

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

December 19, 2002  
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)
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350 Main Street, Suite 307  
Doylestown, Pennsylvania 18901  
(Address of principal executive offices)

(215) 340-4699  
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Item 5. Other Events

On December 19, 2002, Registrant issued a press release to announce an interruption in the supply of its Surfaxin(R) drug product for Part B of Registrant's ongoing Phase 2 clinical trial for Acute Respiratory Distress Syndrome (ARDS) in adults. Registrant presently anticipates that the completion of this part of the ARDS Phase 2 trial will now occur in the second quarter of 2003, a delay of approximately three months. The interruption in supply is not expected to have an effect on Registrant's other ongoing Phase 3 clinical trials for Surfaxin, including the two pivotal, landmark multinational Phase 3 trials for Respiratory Distress Syndrome (RDS) in premature infants and the Phase 3 clinical trial for Meconium Aspiration Syndrome (MAS) in full-term infants.

Item 7. Financial Statements, Pro Forma Financial Statements and Exhibits

(c) Exhibits:

99.1 Press Release dated December 19, 2002.

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

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Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

Date: December 20, 2002

Discovery Laboratories Announces Interruption in Supply of Surfaxin(R)for ARDS  
Phase 2 Trial - Completion Anticipated in Q2 2003

Conference call scheduled for Friday, December 20th at 8:45 AM EST

Doylestown, PA - December 19, 2002 - Discovery Laboratories, Inc. (Nasdaq: DSCO), a late-stage specialty pharmaceutical company leveraging its technology in humanized lung surfactants to develop novel respiratory therapies and pulmonary drug delivery products, announced today that it anticipates a delay in the supply of Surfaxin for Part B of its Phase 2 clinical trial for Acute Respiratory Distress Syndrome (ARDS) in adults. It is now anticipated that this trial will be completed in the second quarter of 2003, a delay of approximately three months. This delay is due to operational difficulties experienced by Akorn, Inc., Discovery's contract manufacturer. The difficulties being experienced by Akorn, are in no way expected to have an effect on Discovery's ongoing Phase 3 clinical trials for Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants.

In a recent press release, Akorn reported that they were experiencing operating difficulties in a production room primarily used for the filling of its customers' sterile pharmaceutical products. Akorn previously expected that this general purpose sterile production room would be operational in mid-November, however, it has not yet returned to full operational status. Akorn believes it has identified the problem and is in the process of returning this sterile production room to full operational status as soon as possible. It is important to note that the difficulties being experienced by Akorn do not involve Discovery's dedicated equipment, raw materials or process to formulate Surfaxin.

Christopher J. Schaber, Executive Vice President and Chief Operating Officer of Discovery commented, "We are in frequent contact with Akorn to effectively manage the impact on our ARDS Phase 2 study. Based on our discussions, we anticipate having our personnel back in their facility in February 2003 when the manufacture of Surfaxin for our ARDS clinical trial is expected to recommence. As for our ongoing Phase 3 clinical trials for RDS, we have an ample supply of Surfaxin to satisfy our needs."

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery commented, "Surfaxin for the treatment of ARDS holds great promise for respiratory medicine and we remain encouraged by the results of Part A of our Phase 2 ARDS trial. Of course, we are disappointed by this interruption. You should know that we have conducted a thorough analysis of our alternatives and considered several clinical drug supply strategies that would possibly have allowed us to optimize patient enrollment while this issue is being resolved. However, conducting our trials in accordance with the highest quality clinical standards is of paramount importance and we rejected all strategies that we believed might jeopardize the successful outcome of our trial."

Surfaxin is manufactured using Discovery-owned specialized equipment under the direct supervision of Discovery's manufacturing and quality control personnel. The drug is formulated and filled in a sterile production room. Discovery presently uses the sterile room facility and filling equipment of its contract pharmaceutical manufacturer, Akorn, Inc. Given the late stage development status of Surfaxin and in line with Discovery's strategy for potential commercialization, the Company's Board of Directors recently approved plans to invest approximately \$1.5 million in 2003 for certain manufacturing scale-up and enhancements, including additional equipment for scale-up at the Akorn facility and establishing alternative manufacturing capabilities with an additional contract manufacturer. This investment was a planned use of the approximately \$12.8 million gross proceeds from the recent November 2002 private financing.

The Company has scheduled a conference call and live audio Web cast for Friday, December 20, 2002 at 8:45 AM EST that is available to shareholders and interested parties on the Internet through <http://audioevent.mshow.com/77862> and at [www.discoverylabs.com](http://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 on both Website addresses.

About Discovery Laboratories, Inc.

Discovery Laboratories, Inc. is a specialty pharmaceutical company leveraging its platform technology in humanized lung surfactants to develop a number of potential novel respiratory therapies and pulmonary drug delivery products. Surfactants are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen. Discovery's technology is being developed initially for critical care patients with life-threatening respiratory disorders where

there are few or no approved therapies available. Surfaxin(R), Discovery's lead product, is currently in Phase 3 clinical trials for Respiratory Distress Syndrome (RDS) in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome (MAS) in full-term infants, and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome (ARDS) in adults. Aerosol formulations are being developed in an effort to treat other respiratory conditions such as asthma, chronic obstructive pulmonary disease, and acute lung injury, and as a novel pulmonary drug delivery vehicle to render drugs more effective when delivered to or via the respiratory tract. Discovery is developing a dedicated sales and marketing capability through a collaboration with Quintiles for the United States, and has a strategic alliance with Esteve for Europe and Latin America.

To the extent that statements in this press release are not strictly historical, including statements as to the Company's 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 including, without limitation, risks associated with the fact that we have presently validated only a single manufacturing facility for our drug product. There can be no assurance that the Company can produce sufficient quantities of drug product under current Good Manufacturing Practice conditions. Should a lack of sufficient drug product delay the completion of any of the Company's clinical studies including, without limitation, further delay of its Phase 2 clinical trial for ARDS, the Company may experience

additional costs that cannot be accurately estimated. Among other 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, the risk that the Company will not be able to raise additional capital or enter into additional collaboration agreements, risks relating to the progress of the Company's research and development and the development of competing therapies and/or technologies by other companies. Those associated risks and others are further described in the Company's periodic filings with the Securities and Exchange Commission including the most recent reports on Forms 10-KSB, 8-K, 10-QSB and 10-Q, and amendments thereto.