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

September 28, 2006
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 September 28, 2006, Discovery Laboratories, Inc. (the "Company") issued a press release to announce that it has filed a briefing package and requested a meeting with the U.S. Food and Drug Administration (the "FDA") to gain the FDA's agreement on the appropriate path towards Surfaxin® (lucinactant) approval for the prevention of Respiratory Distress Syndrome in premature infants. The press release also provides an update on the manufacturing activities. The press release, dated September 28, 2006, is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release, dated September 28, 2006.

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

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

Date: September 28, 2006

Exhibit 99.1

Discovery Labs Updates Progress on Manufacturing Remediation and Surfaxin® FDA Regulatory Matters

Files Briefing Package and Requests Meeting with FDA to Gain Clarity on Key Requirements Leading to Surfaxin Approval

Warrington, PA - September 28, 2006, -- Discovery Laboratories, Inc. (Nasdaq:DSCO), today has formally filed a briefing package and requested a meeting with the FDA to gain the Agency's agreement on the appropriate path towards Surfaxin® (lucinactant) approval for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The package covers certain key Chemistry, Manufacturing and Controls (CMC) matters contained in the April 2006 Surfaxin Approvable Letter received from the FDA, as well as detailing Discovery's comprehensive investigation and remediation of the process validation failure. Discovery anticipates that the meeting will occur in the fourth quarter of 2006.

Importantly, Discovery's investigation into the April 2006 Surfaxin process validation stability failure has determined a most probable root cause. Remediation activities have been implemented that are consistent with the manufacturing procedures that produced the Surfaxin lots used in Discovery's highly successful Phase 3 clinical studies, which demonstrated that Surfaxin was significantly more effective in the prevention of RDS and also improved survival versus comparator surfactants. Discovery remains on-track to commence the manufacture of new process validation lots in the fourth quarter of 2006.

The Approvable Letter contains CMC issues that predominantly relate to active ingredient and drug product specifications and related controls. Notably, the Approvable Letter did not indicate the need for additional clinical trials. To address the process validation stability failure Discovery conducted a comprehensive investigation focused on analysis of manufacturing processes; equipment and process validation; manufacturing components; drug substances; review and assessment of out-of-specification and deviation reports; analytical methods and method validation; and change control documentation. Discovery has been able, through the investigative process, to simultaneously address certain CMC issues.

Discovery has successfully manufactured numerous lots of Surfaxin that achieved a desired stability profile. In December 2005 Discovery acquired and took control of the Totowa, NJ manufacturing operations of Laureate Pharma, Inc. Concurrently, pharmaceutical executives with extensive manufacturing, regulatory, and quality assurance expertise joined Discovery's senior management team. The expertise of these executives coupled with the remediation outcomes is expected to enhance pharmaceutical development across Discovery's broad SRT product pipeline.

Per FDA guidance, the Agency should notify Discovery of the meeting date within 14 days of receipt of Discovery's request and briefing package, and such meetings should occur within 75 days of the written request. While significant progress in Discovery's manufacturing investigation and remediation has been made, the investigation is ongoing and when completed, Discovery intends to finalize a comprehensive investigation report and corrective action plan.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating to the potential results of Discovery’s ongoing manufacturing investigation and remediation and FDA approval of its NDA for Surfaxin. Although Discovery is encouraged by the findings of its investigation to date, the investigation is ongoing and the final results could vary materially from the indications obtained to date. Discovery currently believes that it will succeed in submitting its complete response to the second Approvable Letter, subject to the risks that the final investigation report may identify unforeseen problems that have not yet been discovered. The reader of this release should understand that the failure to satisfactorily investigate and remediate Discovery’s manufacturing issues could result in significant delays and prevent the approval of Surfaxin or other Discovery products.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing 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 its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting premature infants, children and adults.

Discovery’s lead product candidate, Surfaxin, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. Surfaxin® is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia in premature infants. Aerosurf™, Discovery’s aerosolized SRT, is being developed initially to treat premature infants suffering from respiratory disorders and is intended to obviate the need for intubation and conventional mechanical ventilation. Discovery’s SRT pipeline also includes programs addressing Acute Lung Injury, Acute Respiratory Failure, Cystic Fibrosis, Acute Respiratory Distress Syndrome, and other respiratory conditions.

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 aerosol and Surfactant Replacement Therapies), the risk that Discovery will not be able to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all, the risk that approval by the FDA or other health regulatory authorities of any applications filed by Discovery may be withheld, delayed and/or limited by indications or other label limitations, the risk 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 that the Chemistry, Manufacturing and Controls (CMC) section of Discovery’s New Drug Application will not satisfy the FDA, risk in the FDA or other regulatory agency review process generally, risks relating to the ability of Discovery or Discovery’s third party contract manufacturers and development partners to manufacture or provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery’s clinical studies, risks relating to drug manufacturing by Discovery, risks relating to the integration of manufacturing operations into Discovery’s existing operations, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery’s clinical studies, risks relating to the ability of Discovery and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery’s drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with Discovery’s collaboration arrangements, 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.

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

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