

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

November 25, 2003

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 and Regulation FD Disclosure

On November 25, 2003, the Company issued a press release to announce positive primary endpoint results of its pivotal, multinational, landmark phase 3 superiority clinical trial of Surfaxin(R) for Respiratory Distress Syndrome (RDS) in premature infants. This pivotal trial was designed as a controlled, prophylaxis, event-driven, superiority trial to demonstrate the safety and effectiveness of the Company's humanized lung surfactant, Surfaxin, over Exosurf (R), an approved non-protein containing synthetic surfactant with a reference arm to Survanta(R), the leading cow-derived surfactant used in the United States. The trial's independent Data Safety Monitoring Board (DSMB) informed the study's Steering Committee and the Company that the trial had achieved statistical significance in its co-primary endpoints for Surfaxin versus Exosurf. The results of this pivotal study, together with the successful results of an earlier RDS Phase 3 supportive study for Surfaxin versus Curosurf, are intended to form the basis for worldwide regulatory approval, including the filing of a new drug application with the FDA.

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

(c) Exhibits:

99.1 Press Release dated November 25, 2003

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: November 25, 2003

Discovery Laboratories Announces Positive Phase 3 Top-Line Results  
in Pivotal Trial of Surfaxin(R) for the Treatment of  
Respiratory Distress Syndrome in Premature Infants

Significant advancement in promising respiratory pipeline of Surfactant  
Replacement Therapies - Conference Call and Webcast Today at 11:00 a.m. EST

Doylestown, PA -- November 25, 2003 -- Discovery Laboratories, Inc. (Nasdaq: DSCO), announced today positive primary endpoint results of its pivotal, multinational, landmark phase 3 superiority clinical trial of Surfaxin(R) for Respiratory Distress Syndrome (RDS) in premature infants. The trial's independent Data Safety Monitoring Board (DSMB) informed the study's Steering Committee and Discovery that the trial had achieved statistical significance in its co-primary endpoints for Surfaxin versus Exosurf(R) (a non-protein containing synthetic surfactant). Survanta(R), a cow-derived surfactant, served as a reference arm in the trial. Discovery intends to use the results of this pivotal study, together with the successful results of an earlier RDS Phase 3 supportive study, to form the basis for a new drug application (NDA) with the United States Food and Drug Administration in the first quarter of 2004 and regulatory applications for approval in the rest of the world.

The DSMB, comprised of leading neonatologists, statisticians and a bioethicist, were responsible for monitoring the overall safety of the trial. The DSMB informed Discovery that statistical significance was achieved in favor of Surfaxin over Exosurf for the co-primary endpoints of RDS-related mortality through 14 days of life and the incidence of RDS at 24 hours of life. The DSMB also determined that the trial, originally estimated to enroll approximately 1500 patients, could be concluded at 1294 patients. The co-primary endpoint outcomes are as follows:

Co-Primary Endpoints	Surfaxin -----	Exosurf -----	Survanta -----	p-value Surfaxin vs. Exosurf
RDS related mortality through day 14	25/527 (4.7%)	49/509 (9.6%)	27/258 (10.5%)	0.001
Infants with RDS at 24 hours of life	207/527 (39%)	240/509 (47%)	86/258 (33%)	0.006

The DSMB noted no major safety issues during the enrollment phase of the trial. Discovery intends to announce further data relating to key safety and secondary outcome measures from this trial once such data becomes available, which is anticipated to be in the first quarter of 2004.

"More than 2.7 million premature infants are born worldwide each year at risk for serious complications or death from RDS. To treat this disease, doctors and parents are currently limited to using surfactants that are derived from pig and cow lung sources. These animal-derived therapies are clinically effective, but have inherent drawbacks. Tragically, there are hundreds of thousands of premature babies born in the world each year who need, but do not receive, effective surfactant replacement therapy," said Dr. Fernando Moya, Richard W. Mithoff Professor of Pediatrics and Director, Division of Neonatal-Perinatal Medicine at The University of Texas Medical School at Houston, a leading authority in neonatal medicine and the head of the trial's steering committee.

"For the first time in neonatal medicine, we have available in clinical trials, an engineered surfactant that has the most essential attributes of natural human lung surfactant, Surfaxin. These results are extremely encouraging for the pediatric community and represent a significant opportunity to improve the standard of care and provide treatment for RDS in premature infants around the world," continued Dr. Moya.

"These are extremely exciting results and we are grateful for the dedicated efforts of our clinical investigators worldwide," said Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery. "We now have used Surfaxin to treat infants with RDS at leading medical facilities throughout North America, Central and South America, as well as in Western and Eastern Europe. As a result, Surfaxin has gained broad exposure throughout the medical community. This announcement, along with our earlier positive Phase 3 RDS supportive data, and the data from Part A of our ongoing Phase 2 Acute Respiratory Distress Syndrome trial, adds to the series of positive results demonstrated by the clinical trials of our surfactant technology. We look forward to continuing our efforts to build one of the most innovative respiratory pipelines available."

Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer commented, "Our immediate priority is to complete the analysis of all of the study endpoints, assemble a high quality data package to support the filing

of an NDA, and submit the results of the trial for publication in a prominent peer-reviewed journal. We are pleased with the current progress of our manufacturing initiatives and will now increasingly focus on commercialization activities for the potential launch of Surfaxin."

"The neonatal community would welcome an alternative to the currently approved animal-based surfactants. Although these products represented a major advance in neonatal medicine, a number of us have always been concerned about the potential risks associated with the use of these cow- and pig-derived products," said Steven M. Donn, M.D., Professor of Pediatrics and Director of Neonatal-Perinatal Medicine at C.S. Mott Children's Hospital of the University of Michigan Health System. "These data represent an important advancement in treating RDS in infants with an improved, humanized surfactant that does not have the potential to cause adverse immunological responses or transmit animal-borne diseases, based on what we have seen so far," continued Dr. Donn.

About the Pivotal Phase 3 Trial and Discovery's Supportive Phase 3 Trial

The landmark, pivotal trial was designed as a multinational, multicenter, randomized, masked, controlled, prophylaxis, event-driven, superiority trial to demonstrate the safety and efficacy of Discovery's Surfaxin, which is engineered to closely mimic the most essential attributes of human lung surfactant, over

Exosurf, an approved, non-protein containing synthetic surfactant. Survanta, the leading cow-derived surfactant used in the United States, served as a reference arm in the trial. In addition to the co-primary endpoints, the study was designed to evaluate key safety parameters and secondary endpoints which are significant complications of prematurity. These secondary endpoints and certain safety data will remain blinded in accordance with the trial protocol through 36 weeks post conceptual age and long-term follow-up.

The co-primary endpoints and certain secondary endpoints were assessed by an independent adjudication committee comprised of leading neonatologists and pediatric radiologists. This committee provided a consistent and standardized method for assessing primary efficacy data in the trial. As part of the overall evaluation of trial safety, the DSMB also reviewed these adjudicated endpoints.

Discovery also recently announced positive results from its supportive RDS Phase 3 study that was designed as a non-inferiority trial comparing Surfaxin to Curosurf(R), a pig-lung extract believed by many of the world's leading neonatologists to be the best surfactant currently approved.

Surfaxin - an engineered surfactant with the potential to address RDS worldwide

Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. Premature babies are born with a lack of natural surfactant in their lungs. Without surfactant, the air sacs in the lungs collapse and are unable to absorb sufficient oxygen resulting in RDS. The current standard of care for treating these patients is Surfactant Replacement Therapy using animal-derived surfactants. Animal-derived products are prepared using a chemical extraction process from cow and pig lung washes or from the mincing of these animal lungs. Because of the inherent limitations of animal-derived products, the manufacture of large quantities of high quality product can be problematic and their use is largely limited to North America and Western Europe.

Discovery's Surfaxin is an engineered version of natural human lung surfactant and contains a peptide, sinapultide, that is designed to closely mimic the essential human lung surfactant protein B (SP-B). Surfaxin, unlike the animal products, can be produced in virtually unlimited quantities, in consistent pharmaceutical grade quality, and has no risk of potential transmission of animal-associated diseases.

Note to Investors

Discovery will hold a conference call today at 11:00 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 [www.irconnect.com/primecast/dsco/387](http://www.irconnect.com/primecast/dsco/387) and [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 at both website addresses.

## About Discovery Laboratories

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes in infants and adults, Acute Lung Injury, asthma, Chronic Obstructive Pulmonary Disease and upper airway disorders. Surfaxin, Discovery's lead product, is in Phase 3 and Phase 2 clinical trials for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Surfactants are compositions produced naturally in the lungs and essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung 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 critical care and other hospitalized patients.

More information about Discovery Laboratories is available on the Company's Web site at [www.discoverylabs.com](http://www.discoverylabs.com).

The results of the study reported today have not been submitted to or reviewed by any regulatory agency.

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), risks relating to the progress of the Company's research and development, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with sufficient amounts of drug products for completion of any of the Company's clinical studies, other risks relating to the lack of sufficient 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-KSB, 8-K, 10-Q and 10-QSB, and amendments thereto.

### Company Contacts:

John G. Cooper, SVP, CFO  
Kori Beer, IR & Communications  
215-340-4699