

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**

April 20, 2009

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 April 20, 2009, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that, on April 17, 2009, it received a Complete Response letter from the U.S. Food and Drug Administration (FDA) with respect to the Company's new drug application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS).

In its Complete Response letter, the FDA focused on whether a Surfaxin biological activity test (BAT, a quality control stability and release test) can adequately distinguish change in Surfaxin drug product over time and whether the Company has adequately validated the BAT and determined its final acceptance criteria. Validation of the BAT would confirm the comparability of Surfaxin drug product used in the Surfaxin Phase 3 clinical trials to the commercial Surfaxin drug product. The Company believes that data already submitted to the FDA support the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product and demonstrate that the BAT can adequately distinguish change in Surfaxin over time and is an appropriate test for monitoring Surfaxin biological activity throughout its shelf-life. The Company plans to seek an end of review meeting with the FDA to be scheduled as soon as possible. If the meeting is successful, the Company anticipates that Surfaxin may be approved in 2009. The Complete Response letter also included, among other things, (i) a request to tighten one drug product specification, which can be readily implemented, (ii) routine requests to update safety and other information in the NDA, and (iii) information requests about certain regulatory matters. In addition, the FDA indicated that it has approved the trade name Surfaxin.

In connection with this development, the Company is analyzing all aspects of its business with an immediate intention to conserve cash. Although there can be no assurances, the Company is also exploring strategic alternatives, including, but not limited to, potential additional financings, as well as potential business alliances, commercial and development partnerships and other similar opportunities. The press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated April 20, 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, Ph.D

Name: Robert J. Capetola, Ph.D

Title: President and Chief Executive Officer

Date: April 24, 2009



Discovery Labs Receives Complete Response from FDA for Surfaxin[®] for Prevention of RDS

Conference Call Today at 9:00 AM

Warrington, PA — April 20, 2009 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced that, on April 17, 2009, it received a Complete Response letter from the U.S. Food and Drug Administration (FDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In its letter, the FDA focuses primarily on certain aspects of a Surfaxin biological activity test (BAT, a quality control stability and release test) that must be addressed before the Surfaxin application can be approved. Discovery Labs will host a conference call today at 9:00 AM. The call-in number for the conference call is 866-332-5218.

Discovery Labs believes that it has already submitted data necessary to respond to the questions raised by the FDA in the Complete Response letter and that its New Drug Application (NDA) is sufficient to gain marketing approval of Surfaxin. At this time, there are no questions regarding Discovery Labs' Phase 3 clinical trials, no comments regarding drug substance impurities, and no issues related to the manufacturing process for Surfaxin. Discovery Labs plans to seek an end of review meeting with the FDA to be scheduled as soon as possible. If the meeting is successful, Discovery Labs anticipates that Surfaxin may be approved in 2009.

In its Complete Response letter, the FDA focused on whether the BAT can adequately distinguish change in Surfaxin drug product over time and whether Discovery Labs has adequately validated the BAT and determined its final acceptance criteria. Validation of the BAT would confirm the comparability of Surfaxin drug product used in the clinical trials to the commercial Surfaxin drug product. Discovery Labs believes that data already submitted to the FDA support the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product and demonstrate that the BAT can adequately distinguish change in Surfaxin over time and is an appropriate test for monitoring Surfaxin biological activity throughout its shelf-life.

The BAT is only one of numerous methods that Discovery Labs employs in an extensive quality surveillance program to assess product quality and stability of Surfaxin. These highly sophisticated tests monitor the quality of Surfaxin at release and through its shelf-life and represent very sensitive methods for detecting changes in product quality and identifying defective product.

In the Complete Response letter, the FDA also indicated that Discovery Labs needs to tighten one drug product specification, which can be readily implemented. The Complete Response letter also contained routine requests to update safety and other information in the NDA as well as information requests about certain regulatory matters. In addition, the FDA has approved the trade name Surfaxin.

Discovery Labs is analyzing all aspects of its business with an immediate intention to conserve cash. Although there can be no assurances, Discovery Labs is also exploring strategic alternatives, including, but not limited to, potential additional financings, as well as potential business alliances, commercial and development partnerships and other similar opportunities.

Conference Call Details

Discovery Labs will hold a conference call today at 9:00 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=36511&c=DSCO&mediakey=EB96AB4A7B40B715E291DB6D44C8C635&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 95842655.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating, among other things, to Discovery Labs’ understanding of the remaining steps identified in the Complete Response letter dated April 17, 2009 that are necessary for FDA approval of Surfaxin for the prevention of RDS in premature infants and the timing of the anticipated FDA review period. Although Discovery Labs currently is hopeful that it will succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants within the timeline outlined above, these activities and the ultimate outcomes are 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) although Discovery Labs believes that it may be able to schedule an end of review meeting as early as 30 days following a written request, the guidelines require that the meeting be scheduled within 75 days of the request, which would delay the potential resolution of the issues identified by the FDA, potentially delaying the potential approval of Surfaxin; (ii) although Discovery Labs is hopeful that it will be able to reach agreement with the FDA with respect to the validation of the BAT, finalization of acceptance criteria for the BAT and use of the BAT to establish the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product, Discovery Labs and the FDA may not reach agreement with respect any or all of these issues; if Discovery Labs and the FDA do not reach agreement, the FDA will likely require Discovery Labs to perform further studies or undertake other activities, including potentially new clinical trials, that are presently not contemplated by Discovery Labs, and Discovery Labs may be unable to gain approval of Surfaxin, if at all, within the timeline indicated above; (iii) even if Discovery Labs were to agree to and did complete additional activities required by the FDA, the FDA may in the future require other activities as a condition to gaining Surfaxin approval, or may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; (iv) although Discovery Labs thinks it unlikely, the FDA may not be satisfied with Discovery Labs’ responses to other items identified in the Complete Response letter and Discovery Labs may be unable to gain approval of Surfaxin, if at all, within the timeline indicated above; (v) Discovery Labs may identify unforeseen problems that have not yet been discovered; and (vi) the FDA could impose additional requirements to gain approval of Surfaxin. Any failure to satisfy the issues raised by the FDA in the Complete Response letter 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 KL₄ 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 KL₄ 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 KL₄ 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 activities, if any, that will meet satisfy the FDA, (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) that 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 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; 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 build a successful sales and marketing organization 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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