**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**

**August 19, 2005**
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 August 19, 2005, Discovery Laboratories, Inc., a Delaware corporation (the "Company") announced that it had received formal written notification from the U.S. Food and Drug Administration (the "FDA"), following its review of the Company's previously submitted Response Letter, outlining items that need to be addressed in order for the FDA to deem the response complete. The Company's Response Letter to the FDA's Approvable Letter for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants was submitted to the FDA on July 29, 2005. The Company issued a press release providing this information on August 19, 2005. The full text of the press release is set forth in Exhibit 99.1 to this Current Report on Form 8-K.

On August 19, 2005, the Company held a conference call to provide an update of the status of its response to the FDA's Approvable Letter. The Company also provided clarification of the FDA regulatory process for Surfaxin's approval. The Company anticipates that in October 2005 it will submit its response (as an amendment to its Response Letter) to the items outlined by the FDA as requiring further clarification or additional information. The FDA has fourteen days from the date of that submission to respond to the Company as to whether that amendment, together with the previously submitted Response Letter, constitutes a complete response to its Approvable Letter. Should the Company's Response Letter, as amended, be deemed complete, the FDA has a six month target to complete its review of the Company's NDA for Surfaxin. Should the Company's October submission be considered by the FDA to complete the Company's Response Letter and the FDA meets its review cycle target, the Company anticipates that the FDA will approve the Surfaxin NDA in April 2006 with commercial launch to occur in the second quarter of 2006.

The Company also adjusted its previously communicated timelines for the potential European approval of Surfaxin by the European Medicines Evaluation Agency (EMEA) by announcing such approval is now anticipated in the second quarter of 2006. In addition, the Company provided adjustments to its previously reported estimates of quarterly net decreases in cash, cash equivalents, restricted cash and marketable securities (collectively, "Cash") for the third and fourth quarters of 2005. The Company is now projecting net decreases in Cash of $10 million and $12 to $12.5 million for the third and fourth quarters of 2005, respectively.

**Item 9.01. Financial Statements, Pro Forma Financial Statements and Exhibits**

(c) Exhibits:

99.1 Press Release dated August 19, 2005.

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: August 19, 2005

**Exhibit 99.1**

# Discovery Labs Provides Update on Status of Response to FDA Approvable Letter for Surfaxin®

Warrington, PA, August 19, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO) has received formal written notification from the U.S. Food and Drug Administration (FDA), following its review of the Company's previously submitted Response Letter, outlining select items that need to be addressed in order for the FDA to deem the response complete. The Company's Response Letter to the FDA's Approvable Letter for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants was previously submitted on July 29, 2005.

In its written notification, the FDA outlined twelve items, centered on chemistry and manufacturing, that require further clarification or additional information to support the Company's comprehensive response. These items are not related to the quality of the Surfaxin clinical trials or their results. Additionally, the items do not raise any new issues related to the Company's contract drug product manufacturer, Laureate Pharma, Inc. The Company is in the process of addressing these items and anticipates submitting its response to the FDA in October 2005. The approval of Surfaxin is now anticipated in April 2006 with commercial launch to occur in the second quarter of 2006.

Discovery will hold a conference call today at 10:00 AM EDT to further discuss in greater detail 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 to shareholders and interested parties through a live broadcast on the Internet at http://audioevent.mshow.com/251016 and **www.discoverylabs.com**. It is recommended that participants log onto one of these sites at least 15 minutes prior to the call. The Internet broadcast will be available for up to 30 days after the call at both website addresses.

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative for the animal-derived and non-protein containing synthetic surfactants. Discovery's Surfaxin has recently received an Approvable Letter from the FDA for the prevention of RDS in premature infants and is pending approval. Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. Premature babies are born with a lack of natural surfactant in their lungs. Without surfactant, the air sacs in the lungs collapse and are unable to absorb sufficient oxygen resulting in RDS.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating to the timing of FDA matters relating to Discovery’s NDA for Surfaxin for RDS, which assume that all of the conditions in the Approvable Letter are timely satisfied. Any statements contained in this press release that do not describe historical facts are forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include the following: uncertainties relating to Discovery Labs’ ability to successfully address the comments and concerns of the FDA that may be raised during its review process for the Surfaxin NDA; the timing of FDA actions regarding Surfaxin, including the timing of its review of the supporting data or the additional details submitted in relation thereto; the outcome of FDA actions in response to the submissions, including the possibility that the FDA will not consider the submissions complete or that the FDA will require additional information in support of the submissions; the possibility that even if the response is deemed complete by the FDA, the FDA could respond to these submissions by issuing an additional approvable letter with additional conditions for approval or the FDA could issue a not approvable letter; the ability to resolve final labeling for Surfaxin with the FDA; uncertainties regarding market acceptance of Surfaxin; uncertainties relating to third-party reimbursements; uncertainties relating to Discovery Labs’ ability to continue to operate at commercial scale in compliance with FDA regulations and other applicable manufacturing requirements; uncertainties relating to patents and proprietary rights; issues previously raised by earlier FDA inspections of the Totowa, NJ facility of Laureate Pharma, Inc. (Laureate), Discovery’s contract manufacturer for Surfaxin, and other risks identified in Discovery Labs’ Securities and Exchange Commission filings. Many factors could cause the resolution of those or other issues to differ materially from Discovery’s forward-looking statements, including that the timing, scope and duration of a resolution of the issues related to the Approvable Letter will depend on the ability of Discovery (and Laureate) to assure the FDA of the quality and reliability of its basic quality controls, process assurances and documentation requirements that support the commercial production manufacturing process under applicable cGMPs. The reader of this release should understand that the failure to reach resolution of any issues could result in delays in ultimate approval of Discovery’s potential products beyond the first quarter of 2006. Discovery Labs further cautions readers not to place undue reliance on any forward-looking statements which speak only as of the date they are made. Discovery Labs disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery’s technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has received an Approvable Letter from the FDA for Surfaxin, the Company’s lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and has filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Failures in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome (MAS) in full-term infants.

For more information, please visit our corporate website at www.Discoverylabs.com**.**

*To the extent that statements in this press release 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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. Among the factors which could affect Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery's internal sales and marketing organization will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by Discovery, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated risks and others are further described in Discovery'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.*

Company Contacts:

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