

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

October 1, 2007

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 October 1, 2007, Discovery Laboratories, Inc. (the "Company") issued a press release announcing that its new Surfaxin® (lucinactant) process validation batches have demonstrated acceptable stability at six months under the Company's comprehensive testing protocol. This six-month stability data will be included in a formal response to the U.S. Food and Drug Administration's (FDA) April 2006 Approvable Letter for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, to be filed with the FDA in the October 2007 timeframe, followed by an anticipated six-month review cycle by the FDA for the potential approval of the Surfaxin New Drug Application. The press release, dated October 1, 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 October 1, 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  
Name: Robert J. Capetola, Ph.D.  
Title: President and Chief Executive Officer

Date: October 4, 2007



## **Surfaxin® Process Validation Batches Achieve Stability Milestone to Enable Filing of Response to FDA Approvable Letter**

**Warrington, PA — October 1, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO)** today announces that its new Surfaxin® (lucinactant) process validation batches have demonstrated acceptable stability at six months under Discovery Labs' comprehensive stability testing protocol. This six-month stability data will be included, along with other data and information, in a formal response to the U.S. Food and Drug Administrations' (FDA) April 2006 Approvable Letter for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Discovery Labs remains on track to file its response to the FDA Approvable Letter in the October 2007 timeframe, followed by an anticipated six-month review cycle by the FDA for potential approval of the Surfaxin New Drug Application (NDA).

Discovery Labs manufactured three new Surfaxin process validation batches in 2007 after guidance was obtained from the FDA at a December 2006 meeting. At that meeting, Discovery Labs presented information regarding its comprehensive investigation and remediation of the April 2006 process validation stability failure. The meeting also established that Discovery Labs' new Surfaxin process validation batches must demonstrate acceptable stability through six-months prior to the filing of a formal response to the Approvable Letter. Since their manufacture, these new process validation batches have been monitored in accordance with a comprehensive stability testing protocol that complies with International Conference on Harmonization (ICH) guidelines, have demonstrated acceptable stability through six months, and will continue to be monitored through Surfaxin proposed shelf-life.

The FDA Approvable Letter for Surfaxin primarily focuses on the CMC (chemistry, manufacturing and controls) section of the Surfaxin NDA. The Approvable Letter does not require any additional clinical trials, but requests additional information predominantly involving drug product specifications and stability, analytical methods and related controls. In December 2006, Discovery Labs met with the FDA to clarify certain of the key CMC matters identified in the Approvable Letter, and obtain guidance on the appropriate path to potentially gain approval of Surfaxin. The FDA's guidance provided a defined pathway for Discovery Labs to generate additional data from selected experiments that are essential for approval of Surfaxin.

Discovery Labs believes it has made significant progress in addressing the outstanding CMC issues identified in the Approvable Letter and is currently focused on generating, compiling and analyzing supporting information for submission to the FDA. Discovery Labs believes that its progress to date, including achieving the six month process validation stability milestone, supports the filing of the formal response to the Approvable Letter in the October 2007 timeframe.

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## About Surfaxin®

Surfaxin, is a precision-engineered version of natural human lung surfactant and contains Discovery Labs' novel KL-4 peptide. Surfaxin, administered as a liquid-instillate, represents a potential alternative to the commercially available animal-derived surfactants. Data from Discovery Labs' pivotal, multinational SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and results in 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*. In addition, top-line results from Discovery Labs' Phase 2 clinical trial for the prevention and treatment of BPD suggested that infants treated with up to five incremental standard doses of Surfaxin tended to have a lower incidence of death or BPD, a higher survival rate through 36 weeks post-menstrual age, and fewer days on mechanical ventilation. Discovery Labs recently initiated a Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering from Acute Respiratory Failure (ARF). This new trial will explore the expanded application of surfactant therapy to pediatric critical care medicine.

**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 being prepared for inclusion in Discovery Labs' formal response to the Approvable Letter and the potential results of both Discovery Labs' comprehensive manufacturing investigation and the ongoing release and stability testing of the investigational batches and the new process validation batches. Although Discovery Labs is encouraged by the progress that it believes it has made to date, the development of data and other relevant information for the formal response to the Approvable Letter, including the release and stability testing of the investigational batches and the new process validation batches, are ongoing and the final results of these efforts could vary materially from the observations and results obtained to date. Discovery Labs currently believes that it will succeed in submitting its formal response to the Approvable Letter, with six months of successful stability data for the new process validation batches, within the timeframe indicated above, subject, however, to a variety of risks, including that (i) Discovery Labs may not succeed in completing its experiments or developing the data and other information necessary for the formal response, (ii) the new process validation batches may in the future fail to meet designated stability or other release parameters, and (iii) Discovery Labs 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 Approvable Letter, including at least six months of stability data for the new process validation batches, could result in significant delays or additional requirements and potentially prevent the approval of Surfaxin or other Discovery Labs products.

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## 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 Labs' technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery Labs' lead product candidate, Surfaxin<sup>®</sup>, 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 other neonatal and pediatric indications. Aerosurf<sup>™</sup>, Discovery Labs' aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

*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. Among the factors which could affect Discovery Labs actual results and could cause results to differ from those contained in these forward-looking statements are the risk that Discovery Labs may not profitably develop and market its products, the risk that financial market conditions may change, the risk that Discovery Labs will not be able to raise additional capital or enter into additional collaboration agreements, the risk that Discovery Labs will not be able to attract or retain qualified personnel or timely provide for a successful sales and marketing organization, risks relating to the progress of Discovery Labs research and development,, risks in the FDA or other regulatory agency review process generally, including that such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application or that approval by such regulatory agency may be withheld, delayed and/or limited by indications or other label limitations, risks that the Chemical, Manufacturing and Controls section of Discovery Labs New Drug Application will not satisfy the FDA, risks relating to the ability of Discovery Labs or Discovery Labs third party manufacturers and development partners to manufacture or provide Discovery Labs with adequate supplies of drug substances and expertise for completion of any of Discovery Labs clinical studies, risks related to the ability of Discovery Labs and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery Labs drug products with innovative aerosolization technologies, risks relating to drug manufacturing by Discovery Labs, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval process for any products that Discovery Labs may develop independently or with Discovery Labs collaboration arrangements, risks relating to the development by other companies of competing therapies and/or technologies, risks relating to reimbursement and health care reform, and risks relating to securities, product liability and other litigation. 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 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.*

### Company Contact:

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