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

January 22, 2007
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 January 22, 2007, Discovery Laboratories, Inc. (the "Company") announced that it received guidance from the U.S. Food and Drug Administration ("FDA") regarding the key remaining steps necessary for potential approval of Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome ("RDS") in premature infants. The Company had previously filed a briefing package with the FDA in preparation for the meeting on December 21, 2006. The newly received guidance primarily indicates that the defined pathway to the potential approval of Surfaxin does not require additional clinical trials and that the shelf-life for Surfaxin will be determined based upon comparative stability data from historical Surfaxin batches (including previously manufactured clinical, technology transfer, and investigational batches), as well as newly manufactured process validation batches.

As previously disclosed, the Company received a second Approvable Letter from the FDA in April 2006, in which the FDA requested certain information primarily focused on the Chemistry, Manufacturing and Controls section of the Company's New Drug Application ("NDA") for Surfaxin. Based upon the recent FDA guidance, the Company anticipates filing its formal response to the April 2006 Approvable Letter in September or October 2007. Should the FDA deem such response complete, the agency has a six-month target to complete its review of the NDA. The press release, dated January 22, 2007, 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 January 22, 2007.

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: January 22, 2007

Exhibit 99.1

Discovery Labs and FDA Reach Clarity on Path Towards Surfaxin® RDS Approval

Conference Call Scheduled for Today at 11:00 AM

Warrington, PA — January 22, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO) announced today that it has received guidance from the U.S. Food and Drug Administration (FDA) in a recent meeting regarding the key remaining steps necessary for potential approval of Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The guidance provides the clarity and the defined pathway that Discovery believes is necessary to address key remaining issues identified in the April 2006 FDA Approvable Letter. Discovery anticipates filing its formal response to the Approvable Letter in September or October 2007, followed by a six-month review cycle by the FDA for potential approval of its New Drug Application (NDA) for Surfaxin.

The guidance was based on a face-to-face meeting with the FDA on December 21, 2006 as well as the FDA's review of the meeting briefing package submitted by Discovery on September 28, 2006.

- The defined pathway to potential Surfaxin approval does not include a requirement for additional clinical trials.

- The April 2006 Approvable Letter primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the Surfaxin NDA and requested additional information predominantly involving drug product specifications and related controls. With the clarity gained at the FDA meeting, Discovery expects to provide all of the necessary additional information in its formal response to the Approvable Letter.

- Discovery provided information to the FDA regarding its comprehensive investigation and remediation of the April 2006 Surfaxin process validation stability failure including the identification of a most probable root cause. The comprehensive investigation focused on analysis of manufacturing processes; analytical methods and method validation; and active pharmaceutical ingredient suppliers.

  Consistent with Discovery's proposal included in the FDA meeting briefing package, Discovery is planning to initiate the manufacture of new Surfaxin process validation batches this week and will submit six months of related stability data in its forthcoming formal response to the Approvable Letter. Additionally, the FDA indicated that Surfaxin shelf-life will be determined based upon comparative stability data from historical Surfaxin batches, including previously manufactured clinical, technology transfer, and investigational batches, as well as the new process validation batches.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "The encouraging outcome of this important FDA meeting is a reflection of the leadership and efforts of our team of regulatory, manufacturing and quality executives. This executive team is also responsible for improving and enhancing the manufacturing operations that we acquired from our then contract manufacturer. With the clarity gained from the FDA meeting, the top priorities now are completing the necessary work to submit our response to the FDA for Surfaxin approval, and advancing Aerosurf™, our aerosolized surfactant therapy, into Phase 2 clinical trials."

Conference Call Details
Discovery will hold a conference call today at 11:00 AM EST to further discuss the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at http://audioevent.mshow.com/319609 and **www.discoverylabs.com**. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 6538198.

About Surfaxin® and RDS
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 to animal-derived surfactants. Surfaxin's precision-engineered and non-immunogenic nature allows it to be further developed as a therapeutic addressing other pulmonary conditions in neonatal and pediatric medicine. Data from Discovery's pivotal, multinational SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. The SELECT and STAR (a supportive Phase 3 study) trials, as well as a pooled Phase 3 analysis, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*.

RDS afflicts approximately 120,000 premature infants in the United States each year, with a global at-risk population in excess of 500,000 infants. Approximately 75,000 infants are treated annually in the United States with currently-available surfactant products, all of which are animal-derived.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements relating to, among other things, the remaining steps necessary for FDA approval of Surfaxin for the prevention of RDS in premature infants, including information to be prepared for inclusion in Discovery's formal response to the second Approvable Letter and the potential results of Discovery's ongoing manufacturing investigation and remediation. Although Discovery is encouraged by its meeting with the FDA and the findings of its comprehensive investigation to date, both the development of information for the formal response to the second Approvable Letter and the comprehensive investigation are ongoing and the final results of both these efforts 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, including six months of stability data for the new process validation batches, within the indicated timeframe, subject, however, to a variety of risks, including that Discovery may not succeed in developing the information necessary for the formal response, the new process validation batches may fail to meet designated stability or other release parameters and the final comprehensive investigation report may identify unforeseen problems that have not yet been discovered. The reader of this release should understand that the failure to develop all necessary information required to respond to the second Approvable letter or to satisfactorily investigate and remediate Discovery's manufacturing issues could result in significant delays or additional requirements and potentially 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. 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, the success of Discovery's product development, 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 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 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.

Company Contact:

Lisa Caperelli, Investor Relations
215-488-9413