

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 1, 2011

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))
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Item 8.01. Other Events.

On June 1, 2011, Discovery Laboratories, Inc. filed a press release announcing that the Journal of Neonatal-Perinatal Medicine recently published a manuscript reviewing data analysis from the Surfaxin® (lucinactant) Phase 3 clinical trial program.

The press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

99.1 Press release dated June 1, 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/ John G. Cooper
Name: John G. Cooper
Title: President, Chief Financial Officer and
Treasurer

Date: June 1, 2011

Analysis of Surfaxin Data Presented in First Peer-Reviewed Manuscript Describing the Consequences of Reintubation in Preterm Neonates

Surfaxin treated infants observed to have lower incidence of reintubation, an independent risk factor for neonatal morbidity and mortality

Warrington, PA – June 1, 2011, — Discovery Laboratories, Inc. (Nasdaq:DSCO) announced that the *Journal of Neonatal-Perinatal Medicine*, a prominent, peer-reviewed journal widely distributed to neonatal and pediatric intensive care physicians, recently published a manuscript reviewing an important data analysis from the Surfaxin® (lucinactant) Phase 3 clinical trial program. The manuscript is entitled “Reintubation and risk of morbidity and mortality in preterm infants after surfactant replacement therapy” (Guardia et al.) in the *Journal of Neonatal-Perinatal Medicine* (Volume 4, Number 2, 2011). This is the first peer-reviewed manuscript describing neonatal patient compromise following reintubation.

The analysis demonstrates that, for preterm infants at risk for respiratory distress syndrome (RDS) who received prophylactic surfactant therapy and were extubated, subsequent reintubation is a highly predictive risk factor for mortality and major complications of prematurity. The analysis also indicates that infants treated with Surfaxin had a significantly lower incidence of subsequent reintubation and improved survival without reintubation, compared with infants who received comparator animal-derived surfactants Survanta® (beractant) and Curosurf® (poractant alfa), the current standard of care.

Premature infants are often born with a lack of natural lung surfactant resulting in a diagnosis of RDS. The current treatment for moderate to severe RDS typically requires that the infant be intubated (insertion of a breathing tube into the infant’s airway) to allow for respiratory support via mechanical ventilation and subsequent surfactant administration. If surfactant therapy appears to be successful, the endotracheal tube is removed from the infant’s airway (extubated) to allow the infant to breathe without mechanical support. However, infants who are extubated following surfactant therapy often relapse and require reintubation. Although increased mortality and morbidity in adults requiring reintubation is well described in medical literature, the consequences of reintubation in preterm infants have not been previously reported.

Data from Discovery Labs’ Phase 3 RDS clinical trials were assessed in a post-hoc analysis to evaluate the consequences of reintubation as well as the potential effect of surfactant choice on reintubation rates and subsequent clinical outcomes in preterm infants. The recently published manuscript highlights the following observations:

- Infants who were successfully extubated and did not require reintubation experienced low mortality rates across all treatment groups, while infants who were subsequently reintubated had a statistically significant higher mortality rate, 0.5% vs. 18%, respectively ($p < 0.05$).
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- Infants who required reintubation had significantly higher rates of six major complications of prematurity, including bronchopulmonary dysplasia (BPD, a chronic lung condition), necrotizing enterocolitis (a severe intestinal condition often requiring surgery and loss of bowel), sepsis, and intraventricular hemorrhage (bleeding into the brain).
- Infants treated with Surfaxin demonstrated a significantly lower reintubation rate compared with those infants treated with animal-derived surfactants, Curosurf (33% vs. 47% respectively; $p < 0.05$) and Survanta (35% vs. 43% respectively; $p < 0.05$).
- Infants treated with Surfaxin demonstrated a significantly higher combined outcome of survival without reintubation compared with those infants treated with animal-derived surfactants, Curosurf (67% vs. 53% respectively; $p < 0.05$) and Survanta (65% vs. 57% respectively; $p < 0.05$).

Dr. Russell Clayton, Vice President of Research and Development of Discovery Labs, commented, “This article is the first published full description of the consequences of reintubation in a preterm neonate population, clearly indicating that, when possible, neonatal medicine practitioners should choose therapeutic options that will optimize the chances of successful extubation. This analysis of our Phase 3 clinical trial data suggests that treatment with Surfaxin may result in lower reintubation rates compared with treatment with currently available surfactant products. We intend to expand upon this current analysis, with specific focus on understanding the potentially favorable impact on NICU health economics by reducing reintubation frequency in neonates.”

Surfaxin is an investigational drug product that has not been approved by the U.S. Food and Drug Administration (FDA) or any other world health regulatory authority. Top-line data of this post-hoc analysis was previously presented at the 2008 American Association for Respiratory Care (AARC) International Respiratory Congress. The full study results reported above include information that may be of interest to healthcare practitioners; however, the clinical relevance of this post-hoc analysis has not been fully established and further scientific investigation may be warranted.

About Surfaxin

Surfaxin[®] (lucinactant) is Discovery Labs’ lead product based on its proprietary KL₄ surfactant technology and represents the first synthetic, peptide-containing surfactant that, if approved, will provide healthcare practitioners with an alternative therapy to the currently-approved, animal-derived surfactants that are standard of care today. The safety and efficacy of Surfaxin for the prevention of RDS has previously been demonstrated in a comprehensive Phase 3 clinical program.

Discovery Labs filed a New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants and received a Complete Response Letter from the FDA in April 2009. Discovery Labs has been conducting a comprehensive preclinical program intended to satisfy the FDA’s requirements with respect to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit Biological Activity Test (BAT), and, if successful, anticipates filing a Complete Response to the 2009 Complete Response Letter in the third quarter of 2011. After an anticipated six-month FDA review cycle, which is expected to also include, among other things, pre-approval inspections of Discovery Labs’ manufacturing facility, quality assurance / quality control facilities, third-party raw material suppliers and testing laboratories, Discovery Labs anticipates the potential marketing approval of Surfaxin for the prevention of RDS in premature infants in the United States as early as the first quarter of 2012.

About the Journal of Neonatal-Perinatal Medicine (JNPM)

The JNPM is a quarterly journal that publishes, peer-reviewed work including original articles, editorials, reviews, case reports and research content. The mission of the JNPM is to strengthen research and education of the neonatal and perinatal community on the optimal physical, mental and social health and well-being of infants and pregnant mothers through highest quality publications on neonatal-perinatal medicine and to provide examples of best practices in order to improve the quality, safety and effectiveness of mothers-infants' healthcare worldwide. The vision for the journal is to be 'The Reference Journal' in the field of neonatology.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company developing surfactant therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. 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, aerosol and lyophilized formulations. Discovery Labs is also developing its proprietary capillary aerosolization technology and novel patient interfaces, 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: risks relating to the rigorous regulatory requirements required for approval of any drug or drug-device combination products that Discovery Labs may develop, including that: (a) Discovery Labs and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on the matters raised during regulatory reviews, or in connection with its ongoing interactions with the FDA, Discovery Labs may be required to conduct significant additional activities to potentially gain approval of its product candidates, if ever, (b) the FDA or other regulatory authorities may not accept or may withhold or delay consideration of any of Discovery Labs' applications, or may not approve or may limit approval of Discovery Labs' products to particular indications or impose unanticipated label limitations, and (c) changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval; risks relating to Discovery Labs' research and development activities, including (i) time-consuming and expensive preclinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or fail, and (ii) the need for sophisticated and extensive analytical methodologies, including an acceptable biological activity test as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities; risks relating to Discovery Labs' ability to develop and manufacture drug products, and capillary aerosol generators and patient interface systems for clinical studies, and, if approved, for commercialization of drug and combination drug-device products, including risks of technology transfers to contract manufacturers and problems or delays encountered by Discovery Labs, its contract manufacturers or suppliers in manufacturing drug products, drug substances and other materials and capillary aerosol generators and patient interface systems on a timely basis or in an amount sufficient to support Discovery Labs' development efforts and, if approved, commercialization; the risk that Discovery Labs may be unable to identify potential strategic partners or collaborators to develop and commercialize its products, if approved, in a timely manner, if at all; and other risks and uncertainties 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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