**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

**July 1, 2009**
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 July 1, 2009, Discovery Laboratories, Inc. (the "Company") issued a press release and on July 2, 2009 held a conference call reporting on the results of its June 2, 2009 end-of-review meeting with the U.S. Food and Drug Administration (FDA). The meeting was convened to discuss certain issues identified in an April 17, 2009 Complete Response Letter that the FDA had delivered to the Company with respect to the Company's new drug application for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The meeting focused primarily on the Surfaxin fetal rabbit biological activity test (BAT), a quality control stability and release test, and whether (i) data that had been previously submitted to the FDA and generated using both the BAT and a well-established preterm lamb model of RDS adequately supports the comparability between Surfaxin drug product used in Phase 3 clinical trials and the Surfaxin drug product intended to be manufactured for commercial use ("Comparability"), and (ii) the BAT can adequately distinguish change in Surfaxin biological activity over time.

At the meeting, the Company presented a compilation of previously-submitted data from the preterm lamb model and BAT studies, together with a comprehensive statistical evaluation of such data (in the form of a comparative regression analysis) that was intended to establish Comparability to the satisfaction of the FDA. The FDA stated, for the first time, that an agreement that it had reached with the Company in 2006 and 2008 to allow for establishing Comparability using the preterm lamb and BAT studies is unprecedented and the determination of whether the Company has adequately established Comparability is solely within the FDA's discretion. The FDA, for the first time, also stated that data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Based on this newly-defined standard, the FDA indicated that, from the FDA's perspective, the data analysis provided by the Company did not meet that standard. The FDA suggested that the comparability studies in the preterm lamb model and the BAT would not be necessary if the BAT had been implemented to assess Surfaxin drug product used in the Phase 3 clinical trials. As an alternative to demonstrating Comparability using the preterm lamb model and BAT, the FDA suggested that the Company could consider conducting a limited clinical trial employing only the BAT as a path forward to Surfaxin approval.

Although the Company could consider conducting a limited clinical trial to establish Comparability and potentially gain approval of Surfaxin, the Company believes that, given its strategic and financial priorities, it is more prudent to focus resources on the ongoing lyophilized and aerosolized surfactant development programs, including Surfaxin LS™ and Aerosurf®. The Company believes that Surfaxin LS™ and Aerosurf® have the potential to greatly advance the management of RDS and treat more patients suffering from RDS, while creating a significant economic opportunity.

In addition, at the June 2 meeting, with respect to the BAT, (a) the FDA commented that the data presented appears to confirm that the BAT can distinguish active from inactive drug product (although it had previously questioned whether the BAT, when compared to the preterm lamb model, could adequately monitor Surfaxin biological activity over time), and (b) the Company advised the FDA of ongoing efforts to further refine the BAT in accordance with the Company' continuing quality improvement initiatives. The Company believes that the BAT, as an ICH validated method, represents an acceptable quality control test to assess biological activity and is continuing to employ the BAT during the conduct of ongoing clinical trials addressing Acute Respiratory Failure and Cystic Fibrosis, consistent with guidance from the FDA, and plans to use the BAT in its pending clinical programs, Surfaxin LS and Aerosurf for RDS.

With respect to ongoing regulatory activities for Surfaxin, the Company has submitted proposed corrections and additions to the formal FDA minutes. Following finalization of the meeting minutes, the Company will determine its next course of action with respect to the Surfaxin NDA, which may entail further interaction with the FDA to assess whether Surfaxin approval can be gained without additional clinical trials, or potentially exercising its right of appeal through the FDA's Formal Dispute Resolution process.

The press release is attached as Exhibit 99.1 hereto.

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

(d) Exhibits

99.1 Press release dated July 1, 2009

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/ Robert J. Capetola

Name: Robert J. Capetola, Ph.D.
Title: President and Chief Executive Officer

Date: July 2, 2009

Exhibit 99.1

# Discovery Labs Reports on Surfaxin End of Review Meeting with FDA

*Conference Call Thursday, July 2, 2009 at 8:30 AM*

**Warrington, PA – July 1, 2009 -- Discovery Laboratories, Inc. (Nasdaq:DSCO)** announces today, after receipt of written minutes from the United States Food and Drug Administration, the results of its June 2, 2009 meeting with the FDA. This meeting followed the FDA's April 17 Complete Response Letter for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and was convened to discuss resolution of the remaining primary issue necessary for marketing approval of Surfaxin. The meeting focused on the Surfaxin fetal rabbit biological activity test (BAT, a quality control stability and release test), specifically whether data that had been previously submitted to the FDA and generated using both the BAT and a well-established preterm lamb model of RDS adequately supports the comparability of Surfaxin clinical drug product to commercial drug product, and whether the BAT can adequately distinguish change in Surfaxin biological activity over time.

At the recent June 2 meeting, Discovery Labs learned that the FDA will now apply a newly-defined standard to determine whether Discovery Labs has adequately demonstrated comparability of Surfaxin clinical to commercial drug product. This new standard represents a significant hurdle for approval of Surfaxin. Discovery Labs believes that the information provided to the FDA for the meeting demonstrates comparability and supports Surfaxin approval. However, in light of the FDA's newly-defined standard, Discovery Labs now believes that it is unlikely to satisfy this requirement with existing preclinical comparability data and gain Surfaxin approval in the near term.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "With agreement from the FDA, we have diligently pursued initiatives, including multiple preclinical experiments, that were expected to lead to Surfaxin approval for RDS. The totality of this work, along with the FDA's acknowledgment of the robustness of our Phase 3 clinical trial and the tremendous strides made in manufacturing and quality operations, led us to believe that we had comprehensively satisfied all of the FDA requirements. Per the June 2 meeting, the central remaining issue relates to whether data generated using the BAT and preterm lamb model of RDS supports the comparability of Surfaxin clinical to commercial drug product to the FDA's satisfaction. This comparability issue is limited to this New Drug Application and does not alter our existing clinical programs or development plans for our pipeline."

Discovery Labs will now focus on maximizing the inherent value of its novel $KL_4$ surfactant and aerosolization platforms and will minimize development risk by leveraging Surfaxin's established proof-of-efficacy in RDS. The two highest priority pipeline programs are Surfaxin LS™ and Aerosurf® -- drugs that have the potential to greatly advance the management of RDS and treat more patients suffering from RDS, while creating a significant economic opportunity. The synthetic nature and formulation flexibility of Discovery Labs' $KL_4$ surfactant platform also supports expansion into a wide range of respiratory disease conditions. Discovery Labs intends to pursue these opportunities through strategic alliances, although there can be no assurance that such alliances can be obtained.

**Comparability of Surfaxin Clinical Drug Product to Commercial Drug Product**

During Surfaxin's Phase 3 clinical trials, a leading academic neonatologist assessed the biological activity of the clinical batches by measuring respiratory compliance in a well-established preterm lamb model of RDS. After completing Surfaxin's Phase 3 clinical trials, in accordance with discussions with the FDA, Discovery Labs validated and implemented the BAT as a recurring quality control test to confirm biological activity for Surfaxin release and stability testing. Based on agreements reached in meetings with the FDA in 2006 and 2008, Discovery Labs conducted a series of preclinical experiments to establish comparability between Surfaxin drug product used in Phase 3 clinical trials and the Surfaxin drug product intended to be manufactured for commercial use. Accordingly, Discovery Labs initiated a series of side-by-side studies employing both the preterm lamb model of RDS and the BAT and believes that the correlated results demonstrate comparability and support approval of Surfaxin.

At the recent June 2 meeting, Discovery Labs presented a compilation of previously-submitted data from the preterm lamb model and BAT studies, together with a comprehensive statistical evaluation of such data, intended to establish to the satisfaction of the FDA comparability of clinical drug product to Surfaxin drug product to be manufactured for commercial use. The comprehensive statistical evaluation was a comparative regression analysis using an accepted FDA statistical method. Discovery Labs believes that the data and related statistical evaluation that it submitted to the FDA are highly supportive of the comparability of clinical drug product to commercial Surfaxin.

The FDA stated, for the first time, that the 2006 and 2008 agreement with Discovery Labs to establish comparability through these studies is unprecedented and the determination of whether Discovery Labs has adequately established comparability is solely within the FDA's discretion. The FDA now insists, for the first time, that data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Based on this newly-defined standard, the FDA indicated that to adequately establish comparability in this manner would be an extremely high hurdle and that, from the FDA's perspective, the data analysis provided by Discovery Labs did not meet that standard.

The FDA suggested that the comparability studies in the preterm lamb model and the BAT would not be necessary if the BAT had been implemented to assess Surfaxin drug product used in the Phase 3 clinical trials. Additionally, the FDA suggested that, to increase the likelihood of gaining Surfaxin approval and as an alternative to demonstrating comparability using the preterm lamb model and BAT, Discovery Labs could consider conducting a limited clinical trial employing only the BAT as a path forward to Surfaxin approval.

**The BAT as a Quality Control Drug Product Release Assay**

The BAT has been validated as a quality control test in accordance with current Good Manufacturing Practices and ICH guidelines and was implemented for Surfaxin release and stability testing as well as for Discovery Labs' other pipeline programs. The BAT is only one of numerous methods that Discovery Labs employs in an extensive quality surveillance program to assess quality and stability. These highly sophisticated tests monitor drug product quality at release and through shelf-life and represent very sensitive methods for detecting changes in quality over time.

At the June 2 meeting, the FDA commented that the data presented appears to confirm that the BAT can distinguish active from inactive drug product (although it had previously questioned whether the BAT, when compared to the preterm lamb model, could adequately monitor Surfaxin biological activity over time). Also at this meeting, Discovery Labs advised the FDA of ongoing efforts to further refine the BAT in accordance with Discovery Labs' continuing quality improvement initiatives.

Discovery Labs believes that the BAT, as an ICH validated method, represents an acceptable Quality Control test to assess biological activity. Accordingly, Discovery Labs is continuing to employ the BAT during the conduct of ongoing clinical trials addressing Acute Respiratory Failure and Cystic Fibrosis, consistent with guidance from the FDA, and plans to use the BAT in its pending clinical programs, Surfaxin LS and Aerosurf for RDS.

**Discovery Labs Going Forward**

As suggested by the FDA at the June 2 meeting, Discovery Labs could consider conducting a limited clinical trial to support comparability of clinical to commercial Surfaxin drug product and potentially gain approval. However, Discovery Labs believes that, given its strategic and financial priorities, it is more prudent to focus resources on the ongoing lyophilized and aerosolized surfactant development programs. Discovery Labs believes that the best way to address the global RDS patient population is to advance $KL_4$ surfactant programs that are intended to gain worldwide commercial approvals and target both traditional endotracheal tube delivery and novel, less-invasive surfactant administration through aerosolization. Surfaxin LS, Discovery Labs' initial lyophilized product, and Aerosurf, its initial aerosolized surfactant product, may provide benefits that will greatly advance the management of RDS and represent a significant improvement from a medical and economic perspective.

With respect to ongoing regulatory activities for Surfaxin, Discovery Labs has submitted proposed corrections and additions to the formal FDA minutes. Following finalization of the meeting minutes, Discovery Labs will determine its next course of action, which may entail further interaction with the FDA to assess whether Surfaxin approval can be gained without additional clinical trials, or potentially exercising its right of appeal through the FDA's Formal Dispute Resolution process.

"We have worked diligently to satisfy the requirements of the FDA but will now limit investment to gain regulatory approval of Surfaxin in the United States. Our top priority at this time is to leverage the totality of our Surfaxin experience and established pharmacology of our $KL_4$ surfactant to advance our robust pipeline. I firmly believe that the robust nature of our clinical experience and the tremendous progress that we have made in manufacturing and quality operations meaningfully reduces development risk in advancing our promising pipeline programs.

We are pioneering some of the most exciting science in the development of new surfactant applications to improve respiratory critical care medicine. We believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of therapeutic surfactant products targeted to treat a wide range of respiratory conditions. Our pipeline programs, including Surfaxin LS and Aerosurf, are focused on addressing unmet medical needs and represent significant market opportunities. Investing in this pipeline, we believe, is the best strategic decision for our patients, medical practitioners and other stakeholders," commented Dr. Capetola.

Discovery Labs will now focus its efforts primarily on the following lead pipeline programs:

- Respiratory Distress Syndrome (RDS) -- one of the most common, acute, potentially life-threatening disorders with more than 500,000 low birth weight premature infants at risk annually globally. Discovery Labs believes that the RDS market represents a significant opportunity from both a medical and business perspective.

    - Surfaxin LS is a lyophilized formulation of $KL_4$ surfactant, which is a dry powder that is reconstituted to a liquid surfactant prior to administration. This formulation has the potential to improve product flexibility and ease of use for healthcare practitioners, eliminate the need for cold-chain storage and may demonstrate characteristics that further improve product clinical performance. Discovery Labs is planning to meet with regulatory authorities this year with a view towards initiating a late-stage clinical development program in 2010.

    - Aerosurf is $KL_4$ surfactant in aerosolized form using Discovery Labs' proprietary Capillary Aerosolization Technology. The current RDS management approach, while life-saving, often results in serious respiratory conditions and complications due to the invasive method of administration. Aerosurf, if approved, holds the promise to significantly expand the use of $KL_4$ surfactant by providing neonatologists with a novel means of delivering $KL_4$ surfactant without invasive endotracheal intubation and mechanical ventilation. Discovery Labs has met with and received guidance from the FDA with respect to the design of its planned Phase 2 clinical program, which is expected to be initiated in 2010.

- In addition, Discovery Labs has initiated exploratory development programs targeting Acute Respiratory Failure (ARF), Acute Lung Injury (ALI), Cystic Fibrosis (CF), and the feasibility of drug combination therapies utilizing $KL_4$ surfactant:

    - ARF / ALI - Discovery Labs is conducting a Phase 2 ARF clinical trial to determine whether Surfaxin improves lung function and reduces duration of mechanical ventilation in children diagnosed with ARF following exposure to a pathogen infection such as influenza. Additionally, Discovery Labs has initiated a preclinical collaboration assessing the potential utility of aerosolized $KL_4$ surfactant in the prevention and treatment of Acute Lung Injury, a severe form of respiratory failure.

- CF - Aerosolized $KL_4$ surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in CF patients. The trial has been designed to assess the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized $KL_4$ surfactant in CF patients.

- Drug Combination Therapies - Discovery Labs has initiated a preclinical program to assess the potential utility of $KL_4$ surfactant either alone or in combination with the Capillary Aerosolization Technology as a novel approach for direct lung delivery of small and large molecule therapeutics.

**Conference Call Details**

Discovery Labs will hold a conference call on Thursday, July 2, 2009 at 8:30 AM EDT to further discuss the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available through a live broadcast on the Internet at http://investor.shareholder.com/media/eventdetail.cfm?mediaid=37583&c=DSCO&mediakey=A42F707AF3652FE376D31BE1F11CF04A&e=0 and **www.discoverylabs.com**. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 17638259.

**About Discovery Labs**

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' novel proprietary $KL_4$ Surfactant Technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol or lyophilized formulations. In addition, Discovery Labs' proprietary Capillary Aerosolization Technology produces a dense aerosol, with a defined particle size that is capable of potentially delivering aerosolized $KL_4$ surfactant to the deep lung without the complications currently associated with liquid surfactant administration.

Discovery Labs believes that its proprietary technology platform 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. Discovery Labs is focused initially on developing its $KL_4$ surfactant pipeline to build a pediatric franchise that will potentially address several respiratory conditions affecting neonates and young children. 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: (i) Discovery Labs and the U.S. Food and Drug Administration (FDA) will not be able to agree on the matters raised by the FDA during its regulatory review, or the FDA may require Discovery Labs to conduct significant additional activities to potentially gain approval of its product candidates, if ever, (ii) 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 (iii) *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 (a) time-consuming and expensive pre-clinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or fail, and (b) the need for sophisticated and extensive analytical methodologies, including an acceptable biological activity test, if required, 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 aerosolization 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 capillary aerosolization systems on a timely basis or in an amount sufficient to support Discovery Labs' development efforts and, if approved, commercialization; risks that (a) market conditions, the competitive landscape or otherwise, may make it difficult to launch and profitably sell products, (b) Discovery Labs may be unable to identify potential strategic partners or collaborators to market its products, if approved, in a timely manner, if at all, and (c) Discovery Labs' products will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community; the risk that Discovery Labs or its strategic partners or collaborators will not be able to attract or maintain qualified personnel; the risk that Discovery Labs will not be able in a changing financial market to raise additional capital or enter into strategic alliances or collaboration agreements, or that the ongoing credit crisis will adversely affect the ability of Discovery Labs to fund its activities, or that additional financings could result in substantial equity dilution; the risk that Discovery Labs will not be able to access credit from its committed equity financing facilities, or that the share price at which Discovery Labs may access the facilities from time to time will not enable Discovery Labs to access the full dollar amount potentially available under the facilities; the risk that Discovery Labs will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of Discovery Labs' common stock to decline; the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten Discovery Labs' ability to continue as a going concern; the risks that Discovery Labs may be unable to maintain and protect the patents and licenses related to its products, or other companies may develop competing therapies and/or technologies, or health care reform may adversely affect Discovery Labs; risks of legal proceedings, including securities actions and product liability claims; risks relating to reimbursement and health care reform; 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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