

UNITED STATES  
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

Date of Report (Date of earliest event reported) June 4, 2003



**DISCOVERY LABORATORIES, INC.**

(Exact name of registrant as specified in its charter)

<u>Delaware</u>	<u>000-26422</u>	<u>94-3171943</u>
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
<u>350 Main Street, Suite 307 Doylestown, Pennsylvania</u>		<u>18901</u>
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code

(215) 340-4699

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

**Item 5. Other Events**

On June 4, 2003, Registrant issued a press release to announce the conclusion of enrollment and results of key endpoints of its supportive Phase 3 multinational clinical trial of Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants. This supportive study was designed as a non-inferiority trial comparing Discovery's humanized lung surfactant, Surfaxin(R), to Curosurf(R), an approved pig-lung extract. Registrant also reported that further evaluation of secondary endpoints and safety parameters of this supportive clinical trial are currently being conducted.

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

(c) Exhibits  
99.1 Press Release dated June 4, 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        
Name: Robert J. Capetola,  
Ph.D.  
Title: President and Chief  
Executive Officer

Date: June 5, 2003

**Discovery Laboratories Announces Results of its Supportive Phase 3  
Clinical Trial of Surfaxin(R)for Respiratory Distress Syndrome  
in Premature Infants**

**Doylestown, PA – June 4, 2003 – Discovery Laboratories, Inc. (Nasdaq: DSCO)**, a late-stage specialty biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases, announces today the conclusion of enrollment and results of key endpoints of its supportive Phase 3 multinational clinical trial of Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants.

This supportive study was designed as a non-inferiority trial comparing Discovery's humanized lung surfactant, Surfaxin(R), to Curosurf(R), an approved pig-lung extract. Surfaxin is engineered to precisely mimic the essential attributes of natural human lung surfactant. Curosurf is believed by many of the world's leading neonatologists to be the best surfactant currently approved.

The key results from this supportive Phase 3 trial are derived from 252 patients enrolled at 23 trial sites located in the United States, United Kingdom, Spain, France, Poland, Hungary, Portugal, and Canada. The primary endpoint of this trial, considered to be one of the most clinically important factors in evaluating RDS infants, is the incidence of being both alive and without chronic lung disease (commonly called bronchopulmonary dysplasia, or BPD) at 28 days of age.

Based on preliminary analysis of the data, the following encouraging key results are summarized:

1. Patients Alive and Without BPD at 28 Days of Age -- Surfaxin was statistically equivalent to Curosurf and demonstrated an approximate 14% relative difference in favor of Surfaxin for this endpoint.
2. All Cause Mortality at 28 Days of Age -- Surfaxin was statistically equivalent to Curosurf and demonstrated an approximate 27% relative difference in favor of Surfaxin for this endpoint.

Further evaluation of secondary endpoints and safety parameters of this supportive clinical trial are currently being conducted. A detailed analysis of the data from this trial will be presented at the European Society for Pediatric Research (ESPR) meeting in Bilbao, Spain in September 2003.

Thomas E. Wiswell, M.D., a Professor of Pediatrics, Division of Neonatology, SUNY at Stony Brook, a leading neonatologist and member of Discovery's Scientific Advisory Board commented, "It is exciting to have this study, for the first time in neonatal medicine, demonstrate that an engineered humanized surfactant, Discovery's novel Surfaxin, is at least as efficacious as one of the leading animal-derived surfactants. Although the currently approved animal-derived surfactants are clinically effective, they have potential drawbacks. There are hundreds of thousands of premature babies born in the world each year that need and do not receive effective surfactant replacement therapy.

I am optimistic about Surfaxin. Surfaxin mimics the most active protein found in human surfactant (the essential surfactant protein, SP-B) and, in contrast to the animal-derived products, Surfaxin has the potential to be produced in virtually unlimited quantities, at lower costs, and without infectious or antigenic consequences. I anxiously await the results of Discovery's ongoing pivotal, landmark trial in the fall of this year."

Premature babies are born with a lack of natural surfactant in their lungs. Without this surfactant the air sacs in the lungs will collapse and be unable to absorb sufficient oxygen. The current standard of care for treating these patients is Surfactant Replacement Therapy using animal-derived surfactants. These products are prepared using a chemical extraction process from minced cow and pig lung. Because of the inherent limitations of animal-derived products, the manufacture of large quantities of high quality product can be problematic. Discovery's Surfaxin, as a synthetic, engineered surfactant, is intended to address this limitation. Surfaxin, unlike the animal products, can be produced in virtually unlimited quantities and has no risk of potential transmission of animal-associated diseases.

Sunil Sinha, M.D., Ph.D., F.R.C.P, a leading European neonatologist and a Professor of Paediatrics at South Cleveland Hospital, United Kingdom, stated, "Discovery's Surfaxin is a surfactant of the highest quality and no other lung surfactant like it is currently available. In this trial, leading clinicians in Europe and North America treated infants at risk for RDS with this humanized, engineered lung surfactant. These results are very exciting for the paediatric community and strongly suggest that Surfaxin is as good as Curosurf, which is considered to be the "benchmark" of animal-derived surfactants. Surfaxin is designed to overcome the limitations of animal-derived surfactants, such as the inability to supply doctors outside of Western Europe and the United States with a surfactant to treat the approximately 2.5 million infants that are presently without this life-saving therapy.

Doctors and parents currently have no choice in treating RDS infants other than with surfactants that are derived from pig and cow sources. These important results offer the promise that Surfaxin, without the drawbacks of the animal-derived versions, could be available to treat infants at risk for and suffering from RDS in the near future. The worldwide paediatric community looks forward with great anticipation to reviewing the full data at the ESPR meeting in September 2003."

Discovery is also conducting a pivotal, multinational landmark Phase 3 trial for RDS infants that is intended, if successful, to provide the basis for New Drug Applications with the FDA and other worldwide regulatory authorities. This pivotal trial is designed to treat up to 1,500 patients and demonstrate the superiority of Surfaxin over the only commercially available synthetic surfactant and has a reference arm comparing Surfaxin to a bovine-derived (cow) surfactant. This pivotal trial is expected to be completed and data announced early in the fourth quarter of 2003. In order to reallocate resources from our supportive Phase 3 RDS trial to this pivotal Phase 3 trial, we decided to conclude the supportive Phase 3 RDS trial at this time.

### About Discovery Laboratories

Discovery Laboratories, Inc. is a specialty pharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes, Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disease (COPD), and upper airway disorders. Discovery's surfactant technology produces an engineered version of natural human lung surfactant that is designed to precisely mimic the essential properties of human lung surfactant. Discovery believes that through its surfactant technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for hospitalized and ambulatory patients. Surfaxin, Discovery's lead product, is in three Phase 3 and two Phase 2 clinical trials for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Discovery's first aerosol surfactant product is positioned to enter clinical trials for hospital patients with severe asthma or acute lung injury. Discovery has a commercialization alliance with Quintiles Transnational Corp. and a strategic alliance with Laboratorios del Dr. Esteve S.A.

*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 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 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. 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-QSB and 10-Q, and amendments thereto.*

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