
**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**

October 3, 2013

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))
-

Item 8.01. Other Events.

On October 4, 2013, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing that the U. S. Food and Drug Administration has agreed to the Company’s updated product specifications for SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. The press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated October 4, 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, cash outflows, future revenues, the timing of planned clinical trials 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. Any forward-looking statement made by us in this Current Report on Form 8-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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: October 4, 2013



Discovery Labs Announces FDA Approval of SURFAXIN® (lucinactant) Updated Product Specifications

Commercial Introduction of SURFAXIN Planned for the Fourth Quarter of 2013

Warrington, PA — October 4, 2013 — Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today announced the U.S. Food and Drug Administration (FDA) has agreed to the Company's updated product specifications for SURFAXIN® (lucinactant) Intratracheal Suspension which was approved for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. The Company has initiated manufacturing of SURFAXIN for its planned commercial introduction in the fourth quarter of 2013. SURFAXIN is the first FDA-approved synthetic, peptide-containing surfactant available for the prevention of RDS in premature infants and the only approved alternative to animal-derived surfactants currently used today.

"We are pleased that the FDA has agreed with our updated product specifications and are appreciative of the process that has led to this decision," said John G. Cooper, Chief Executive Officer of Discovery Labs. "SURFAXIN represents the first milestone in our goal of transforming the treatment of RDS and is an important medical advancement for the neonatology community and parents of preterm infants who will soon have an effective alternative to animal-derived surfactants for the prevention of RDS."

ABOUT SURFAXIN

The U.S. Food and Drug Administration (FDA) approved SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants who are at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal derived surfactants.

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 DISCOVERY LABS

Discovery Laboratories, Inc. is a specialty biotechnology company focused on advancing a new standard in respiratory critical care. Discovery Labs' novel proprietary KL4 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 KL4 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.

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' plans to manufacture commercial lots of SURFAXIN and the timing of the commercial launch and market acceptance of SURFAXIN, 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. Any forward-looking statement in this release speaks only as of the date on which it is made. The Company assumes no obligation to update or revise any forward-looking statements.

Contact Information:

Investor Relations

Michael Rice, LifeSci Advisors: 646.597.6979 or mrice@lifesciadvisors.com

Public Relations

Michael Parks, Pitch360 Incorporated: 484.356.7105 or michael@pitch360inc.com

Company

John Tattory, Vice President, Finance: 215.488.9418 or jtattory@discoverylabs.com
