with the response, Discovery Labs expects to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013.

In the third quarter of 2012, during a routine review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, Discovery Labs determined that one of its analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was necessary. The Company proactively communicated these findings to the FDA, improved and revalidated the analytical chemistry method, and submitted updated product specifications to the FDA. Subsequently, the FDA requested information and provided recommendations intended to clarify certain aspects of the updated product specifications and the revalidated analytical chemistry method. Discovery Labs has now responded to the FDA's request.

Improvement of the method and the proposed change in SURFAXIN product specifications is expected to have no impact on Discovery Labs' development programs, including AEROSURF®. The AEROSURF program currently remains on track for the initiation of phase 2 clinical program in the fourth quarter of 2013.

**ABOUT SURFAXIN®**

SURFAXIN (lucinactant) Intratracheal Suspension is a synthetic, peptide-containing surfactant. SURFAXIN is indicated for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. The safety and efficacy of SURFAXIN for the prevention of RDS in premature infants was demonstrated in a large, multinational phase 3 clinical program that included 1294 patients.

**IMPORTANT SAFETY INFORMATION**
SURFAXIN is intended for intratracheal use only. The administration of exogenous surfactants, including SURFAXIN, can rapidly affect oxygenation and lung compliance. SURFAXIN should be administered only by clinicians trained and experienced with intubation, ventilator management, and general care of premature infants in a highly supervised clinical setting. Infants receiving SURFAXIN should receive frequent clinical assessments so that oxygen and ventilatory support can be modified to respond to changes in respiratory status.

Most common adverse reactions associated with the use of SURFAXIN are endotracheal tube reflux, pallor, endotracheal tube obstruction, and need for dose interruption. During SURFAXIN administration, if bradycardia, oxygen desaturation, endotracheal tube reflux, or airway obstruction occurs, administration should be interrupted and the infant's clinical condition assessed and stabilized.

SURFAXIN is not indicated for use in acute respiratory distress syndrome (ARDS).

For more information about SURFAXIN, please visit www.surfaxin.com.

**ABOUT AEROSURF®**
AEROSURF (lucinactant for inhalation), Discovery Labs' aerosolized $KL_4$ surfactant product, is under development to address respiratory distress syndrome in premature infants. Through the effective delivery of aerosolized $KL_4$ surfactant using Discovery Labs' proprietary capillary aerosol generator technology, AEROSURF may significantly expand the surfactant-eligible treatment population by providing neonatologists with a means of administering surfactant without the risks currently associated with invasive endotracheal intubation and mechanical ventilation.

**ABOUT DISCOVERY LABS**
Discovery Laboratories, Inc. is a specialty biotechnology company focused on advancing a new standard in respiratory critical care. Discovery Labs' novel proprietary $KL_4$ surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant. Discovery Labs is also developing its proprietary drug delivery technologies to enable efficient delivery of aerosolized $KL_4$ surfactant and other inhaled therapies. Discovery Labs' strategy is initially focused on neonatology and improving the management of respiratory distress syndrome (RDS) in premature infants. Discovery Labs believes that its RDS product portfolio has the potential to become the new standard of care for RDS and, over time, significantly expand the current worldwide RDS market.

For more information, please visit the Company's website at www.Discoverylabs.com.

**DISCLOSURE NOTICE**

While Discovery Labs expects that the FDA will agree with its submission and respond to its response within the time set forth above, there can be no assurance that the FDA will accept Discovery Labs' proposed updated product specifications and respond within the time set forth above, or that Discovery Labs will be able to proceed with the commercial introduction of SURFAXIN, if at all, in the fourth quarter of 2013. Any extended delay in the commercial availability of SURFAXIN could have a material adverse effect on Discovery Labs' ability to fund its operations and its development programs. Readers are referred to, and encouraged to read in their entirety, the Form 8-K that Discovery Labs filed with the Securities and Exchange Commission (SEC) concurrently with the issuance of this press release, and Discovery Labs' Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 that was filed with the SEC on May 7, 2013, which includes further detail on the Company's business plans and operations, financial condition and results of operations.

***Forward-Looking Statements***

*The information in this press release includes certain "forward-looking" statements relating, among other things, to Discovery Labs' correspondence with the FDA concerning its submission of updated SURFAXIN product specifications and the FDA's response containing recommendations and requests for information, and Discovery Labs' expectation that it will be able to proceed with the commercial sale of SURFAXIN in the fourth quarter of 2013. These and other similar statements included herein are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. While Discovery Labs currently believes that it will succeed in meeting the timelines outlined above, such forward-looking statements are subject to a variety of risks and uncertainties that could cause actual results to be materially different. Examples of such risks and uncertainties, including those related to the Company's research and development and commercialization programs, are described in Discovery Labs' filings with the SEC, including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement in this release speaks only as of the date on which it is made. Discovery Labs assumes no obligation to update or revise any forward-looking statements.*

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