**UNITED STATES**
**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**

**February 1, 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:

[ ] 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, 2005, Discovery Laboratories, Inc., a Delaware corporation (the "Company") announced that the United States Food and Drug Administration (FDA) had issued an inspection report (Form FDA-483) to Laureate Pharma, L.P. (Laureate), the Company's contract manufacturer of Surfaxin®, citing certain observations concerning Laureate's compliance with current Good Manufacturing Practices (cGMPs) in connection with its review of the Company's New Drug Application (NDA) for Surfaxin for the prevention of Respiratory Distress Syndrome in premature infants. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. In response, the Company and Laureate submitted a cGMP Action Plan on January 31, 2005, outlining corrective measures anticipated to be completed by July 2005. Assuming the adequacy of such corrective actions and the approval of the Company's NDA for Surfaxin, the Company anticipates that the commercial launch of Surfaxin will occur in the fourth quarter of 2005. The Company's other clinical programs currently in progress are not affected by this inspection report and remain on track. However, if the inspection observations noted in the Form 483 are not resolved in the time period stated above, a delay may occur in these programs. The Company does not expect that the foregoing will have an effect on the Company's European regulatory filings. The Company issued a press release providing this update on February 1, 2005. The full text of the press release is set forth in Exhibit 99.1.

The Company anticipates receiving a Prescription Drug User Fee Act letter (PDUFA letter) from the FDA on or about February 13, 2005, the subject of which will consist of a review of the Surfaxin NDA, including information regarding the FDA's inspection activities with respect to Laureate. Based on the nature of the inspection observations contained in the Form 483, the Company currently anticipates that the PDUFA letter will constitute of a "Class 2" response. A "Class 2" response allows the FDA up to six months following the completion of the remedial actions outlined in the cGMP Action Plan to review the Company's response to the PDUFA letter and to conduct a reinspection of Laureate's subject facility in Totowa, NJ. However, the Company believes that soon after the FDA receives the Company's response to the PDUFA letter, an opportunity will exist for the FDA to permit the Company to address the cGMP Action Plan at the same time as the FDA's review of the Company's NDA for Surfaxin. In such case, the Company believes that the potential approval of Surfaxin could take place in the fourth quarter of 2005. There can be no assurance, however, that the FDA will agree to a parallel review and remediation approach, in which event the commercial launch of Surfaxin, if approved, could be delayed until at least the first quarter of 2006.

On February 1, 2005, the Company held a conference call where it disclosed that as of December 31, 2004, the Company had cash, cash equivalents, restricted cash and marketable securities of approximately $32.7 million. In addition, the Company reported that it currently had approximately $67.8 million available under its Committed Equity Financing Facility (CEFF) from Kingsbridge Capital Ltd., approximately $2.6 million available under its line of credit with PharmaBio Development Inc., and approximately $6.0 million available under its capital lease facility with the Life Science and Technology Finance Division of General Electric Capital Corporation, in each case subject to the terms and conditions of such facility or line of credit, as applicable.

In addition, the Company provided estimates of a net decrease in cash, cash equivalents, restricted cash and marketable securities of approximately $8.5 to $9.5 million for each of the first two quarters of fiscal year 2005, after taking into account its potential use of the line of credit available from PharmaBio. The Company also estimated that its current working capital is sufficient to meet planned activities into the fourth quarter of fiscal year 2005, before taking into account any amounts that may be available through use of the CEFF. The Company also reported that it was reassessing the revamping of its sales and marketing resources in light of the delayed potential commercial launch of Surfaxin. The Company also reported that it anticipates raising a minimum of $20 to $25 million in equity capital prior to the potential launch of Surfaxin, either through the terms of its existing financing arrangements or otherwise; provided that there can be no assurance that the Company will be able to obtain terms favorable to it or at all.

The Company continues to believe that it will need additional financing from investors or collaborators to complete research and development and commercialization of its current product candidates. The Company's working capital requirements will depend upon numerous factors, including, without limitation, the progress of its research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of pre-launch marketing activities, levels of resources that it devotes to the development of manufacturing and marketing capabilities, levels of resources that the Company's collaboration partners devote to the development of sales and marketing capabilities, technological advances, status of competitors, the Company's ability to establish collaborative arrangements with other organizations, the Company's ability to defend and enforce the Company's intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

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

(c) Exhibits:

99.1 Press Release dated February 1, 2005

Cautionary Note Regarding Forward-looking Statements:

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 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 release 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.**

Date: February 1, 2005

By: /s/ Robert J. Capetola

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

**Discovery Labs Provides Update on FDA Pre-Approval Inspection Activities Pertaining to Surfaxin® NDA Status**

*Conference Call today at 8:45 AM EST*

**Warrington, PA — February 1, 2005 —** Discovery Laboratories, Inc. (Nasdaq: DSCO) is providing an update regarding key pre-approval inspection activities conducted by the U.S. Food and Drug Administration (FDA) in connection with the review of Discovery's New Drug Application (NDA) for Surfaxin® for the prevention of Respiratory Distress Syndrome in premature infants. The reporting of these inspection activities and the review of the Surfaxin NDA are the subject of a PDUFA letter that the Company anticipates receiving from the FDA on or about February 13, 2005.

The FDA has conducted pre-approval inspections of the NDA's major components which include preclinical, clinical, chemistry, and manufacturing. To date, the results of the FDA's pre-approval inspections of Discovery's clinical data and clinical study sites have been extremely favorable. The Company believes that the clinical data is sufficient for approval and does not anticipate the need for additional trials to support approval.

With respect to manufacturing, the FDA recently issued a Form 483 to Laureate Pharma, Inc. (Laureate), Discovery's contract manufacturer of Surfaxin, citing inspection observations relating to compliance with current Good Manufacturing Practices (cGMPs) and other processes to be used for commercial production of the product. In response, Laureate and Discovery submitted a cGMP Action Plan on January 31, 2005 outlining measures intended to address the FDA's observations. The corrective actions outlined in the Action Plan are anticipated to be completed by July 2005. The commercial launch of Surfaxin, if approved, is now anticipated to occur in the fourth quarter of 2005.

The general theme of the inspection observations relates to basic quality controls, process assurances and documentation requirements that support the commercial production process. The Company believes that the Form 483 inspection observations are highly correctable in a reasonable period of time and do not relate to any clinical material produced to date. Based on the Form 483 issued to Laureate, Discovery now anticipates receiving a PDUFA letter constituting a Class 2 response, which will allow the FDA up to six months to review Discovery's NDA response and conduct a reinspection of Laureate's Totowa facility.

The FDA's Form 483 observations should be considered in light of the following:

- The raw materials contained in Surfaxin are purchased from third parties. These vendors have been inspected by the FDA with no significant observations noted to date.

- Discovery employs its own manufacturing equipment with its proprietary process on the premises of Laureate in Totowa, New Jersey. There are no fundamental flaws with the general manufacturing process of Surfaxin.

- There are no safety issues with the Surfaxin material that has been manufactured and shipped from Laureate to Discovery's clinical trial sites for use in its ongoing trials.

Discovery and Laureate have formed an Executive Steering Committee, consisting of Discovery's Chief Operating Officer, Laureate's President, and the Chairman of Laureate's Board of Directors, to oversee the correction of these observations in the shortest possible time.

Discovery's on-going clinical programs in Acute Respiratory Distress Syndrome in adults, Bronchopulmonary Dysplasia in premature infants, and aerosolized surfactant administered through nasal continuous positive airway pressure (nCPAP) for neonatal respiratory failures in premature infants are not affected and remain on track. If the inspection observations noted in the Form 483 issued to Laureate are not resolved in the time period stated above, a delay could occur in these programs.

Discovery will hold a conference call today at 8:45 AM EST. The call in number is 800-665-0669. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at **http://www.irconnect.com/primecast/dsco/481/** 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.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements relating to the plans and activities designed to resolve cGMP deficiencies identified by FDA. The resolution of the issues with the FDA is subject to substantial risks and uncertainties. Many factors could cause actual results to differ materially from the forward-looking statements made herein, including that the timing, scope and duration of the resolution of the manufacturing and cGMP issues will depend on the ability to assure the FDA of the quality and reliability of manufacturing systems and controls, and the extent of the remedial and prospective obligations to be undertaken. Other risk factors include that any failure to meet cGMP can result in delays in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for the production and sale of products, fines and other civil or criminal sanctions. For further details and a discussion of these and other risks and uncertainties, see Discovery's Securities and Exchange Commission filings, including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

**About Discovery Laboratories**

**Discovery Laboratories, Inc. is a biopharmaceutical 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 precisely engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human 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 filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of Respiratory Distress Syndrome in premature infants. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome in full-term infants.**

**More information about Discovery is available on the Company's Web site 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 the Company's product development, events conditioned on stockholder or other approval, 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 release 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 the Company's actual results and could cause results to differ from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, risks relating to the progress of the Company's research and development, the risk that the Company 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 the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that the Company's internal sales and marketing organization will not succeed in developing market awareness of the Company's products, risk that the Company'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 the Company, 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 the Company for any such drug product, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with adequate supplies of drug substance and drug products for completion of any of the Company's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of the Company'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 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.*

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