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

February 16, 2010
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 February 16, 2010, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that, in response to written guidance recently received from the U.S. Food and Drug Administration (FDA), it will now focus on a plan that entails solely performing additional preclinical work, instead of conducting a limited clinical trial, to potentially gain FDA marketing approval for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Based on prior guidance received from the FDA, the Company expected that a limited, pharmacodynamic-based (PD) clinical trial in preterm infants would be required to address the sole remaining Chemistry, Manufacturing & Control (CMC) issue regarding the final validation of a fetal rabbit Biological Activity Test (BAT, an important quality control release and stability test) necessary for Surfaxin approval. The recently-received guidance from the FDA advises that, since an acceptable and well-established animal model (preterm lamb) of RDS already exists, which could be used as an acceptable alternative to a clinical trial in human preterm infants, a PD clinical trial approach is not appropriate.

In September 2009, the Company discussed in detail with the FDA a proposed process to optimize the precision of the BAT method and its subsequent validation. Following the FDA's supportive assessment of the proposed optimization process, the Company initiated BAT optimization activities and a related revalidation program, which is well underway and presently meeting all pre-specified acceptance criteria. Upon successful conclusion of BAT optimization and revalidation, the Company plans to conduct a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and the well-established preterm lamb model of RDS.

The comprehensive preclinical program will employ several different Surfaxin batches to assess the short-term physiologic responses to Surfaxin (via measurement of respiratory compliance) after administration in both the preterm lamb model and the optimized BAT at various time points. The resulting data will be examined to evaluate the relative changes, over time, in biological activity upon Surfaxin administration to determine the degree of comparability between the optimized BAT and the preterm lamb model. The Company plans to seek FDA advice regarding important aspects of the preclinical program, including study design and appropriate success criteria and believes that continued interactions with the FDA are an important element in assuring the adequacy of the preclinical program.

The comprehensive preclinical program will utilize the Company's extensive experience with both the BAT and the well-established preterm lamb model and take into account (i) the FDA's recent supportive assessment of the Company's proposed BAT optimization and revalidation, (ii) the encouraging progress of the ongoing BAT optimization and revalidation, (iii) the FDA's recognition of the utility of the well-established preterm lamb RDS model as an acceptable animal model for human preterm RDS, and (iv) the Company's comprehensive experience and existing relationships with well-recognized academic centers of excellence who routinely employ the preterm lamb model and have demonstrated expertise in measuring respiratory compliance in this model.

The information in this Form 8-K includes certain “forward-looking” statements relating, among other things, to the Company’s understanding of the remaining questions identified in the April 2009 Complete Response Letter for Surfaxin that must be addressed to gain FDA approval of Surfaxin and the outcomes of the June 2, 2009 end-of-review meeting, the September 29, 2009 teleconference held with the FDA, and the recently-received written guidance from the FDA. Although the Company currently believes that it may still succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants, these activities and the ultimate outcomes remain 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, risks that (i) the FDA may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; and (ii) the Company may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin. Although the Company is encouraged that its revalidation processes are well underway and presently meeting all pre-specified acceptance criteria, even if the Company’s efforts to optimize and revalidate the BAT are successful, it may not succeed with its planned side-by-side studies or, even if it does succeed with the side-by-side studies, the FDA may not accept the results or may interpret the data in a different manner such that, ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to secure FDA approval or further delay associated with the FDA’s review process could potentially delay or prevent the approval of the Company’s other products and would have a material adverse effect on the Company’s business.

The press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated February 16, 2010

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/ W. Thomas Amick
Name: W. Thomas Amick
Title: Chairman of the Board and Interim Chief Executive Officer

Date: February 16, 2010

Discovery Labs Receives FDA Guidance Regarding Pathway to Potential SURFAXIN® Approval

Warrington, PA – February 16, 2010 -- Discovery Laboratories, Inc. (Nasdaq:DSCO) announced today that, in response to written guidance recently received from the U.S. Food and Drug Administration (FDA), it will now focus on a pathway that would entail solely performing additional preclinical work, instead of conducting a limited clinical trial, to potentially gain FDA marketing approval for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Based on prior guidance received from the FDA, Discovery Labs expected that a limited, pharmacodynamic-based (PD) clinical trial in preterm infants would be required to address the sole remaining Chemistry, Manufacturing & Control (CMC) issue regarding the final validation of a fetal rabbit Biological Activity Test (BAT, an important quality control release and stability test) necessary for Surfaxin approval. The recently-received guidance from the FDA advises that since an acceptable and well-established animal model (preterm lamb) of RDS already exists and this model could be used as an acceptable alternative to a clinical trial in human preterm infants, that a PD clinical trial approach is not appropriate. Compared to the conduct of a PD clinical trial, a comprehensive preclinical program, if successful, presents an opportunity to significantly reduce the time and expense required to gain potential Surfaxin approval and Discovery Labs believes a Complete Response could be submitted to the FDA in the first quarter of 2011.

The safety and efficacy of Surfaxin for RDS has previously been demonstrated in a comprehensive Phase 3 clinical program. Consistent with previous communications from the FDA, there continues to be no questions regarding clinical trial data and no indication that the FDA has any concerns related to other quality assurance tests or the manufacturing process for Surfaxin. The FDA has also acknowledged that Discovery Labs had successfully demonstrated in the preterm lamb model the comparability of Surfaxin clinical drug product to the to-be-marketed Surfaxin drug product.

Comprehensive Preclinical Program to Resolve Remaining CMC Issue

In September 2009, Discovery Labs discussed in detail with the FDA a proposed process to optimize the precision of the BAT method and its subsequent validation. Following the FDA's supportive assessment of the proposed optimization process, Discovery Labs initiated BAT optimization activities and a related revalidation program which is well underway and presently meeting all pre-specified acceptance criteria. Upon successful conclusion of BAT optimization and revalidation, Discovery Labs plans to conduct a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and the well-established preterm lamb model of RDS. The results from these studies are intended to satisfy the FDA as to the BAT's ability to adequately discriminate biologically active from inactive Surfaxin drug product and establish the Surfaxin drug product's final acceptance criteria (with respect to biological activity as assessed by the BAT) for release and ongoing stability. Discovery Labs believes that implementing these method improvements to optimize the BAT make it more likely that the

results of the planned preclinical program will demonstrate the level of comparability between data generated using the BAT and the preterm lamb model that the FDA requires.

The comprehensive preclinical program will employ several different Surfaxin batches to assess the short-term physiologic responses to Surfaxin (via measurement of respiratory compliance) after administration in both the preterm lamb model and the optimized BAT at various time points. The resulting data will be examined to evaluate the relative changes, over time, in biological activity upon Surfaxin administration to determine the degree of comparability between the optimized BAT and the preterm lamb model. The FDA has previously invited Discovery Labs to seek FDA advice with respect to the ongoing BAT optimization and revalidation process. Discovery Labs also plans to seek FDA advice regarding important aspects of the preclinical program, including study design and appropriate success criteria. Discovery Labs believes that continued interactions with the FDA are an important element in assuring the adequacy of the preclinical program.

The comprehensive preclinical program will utilize Discovery Labs' extensive experience with both the BAT and the well-established preterm lamb model and take into account (i) the FDA's recent supportive assessment of Discovery Labs' proposed BAT optimization and revalidation, (ii) the encouraging progress of the ongoing BAT optimization and revalidation, (iii) the FDA's recognition of the utility of the well-established preterm lamb RDS model as an acceptable animal model for human preterm RDS, and (iv) Discovery Labs' comprehensive experience and existing relationships with well-recognized academic centers of excellence who routinely employ the preterm lamb model and have demonstrated expertise in measuring respiratory compliance in this model.

W. Thomas Amick, Chairman and interim Chief Executive Officer of Discovery Labs, commented, "The comprehensive preclinical program as a path to resolve our remaining CMC issue represents a potentially streamlined approach to gaining potential Surfaxin approval, as compared to conducting a PD clinical trial. Discovery Labs believes that it is in an advantaged position to prospectively design the preclinical program to satisfy the FDA's requirements. We have worked productively with the FDA to advance the BAT optimization program and intend to avail ourselves of the FDA's willingness to provide continued guidance as we work through final steps for potential Surfaxin approval."

Discovery Labs has a number of significant development milestones through the next year. With respect to Surfaxin, Discovery Labs anticipates completing the BAT optimization program in the second quarter of 2010 which could position it to conduct the remainder of the preclinical program with a goal of filing a Complete Response for Surfaxin in the first quarter of 2011. Furthermore, Discovery Labs anticipates advancing its clinical programs for its RDS pipeline candidates, Surfaxin LS™ and Aerosurf® in 2010. Additionally, in the first half of 2010, Discovery Labs' KL_4 pipeline programs are expected to yield important Phase 2 clinical milestones, including results from an ongoing clinical trial in children up to two years of age with Acute Respiratory Failure and an investigator-initiated clinical trial for patients with Cystic Fibrosis. An important financial objective for Discovery Labs is to secure the necessary capital, preferably through strategic alliances, to advance these clinical-stage initiatives.

Background

In April 2009, Discovery Labs received a Complete Response Letter from the FDA with respect to its new drug application (NDA) for Surfaxin for the prevention of RDS in premature infants. The letter focused primarily on certain aspects of the BAT, specifically whether preclinical data generated using both the BAT and a well-established preterm lamb model of RDS adequately supports the comparability of Surfaxin clinical drug product to the to-be-manufactured Surfaxin drug product, and whether the BAT can adequately distinguish change in Surfaxin biological activity over time.

During the conduct of Phase 3 clinical trials, Discovery Labs employed an array of quality control tests, but did not employ the BAT to evaluate biologic activity of the Surfaxin clinical drug product. After completing the Phase 3 clinical trials, 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 guidance received from the FDA in meetings in 2006 and 2008, Discovery Labs conducted 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. These experiments employed the preterm lamb model of RDS.

Data from the preterm lamb experiments and BAT results, together with a comprehensive statistical evaluation of such data, were presented to and discussed with the FDA at an end-of-review meeting held on June 2, 2009. The evaluation was based on a comparison of regression lines, calculated using an accepted FDA statistical analysis. However, the FDA did not accept Discovery Labs' statistical analysis as a definitive demonstration of comparability and indicated that, to gain approval of Surfaxin with this approach, data generated from the preterm lamb model and BAT studies must also demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. At that time, both the FDA and Discovery Labs believed that, given expected variability of animal study results and the variability observed in the prior version of the BAT, it was unlikely that it could establish comparability applying the FDA's then-articulated standard.

At the June 2009 meeting, the FDA also suggested that, since Discovery Labs had not employed a fetal rabbit BAT during the conduct of its Phase 3 clinical trials, as an alternative to demonstrating comparability using preclinical studies, and to increase the likelihood of gaining approval of Surfaxin, Discovery Labs could consider conducting a limited clinical trial while simultaneously employing the BAT for release and ongoing stability testing of Surfaxin drug product. On September 29, 2009, Discovery Labs held a conference call with the FDA to discuss its plans to further optimize the BAT in accordance with its continuing quality improvement initiatives and to gain clarity as to whether a PD clinical trial would satisfy the FDA's requirement for a limited clinical trial. During that meeting, the FDA indicated that the concept of using a PD clinical trial to assist in the demonstration of the biologic activity of Surfaxin was acceptable and provided direction regarding certain trial design specifics. After incorporating the FDA's comments, Discovery Labs submitted the full protocol and supportive information for FDA review on November 16, 2009.

The recently received guidance from the FDA recognizes that since the well-established preterm lamb model represents an acceptable animal model of RDS, this model could serve as an alternative to a clinical trial in human preterm infants. Therefore, the FDA concluded that design and ethicality complexities make it inappropriate for Discovery Labs to pursue a PD clinical trial in human preterm neonates.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements relating, among other things, to Discovery Labs' understanding of the remaining questions identified in the April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin and the outcomes of the June 2, 2009 end-of-review meeting, the September 29, 2009 teleconference held with the FDA, and the recently-received written guidance from the FDA. Although Discovery Labs currently believes that it may still succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants, these activities and the ultimate outcomes remain 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, risks that (i) the FDA may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; and (ii) Discovery Labs may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin. Any failure to satisfy the issues raised by the FDA, in the Complete Response letter or in related discussions, could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially delay or prevent the approval of Discovery Labs' other products.

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. 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 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 pre-clinical 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, 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; 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; 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 (CEFFs), or that the minimum share price at which Discovery Labs may access the CEFFs from time to time will prevent Discovery Labs from accessing the full dollar amount potentially available under the CEFFs; the risk that Discovery Labs or its strategic partners or collaborators will not be able to retain, or attract, qualified personnel; the risk that Discovery Labs will be unable to regain compliance with The Nasdaq Global Market listing requirements prior to the expiration of the grace period currently in effect, which could eventually result in delisting of Discovery Labs' common stock and cause 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 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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