**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**

**April 15, 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 April 15, 2013, Discovery Laboratories, Inc. (the "Company") issued a press release ("Press Release") announcing an update with respect to SURFAXIN® (lucinactant) intratracheal suspension. SURFAXIN is the first and only synthetic, peptide-containing surfactant approved by the U.S. Food and Drug Administration ("FDA") and the only alternative to animal-derived surfactants that today are the standard of care for respiratory distress syndrome (RDS) in premature infants. On October 24, 2012, the Company filed a Current Report on Form 8-K announcing that, during a review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, the Company had determined that one of its analytical chemistry methods used to assess its drug product's conformance to specifications required improvement and that an update to product specifications would be necessary. Thereafter, the Company communicated its findings to the FDA, improved and validated the analytical method, and submitted updated product specifications to the FDA. The Company anticipated that, if its efforts were successful and the FDA agreed with its submission, the availability of SURFAXIN drug product would be delayed until the second quarter of 2013. Recently, as set forth in the Press Release, the Company received a response from the FDA that requested clarification and provided recommendations regarding the recently updated product specifications for SURFAXIN.

The FDA correspondence includes a request for specific information intended to clarify certain aspects of the updated product specifications and the revalidated analytical chemistry method, including recommendations regarding how the product specifications should be documented and notated; a specific recommendation for the upper limit of a single product specification, which the Company can readily accept; a request for two existing and readily available documents related to the improved analytical chemistry method; and a request for supporting data using the recently improved and revalidated analytical chemistry method that is being generated from recent SURFAXIN batches. The Company plans to provide a response to the FDA within two months. FDA procedure provides up to four months for it to review the information provided. Based on the anticipated time required to respond and await confirmation from the FDA, the Company anticipates that, if its plan is successful and confirmed by the FDA within this timeline, 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.

Disclosure Notice

The information in the Press Release and this Form 8-K includes "forward-looking" statements relating, among other things, to the Company's plans regarding the commercial introduction of SURFAXIN drug product, including plans to prepare and submit to the FDA additional information supporting its request to update certain SURFAXIN product specifications. These and other similar statements are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. While the Company currently believes that it will succeed in meeting the timelines outlined in the Press Release and this Form 8-K, such forward-looking statements are subject to a variety of risks and uncertainties that could cause actual results to be materially different. These risks and uncertainties include, but are not limited to, the risk that the Company will be unable to successfully complete the work necessary to support its submission to the FDA within the timeline outlined above, if at all; risks that the FDA will not accept the Company's submission, or may require additional information that would require additional time, or may not respond within the time outlined in the guidelines set forth in the Prescription Drug User Fee Act (PDUFA) (which suggest four months for submissions of the type planned by the Company); and the risk that the Company may identify unforeseen problems that have not yet been discovered that could adversely affect the Company's plans. In addition, the FDA may determine to initiate a facility inspection to review the Company's approach and response to dealing with the issues identified in its review of the analytical method. Any failure to satisfy any issues raised by the FDA could significantly delay, or preclude outright, gaining agreement on acceptable updated product specifications, or could result in an action by the FDA to restrict the Company's ability to commercialize some or all of the Company's products, which could potentially delay or prevent the commercial availability of SURFAXIN drug product.

In addition, although the Company currently believes that it will be successful in meeting its strategic planning goals within the time frames outlined in the Press Release and this Form 8-K, there can be no assurance that the Company will be successful in identifying and implementing strategic and/or financial transactions, or otherwise, to provide the resources required to meet its near-term capital and other requirements, including with respect to the additional period required to deal with the recommendations and requests identified in the FDA correspondence; that the Company will be able to manufacture and release SURFAXIN drug product within the anticipated timeline, if at all, including to generate data for inclusion in the Company’s response to the FDA and for commercial sale in the fourth quarter of 2013; that during the period required to gain agreement with the FDA, the Company will be able to retain and attract commercial and medical affairs personnel to successfully execute and support the commercial introduction of SURFAXIN and AFECTAIR®, the Company’s disposable, aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units; that the revenues, if any the Company may realize from the sale of SURFAXIN and the sale of AFECTAIR devices, will be in line with current expectations and realized within the Company’s anticipated timing; that the Company will successfully identify one or more strategic partners or collaboration arrangements to support development and, if approved, commercial introduction of AEROSURF®, the Company’s drug/device combination product consisting of the Company’s $KL_4$ surfactant and capillary aerosol generator (CAG); that the Company will successfully initiate the planned phase 2 clinical program for AEROSURF in the fourth quarter of 2013, as planned, if at all, or that the Company will successfully develop and gain approval, in the United States and elsewhere, to market AEROSURF; or that the revenues, if any, that the Company generates in the future will be sufficient at any time to fund the further development of its research and development programs and support its operations. If the Company is unable to identify and enter into strategic or financial transactions to provide resources to support the commercial introduction of the Company’s products, including its manufacturing and commercial and medical affairs organizations and its operations, it may be unable to launch its products and therefore, would be unable to generate revenues from its approved products to support its business. If the Company is unable to identify and enter into strategic alliances and other transactions to support its operations and the development of, and if approved, commercialization of, its product candidates, including AEROSURF, the Company may be may be forced to limit its activities and potentially consider other means of creating value for its stockholders, such as licensing the development and/or commercialization of products that it otherwise would plan to develop itself. There can be no assurance that the Company’s efforts will be successful, that, if successful, will be completed within its anticipated timeline, or that the Company will be able to secure the resources necessary to support its activities when needed and on acceptable terms, if at all.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated April 15, 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 the Company’s product development 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: Chief Executive Officer, President and Chief Financial Officer

Date: April 15, 2013

**Exhibit 99.1**

**Discovery Labs Receives FDA Recommendations and Request for Clarification Regarding Recently-Submitted SURFAXIN® (lucinactant) Updated Product Specifications**

**Warrington, PA — April 15, 2013** — Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today announced that the U.S. Food and Drug Administration (FDA) has requested clarification and provided recommendations regarding the recently-updated product specifications for SURFAXIN®. Discovery Labs plans to provide a response to the FDA within two months. FDA procedure provides up to four months for FDA review of 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 validated the analytical chemistry method, and submitted updated product specifications to the FDA.

The recently-received FDA correspondence includes a request for specific information intended to clarify certain aspects of the updated product specifications and the revalidated analytical chemistry method, including:

- Recommendations regarding how the product specifications should be documented and notated
- A specific recommendation for the upper limit of a single product specification that Discovery Labs can readily accept
- A request for two existing and readily available documents related to the improved analytical chemistry method
- Request for supporting data using the recently improved and revalidated analytical chemistry method that is being generated from recent SURFAXIN batches.

“We appreciate the FDA’s recommendations,” said Dr. Russell G. Clayton, Senior Vice President, Research & Development, at Discovery Labs. “Our team is compiling the information and we will continue to communicate with the FDA to ensure our response meets its needs.”

Discovery Labs believes that its product portfolio and development pipeline based on KL4 surfactant and aerosol delivery technologies can bring transformational improvements to neonatal respiratory critical care. The current improvement and validation of the analytical chemistry method used to assess specification conformance for SURFAXIN drug product has no technical impact on the AEROSURF® program. The AEROSURF program currently remains on track for the phase 2 clinical program in the fourth quarter of 2013.

“We are committed to SURFAXIN, AFECTAIR® and AEROSURF with the goal of building a specialized biotechnology company that has the potential to establish new standards in respiratory critical care, beginning with neonatology,” said John G. Cooper, President and Chief Executive Officer at Discovery Labs. “As we address the FDA’s recommendations on SURFAXIN, we will also assess various strategic and financial alternatives to support the execution of our fundamental strategy.”

**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 (lucinactant) intratracheal suspension 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 AFECTAIR**
The AFECTAIR technology was developed as a proprietary, disposable device that simplifies the delivery of aerosolized medications to critical-care patients requiring ventilatory support such as intermittent mechanical ventilation or continuous positive airway pressure. To date, *in vitro* studies suggest that the AFECTAIR technology may be an effective new solution for delivering aerosolized medicine to infants receiving ventilatory support while providing healthcare professionals with a simplified alternative to current practices. According to national health statistics and internal market assessment data, it is estimated that each year approximately 355,000 pediatric patients in the United States are eligible to receive aerosolized medications while requiring ventilator support.

Discovery Labs is also pursuing European Conformity (CE) marking for potential commercialization of AFECTAIR for infants in the European Union (EU) in 2013.

**ABOUT AEROSURF**

AEROSURF (lucinactant for inhalation), Discovery Labs' initial 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**

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 to be filed with the SEC on or before May 10, 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' plans related to the recommendations and requests included in a recently-received FDA communication, its plans to manufacture and release SURFAXIN drug product, including to generate data for inclusion in its response to the FDA and for commercial sale in the fourth quarter of 2013, and its plans to prepare and submit to the FDA additional information supporting a request to update SURFAXIN product specifications within an anticipated two months. 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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