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 1, 2011
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:

☐ 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 February 1, 2011, Discovery Laboratories, Inc. (the "Company") issued a press release providing an expanded update regarding its ongoing efforts to file a Complete Response intended to gain U.S. Food and Drug Administration ("FDA") marketing authorization of Surfaxin® for the prevention of respiratory distress syndrome ("RDS") in premature infants. The Company previously announced on January 10, 2011, that the FDA had recently provided detailed, written direction in response to an earlier submitted proposal by the Company to its ongoing comprehensive preclinical program intended to gain Surfaxin approval.

The Company believes that a key remaining step to potentially gain FDA marketing approval for Surfaxin is to satisfy the FDA as to the final validation of the fetal rabbit biological activity test ("BAT"). The BAT is an important quality control release and stability test for Surfaxin. Final BAT validation is intended to satisfy the FDA with respect to the ability of the BAT to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product. The Company has been conducting a comprehensive preclinical program with regard to this key remaining step. The BAT has undergone a number of method refinements intended to optimize its performance and reduce assay variability. The optimized BAT has subsequently been used to generate data to support BAT validation as well as to demonstrate concordance between the BAT and the well-established preterm lamb model of RDS by performing a series of prospectively-designed, side-by-side preclinical studies (i.e., concordance studies). Data from the preterm lamb model and BAT concordance studies are intended to support final BAT validation and to demonstrate comparability of drug product used in the Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use.

The Company has been interacting with the FDA in an effort to ensure that the comprehensive preclinical program (and the Complete Response) ultimately will satisfy the FDA as to the final validation of the BAT. The FDA's most recent communication clearly indicates that several aspects of the Company's proposed approach to the BAT validation are reasonable and provides detailed, written direction regarding certain components of the Company's comprehensive pre-clinical program. The Company believes that it can incorporate the FDA's direction into its ongoing efforts to complete the comprehensive preclinical program and be in a position to file a Complete Response for Surfaxin by early third quarter 2011, which, after an anticipated six-month FDA review cycle, could lead to potential Surfaxin approval early in the first quarter 2012.

The press release is attached as Exhibit 99.1 hereto and the text of the press release is incorporated herein by reference to such exhibit.

The information in this Form 8-K includes certain "forward-looking" statements relating, among other things, to the Company's understanding of the recently-received written guidance from the FDA and the remaining questions identified in the FDA's April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin. Although the Company currently believes that it may still succeed in submitting a Complete Response and gaining approval of its New Drug Application for Surfaxin for the prevention of RDS in premature infants, anticipated activities will require that the Company raise significant amounts of additional capital. The Company has initiated activities relating to this most recent FDA communication, and is presently assessing whether to request further clarification from the FDA on certain technical aspects of the comprehensive preclinical program, and also anticipates potential further interactions with the FDA in advance of filing a Complete Response. Such potential interactions with the FDA could affect the ultimate timing, conduct and outcomes of remaining steps necessary to gain Surfaxin approval, including the potential filing of the Complete Response. In addition to uncertainties related to the FDA's review of the Complete Response, the Company presently anticipates that the FDA will likely inspect and otherwise assess the manufacturing and quality assurance/quality control facilities for Surfaxin including those of third-party raw material suppliers and testing laboratories. The outcomes of such FDA activities could also affect the ultimate timing and remaining steps necessary to gain Surfaxin approval. In addition, the foregoing 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 accept the additional data or may interpret the data in a different manner such that, ultimately, the FDA may not approve Surfaxin or that the FDA may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; (ii) the Company may be unable to complete the manufacture of additional Surfaxin batches to address the FDA's request for additional data in a timely manner, (iii) 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; (iv) the Company may be unable to raise sufficient additional capital, through financings, strategic collaborations, or otherwise; and (v) other risks included in the Company's most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. 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 the Company's other products and would have a material adverse effect on the Company's business.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated February 1, 2011

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 Chief Executive Officer

Date: February 2, 2011

Discovery Labs Provides Expanded Update Regarding its Program for Surfaxin® U.S. Marketing Authorization

Company to Hold Conference Call to Detail Progress Towards Surfaxin Complete Response

Warrington, PA — February 1, 2011 — Discovery Laboratories, Inc. (Nasdaq: DSCO) is providing an expanded update regarding ongoing efforts to file a Complete Response intended to gain U.S. Food and Drug Administration (FDA) marketing authorization for Surfaxin® for the prevention of respiratory distress syndrome (RDS) in premature infants. On January 10, 2011, Discovery Labs issued a press release reporting that the FDA had recently provided detailed, written direction in response to an earlier submitted proposal by Discovery Labs relating to its ongoing comprehensive preclinical program intended to gain Surfaxin approval. Throughout the conduct of the program, Discovery Labs has been interacting with the FDA and incorporating the FDA's guidance into its efforts to complete the program and file the Surfaxin Complete Response. The filing of the Complete Response is currently targeted for early third quarter 2011 and anticipated to lead to a potential approval early in the first quarter 2012.

The Company will host a conference call this morning at 10:00 AM EST to provide an update regarding certain activities relating to the Surfaxin Complete Response. The call-in number is 866-332-5218 (additional call-in information below).

If approved, Surfaxin would become the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine. The safety and efficacy of Surfaxin for neonatal RDS has previously been demonstrated in a large, multinational Phase 3 clinical program.

Surfaxin® for Neonatal RDS – Status of Comprehensive Preclinical Program for Filing Complete Response to Gain FDA Marketing Authorization

Discovery Labs believes that a key remaining step to potentially gain FDA marketing approval for Surfaxin is to satisfy the FDA as to the final validation of the fetal rabbit biological activity test (BAT). The BAT is an important quality control release and stability test for Surfaxin. Final BAT validation is intended to satisfy the FDA with respect to the ability of the BAT to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product. Discovery Labs has been conducting a comprehensive preclinical program with regard to this key remaining step. The BAT has undergone a number of method refinements intended to optimize its performance and reduce assay variability. The optimized BAT has subsequently been used to generate data to support BAT validation as well as to demonstrate concordance between the BAT and the well-established preterm lamb model of RDS by performing a series of prospectively-designed, side-by-side preclinical studies (i.e., concordance studies). Data from the preterm lamb model and BAT concordance studies are intended to support final BAT validation and to demonstrate comparability of drug product used in the Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use.

Discovery Labs has been interacting with the FDA in an effort to ensure that the comprehensive preclinical program (and the Surfaxin Complete Response) will ultimately satisfy the FDA as to the final validation of the BAT. The FDA's most recent communication clearly indicates that several aspects of Discovery Labs' proposed approach to the BAT validation are reasonable and provides detailed, written direction regarding certain components of Discovery Labs' comprehensive pre-clinical program. Discovery Labs believes that it can incorporate the FDA's direction into its ongoing efforts to complete the comprehensive preclinical program and be in a position to file a Surfaxin Complete Response by early third quarter 2011, which, after an anticipated six-month FDA review cycle, could lead to potential Surfaxin approval early in the first quarter 2012.

BAT Optimization and Final Validation: Before undertaking steps to optimize the BAT, Discovery Labs submitted a proposal to FDA outlining several specific method refinements intended to improve BAT performance and reduce assay variability. After taking into account the FDA's response, Discovery Labs incorporated the proposed method refinements into the BAT and conducted testing that demonstrates that all pre-specified acceptance criteria were met and that BAT optimization has resulted in a greater-than-40% reduction in assay variability relative to the BAT methodology that was employed prior to 2010.

Following BAT optimization, at the FDA's suggestion, Discovery Labs submitted an additional proposal regarding specific and detailed aspects of final BAT validation. With respect to certain technical criteria relating to final BAT validation, the recent communication directs Discovery Labs to increase the sample size of specified data sets by testing additional Surfaxin batches. Discovery Labs currently has data from several batches that have previously been manufactured and analyzed. To be responsive to FDA's direction, Discovery Labs has initiated and anticipates completing manufacture of additional Surfaxin batches in the first quarter of this year. The additional batches will be tested using the optimized BAT and the additional data will be incorporated into the Complete Response.

Concordance Studies – Throughout the conduct of the comprehensive preclinical program, Discovery Labs has interacted with the FDA on certain aspects of the concordance studies. Multiple Surfaxin batches have been used to assess the biological activity of Surfaxin via measurement of respiratory compliance at various time points across the proposed shelf-life in both the preterm lamb model and the optimized BAT. The FDA has previously indicated that, to gain Surfaxin approval, data generated in the concordance studies must demonstrate the same relative changes in biological activity over time in both models using both regression analysis as well as a point-to-point comparison. Discovery Labs has evaluated the concordance data generated to date by these models using both regression analysis and point-to-point comparisons. Discovery Labs believes that these data demonstrate the same relative changes in biological activity over time in both the optimized BAT and the preterm lamb models and support the comparability of drug product used in the phase 3 clinical program and Surfaxin drug product to be manufactured for commercial use.

The most recent proposal submitted by Discovery Labs to the FDA also requested clarification with respect to certain limited technical aspects of the concordance study. The FDA's response includes detailed direction with respect to generating limited additional confirmatory data through further concordance testing. Discovery Labs plans to generate these additional data for inclusion in the Complete Response, which data must be consistent with the concordance data generated to date.

DISCLOSURE NOTICE:

The information in this press release includes certain "forward-looking" statements relating, among other things, to Discovery Labs' understanding of the recently-received written guidance from the FDA and the remaining questions identified in the FDA's April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin. Discovery Labs has interacted with the FDA in an effort to ensure that the comprehensive preclinical program (and the Surfaxin Complete Response) will ultimately satisfy the FDA. In addition, Discovery Labs is presently assessing whether to request further clarification from the FDA on certain technical aspects of the comprehensive preclinical program. There can be no assurances, however, that the FDA will be satisfied with all aspects of the comprehensive preclinical program or that, should Discovery Labs request further clarification, that the FDA will provide further direction prior to the planned filing of the Complete Response. In any event, such potential interactions with the FDA or lack thereof could affect the ultimate timing, conduct and outcomes of remaining steps necessary to gain Surfaxin approval, including the potential filing of the Complete Response. In addition to uncertainties related to the FDA's review of the Complete Response, Discovery Labs presently anticipates that the FDA will likely inspect and otherwise assess the manufacturing and quality assurance/quality control facilities for Surfaxin including those of third-party raw material suppliers and testing laboratories. The outcomes of such FDA activities could also affect the ultimate timing and remaining steps necessary to gain Surfaxin approval.

The completion of the aforementioned activities will require Discovery Labs to raise significant amounts of additional capital and, notwithstanding, 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; (ii) Discovery Labs may be unable to complete the manufacture of additional Surfaxin batches within the time frame set forth above, (iii) 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; and (iv) Discovery Labs may be unable to raise sufficient additional capital, through financings, strategic collaborations, or otherwise. 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.

Surfaxin is an investigational drug product and is not approved by the FDA or any other world health regulatory authority for use in humans.

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 and 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 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.

Conference Call Details

Discovery Labs will hold a conference call today, February 1, 2011, at 10:00 AM EST to further discuss the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. An audio webcast will be available through a live broadcast on the Internet at http://us.meeting-stream.com/discoverylaboratories_020111 and www.discoverylabs.com. A replay of the conference call will be available two hours after the call's completion and remain available through February 8, 2011. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 40660551.

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 the Company's comprehensive preclinical program, development and manufacturing activities and related regulatory efforts, 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.

Contact Information:

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215-488-9490