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

December 3, 2004
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 1.01. Entry into a Material Definitive Agreement.

On December 3, 2004, Discovery Laboratories, Inc. (the "Company") and Laboratorios del Dr. Esteve S.A. ("Esteve") entered into an Amended and Restated Sublicense and Collaboration Agreement (the "Collaboration Agreement"); an Amended and Restated Supply Agreement (the "Supply Agreement"); and a Common Stock Letter Agreement (the "Common Stock Letter Agreement"). In entering into these three agreements, the Company and Esteve restructured their strategic alliance for the development, marketing and sales of the Company's products in Europe and Latin America. The Company's press release announcing the restructured strategic alliance is attached hereto as Exhibit 99.1.

Collaboration Agreement

In amending the Collaboration Agreement, the Company regained full commercialization rights for its surfactant replacement therapy ("SRT") products including Surfaxin, for Respiratory Distress Syndrome ("RDS") and Acute Respiratory Distress Syndrome ("ARDS") in Central America, South America and most countries in Europe. Esteve retained the commercialization rights for Andorra, Greece, Italy (including the Republic of San Marino and the Vatican City), Portugal, and Spain (collectively, the "Licensed Territory"). In consideration for regaining commercial rights for such markets, (i) the Company issued to Esteve 500,000 shares (the "Shares") of common stock, par value $.001 per share, of the Company ("Common Stock") for no cash consideration and (ii) the Company agreed to pay to Esteve 10% of cash up-front and milestone fees (not exceeding $20 million in the aggregate) that the Company may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain of the Company's SRT products in the territory for which the Company had previously granted a license to Esteve.

The Company granted to Esteve rights to additional potential SRT products in the Company's pipeline, including: (i) the Company's neonatal intensive care unit SRT pipeline including Surfaxin for RDS and Bronchopulmonary Dysplasia, SRT for Meconium Aspiration Syndrome and aerosol formulations for Neonatal Respiratory Failures administered through nasal continuous positive airway pressure; and (ii) the Company's Hospital SRT pipeline including Surfaxin for ARDS, and aerosol formulations for Acute Lung Injury, Asthma and Chronic Obstructive Pulmonary Disease. In addition, the Company granted to Esteve the right to practice the methods which relate to the development or therapeutic use of such licensed products which are proprietary to the Company or with respect to which the Company has the power or right to grant such license.

Subject to prior termination as provided in the Collaboration Agreement, Esteve's exclusive right of first negotiation regarding the right to license future products developed by the Company in the territory has been amended so as to be limited to a maximum of two future products. The term for such right of first negotiation has been extended until December 3, 2009. In addition, the Collaboration Agreement specifies that any such future collaborative agreements would provide for suitable up-front cash payments and cash milestones and shared responsibility for clinical development work and expenses related to the new technology. Esteve would be responsible for customary commercialization activities and costs associated with any such future products and the Company would be responsible for the manufacture of any such future products.

Primarily upon attainment of marketing regulatory approvals from the European Agency for the Evaluation of Medicinal Products ("EMEA") for the covered SRT products, Esteve shall pay to the Company certain specified cash amounts. Esteve will contribute to Phase 3 clinical trials for the covered SRT products, by conducting and funding development performed in the Licensed Territory.

Several committees comprising three representatives from each of Esteve and the Company will be responsible for managing and overseeing the relationship between the parties. The overall strategic relationship between Esteve and the Company will be managed and governed by a steering committee, while a development committee will oversee the development in the Licensed Territory of the products licensed to Esteve and a commercialization committee will oversee the commercialization in the Licensed Territory of such products.

Supply Agreement

Pursuant to the Supply Agreement, Esteve will pay to the Company a transfer price on sales of Surfaxin and other SRT products greater than the transfer price provided for prior to the amendment. The Company will be responsible for the manufacture and supply of all of Esteve's product requirements under the Supply Agreement, including Surfaxin. Esteve will be responsible for all sales and marketing in the Licensed Territory.

Common Stock Letter Agreement

Pursuant to the Common Stock Letter Agreement, the Company issued the Shares to Esteve in consideration for Esteve's agreement to enter into the Collaboration Agreement. During the term of the Collaboration Agreement, Esteve has agreed: (i) that it will not purchase or become the beneficial owner of any shares of Common Stock which would result in Esteve and its affiliates beneficially owning more than nineteen percent (19%) of the issued and outstanding shares of Common Stock and (ii) that it will not knowingly sell the Shares to a person or entity which actively sells, distributes, markets, develops, or produces a pharmaceutical product which directly competes with the Company. Esteve will have up to two "demand" registration rights that require the Company to register the Shares for resale under the Securities Act of 1933 (the "Securities Act"). In addition, subject to certain limitations, Esteve has customary "piggyback" rights to include the Shares in other registrations of securities filed by the Company for resale under the Securities Act. Until the earlier of such time as Esteve beneficially owns less than 1.5% of the issued and outstanding shares of Common Stock of the Company or the completion of the Company's annual meeting of shareholders for the calendar year 2006, Esteve has agreed to vote in favor of all persons nominated by the then current Board of Directors for election to the Board of Directors and otherwise in accordance with the recommendations of the Board of Directors with respect to any issues other than those relating to the agreements between the Company and Esteve.

Esteve is a significant shareholder of the Company and Antonio Esteve, Ph.D., Director of Scientific and Commercial Operations of Esteve, serves as a member of the Company's Board of Directors.

Item 3.02. Unregistered Sales of Equity Securities.

As described in Item 1.01, the Company entered into a Common Stock Letter Agreement with Esteve on December 3, 2004, pursuant to which the Company has issued the Shares to Esteve for no additional consideration. The Shares have not been registered under the Securities Act and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act. As a result of the issuance of the Shares, the Company expects to take a charge against earnings equal to approximately $4.2 million for the fourth quarter of fiscal 2004. The Shares were issued to Esteve in a private transaction exempt from registration pursuant to Section 4(2) of the Securities Act.

Item 8.01. Other Events.

On December 7, 2004, the Company issued a press release to announce preliminary data from its Surfaxin Phase 2 clinical trial for the treatment of ARDS in adults. The full text of the press release is set forth in Exhibit 99.2 hereto.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits:

99.1	Press Release dated December 7, 2004.
99.2	Press Release dated December 7, 2004.

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: December 9, 2004

Discovery Labs and Esteve Restructure Their Strategic Alliance

Discovery regains rights in key European markets and Latin America

Esteve broadens access to SRT products and will commercialize in key Southern European markets.

Warrington, PA — December 7, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO) and Laboratorios del Dr. Esteve S.A. (Esteve) have restructured their strategic alliance for the development, marketing and sales of Discovery's products in Europe and Latin America. Under the revised collaboration, Discovery has regained full commercialization rights in key European markets, Central America and South America for its Surfactant Replacement Therapies (SRT), including Surfaxin® for Respiratory Distress Syndrome (RDS) in premature infants and Acute Respiratory Distress Syndrome (ARDS) in adults. Esteve will focus on the key Southern European markets, and now has development and marketing rights to a broader portfolio of Discovery's potential SRT products. This restructured collaboration supersedes the existing sublicense and supply agreements between Discovery and Esteve entered into in March 2002.

The company will host a conference call today at 11:00 AM EST. The call in number is 800-665-0669.

On December 3, 2004 Discovery and Esteve agreed to restructure their business arrangements by entering into amended collaboration, supply and common stock agreements. The key arrangements and terms are as follows:

Discovery regained full commercialization rights for its SRT products including Surfaxin, for RDS and ARDS in Europe (excluding Southern Europe which is retained by Esteve, as mentioned below), Central America, and South America. In connection with regaining the commercial rights for these markets:

- Discovery issued 500,000 shares of its common stock to Esteve at no cost to Esteve.

- Discovery will pay Esteve 10% of cash up-front and milestone fees that Discovery may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain of its SRT products in the territory previously licensed to Esteve. The total amount of such cash payments by Discovery to Esteve shall not exceed $20 million.

Esteve will retain full commercialization rights in its core operating markets in Southern Europe, principally Spain, Italy, Portugal and Greece. Discovery has granted Esteve rights to additional potential SRT products in Discovery's pipeline to now include (i) Discovery's NICU SRT pipeline including Surfaxin for RDS and Bronchopulmonary Dysplasia (BPD), SRT for Meconium Aspiration Syndrome (MAS), and aerosol formulations for Neonatal Respiratory Failures administered through nasal continuous positive airway pressure (nasal CPAP); and (ii) Discovery's Hospital SRT pipeline including Surfaxin for ARDS, and aerosol formulations for Acute Lung Injury (ALI), Asthma, and Chronic Obstructive Pulmonary Disease (COPD).

- Esteve will pay Discovery a transfer price on sales of Surfaxin and other SRT products. The transfer prices are increased from those provided for in the previous collaborative agreement. Discovery will be responsible for the manufacture and supply of all products, including Surfaxin and Esteve will be responsible for all sales and marketing in the revised territory.

- Esteve shall pay to Discovery specified cash fees based upon achieving certain milestones, primarily upon obtaining EMEA regulatory approvals for the covered SRT products.

- Esteve will contribute to Phase 3 clinical trials for the covered SRT products, by conducting and funding development performed in Southern Europe.

Discovery expects to take a charge against earnings equal to approximately $4.2 million for the fourth quarter of 2004, primarily in connection with the issuance of such shares and other related matters associated with the restructured strategic alliance.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, “We have enjoyed a long-standing relationship with Esteve. They remain a top shareholder with approximately 2.6 million shares and Dr. Antoni Esteve is a valuable member of our board of directors. Together we have approached this decision to redefine our alliance with the intent to optimize the medical and economic value of the Surfaxin brand. Esteve now has access to the full complement of our present NICU and Hospital SRT pipeline, and can focus their efforts in their core commercial markets. Discovery may now pursue additional partners with commercial strength in Northern and Eastern Europe. Given the robustness of the Surfaxin RDS data, and encouraging ARDS Phase 2 data, we believe we are well positioned to secure additional collaborative commercialization opportunities.”

Dr. Antoni Esteve, Director of Scientific and Commercial Operations at Esteve, commented, “We believe that Discovery’s SRT has the promise to dramatically improve respiratory medicine in the next decade, beginning with the potential launch of Surfaxin for RDS. The redefined arrangement with Discovery will allow Esteve to reinforce our respiratory pipeline by having access to a wider SRT product platform and to focus our development and marketing efforts in our core markets, Southern Europe, while facilitating Discovery’s implementation of its global SRT strategy.”

About Discovery Laboratories

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery’s technology produces a precisely engineered surfactant that is designed to closely mimic the essential properties of natural 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 patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of RDS in premature infants. Discovery is also conducting various clinical programs to address ARDS in adults, BPD, a form of chronic lung disease in infants, Neonatal Respiratory Failures in premature infants, severe asthma in adults, and MAS in full-term infants.

More information about Discovery is available on the Company's Web site at **www.DiscoveryLabs.com**.

About Laboratorios del Dr. Esteve

Esteve is one of the largest pharmaceutical-chemical corporations in Southern Europe, with an international presence through subsidiaries in Italy and Portugal and worldwide licensees and distributors. Since 1960, Esteve has established strategic alliances with multinational pharmaceutical-chemical companies to market their products in Southern Europe. Esteve has established its own successful research and development capabilities, developing new chemical entities and manufacturing active pharmaceutical ingredients with its research products marketed in over 90 countries.

More information about Esteve is available at www.esteve.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, 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 Surfactant Replacement Therapies), risk that the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that the Company's internal sales and marketing organization will not succeed in developing market awareness of the Company's products, risk that the Company's internal sales and marketing organization will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by the Company, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by the Company for any such drug product, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with adequate supplies of drug substance and drug products for completion of any of the Company's clinical studies, other risks relating to the lack of adequate supplies of drug substance and 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-Q and 8-K, and any amendments thereto.

Company Contacts:
John G. Cooper, EVP and CFO
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215-488-9300

Discovery Labs Announces Encouraging Preliminary Data from ARDS Phase 2 Clinical Trial

Expands trial to strengthen endpoint signal prior to designing potential Phase 3 trial

Warrington, PA — December 7, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO), announced encouraging preliminary data from its Surfaxin^{O} Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults. **Discovery will hold a conference call today at 11:00 AM EST. The call in number is 800-665-0669.**

The ARDS Phase 2 trial is comprised of two parts; a dose-escalation/safety phase and an efficacy/safety phase. As of November 15, 2004, a total of 89 patients were enrolled in the trial and completed the 28-day study. The table below shows results from 78 evaluable patients. These evaluable patients received either one of two dosing regimens chosen for the efficacy/safety phase, or Standard of Care.

Endpoint	**Surfaxin Dose Group A** [1] *(N=29)*	**Surfaxin Dose Group B** [2] *(N=29)*	**Standard of Care Group** *(N=20)*	**Relative Difference in Favor of Group B vs. Standard of Care**
All cause Mortality @ Day 28	13.8%	13.8%	20.0%	31.0%
Incidence of being Alive & off MV @ Day 28	69.0%	82.8%	75.0%	10.4%

[1] **Dose Group A:** Two Surfaxin lavages totaling up to 57,000 mg of phospholipid

[2] **Dose Group B:** Two Surfaxin lavages and boluses totaling up to 61,000 mg phospholipid

Both Surfaxin dose groups showed a 31% relative improvement in overall mortality assessed at Day 28 versus Standard of Care. With respect to the primary endpoint of the incidence rate of being alive and off mechanical ventilation at Day 28, 69% of Dose Group A patients, 82.8% of Dose Group B patients, and 75% of the Standard of Care patients, were alive and off mechanical ventilation. With respect to overall safety, no differences were apparent between the two Surfaxin treatment groups.

Antonio Anzueto, M.D., Professor of Medicine at the University of Texas Health Science Center at San Antonio, commented, “Following my review of the preliminary data, I am impressed with these observations. The separation between Surfaxin and Standard of Care, especially with regard to all cause mortality is impressive even with the uncharacteristically low rate of mortality in the Standard of Care group in this trial.”

Based on these data and in consultation with the Company’s clinical advisors, the current ARDS Phase 2 protocol has been modified to better establish the endpoint signal in key clinical outcomes in order to properly power and design a potential Phase 3 clinical trial. The modified protocol allows for increased enrollment of up to 160 patients. The remainder of the trial will be comprised of Surfaxin Dose Group B (lavage with bolus) and Standard of Care. The Phase 2 trial is expected to be completed by the fourth quarter of 2005.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, stated, “These data, especially with regard to all cause mortality, support our belief that our Surfactant Replacement Therapy (SRT) lavage, or lung wash, is the most scientifically sound approach to the treatment of ARDS. We remain committed to advancing this trial with the scientific rigor necessary to bring this potentially life-saving therapy to patients, and believe that expanding the trial to 160 patients will better allow us to understand the appropriate patient population and primary endpoints for a potential Phase 3 clinical trial.”

R. Duncan Hite, M.D., Director of Medical Intensive Care and Critical Care Research, Wake Forest University Health Sciences, commented, “These data are encouraging. Other ARDS trials utilizing surfactants have failed to show a mortality benefit. These data support the premise that the use of high dose Surfaxin, a precisely-engineered surfactant, in combination with the bronchoscopic segmental lavage procedure could prove to be the optimal therapy for ARDS patients. I believe the expansion of Discovery’s Phase 2 clinical trial is a logical approach. It is smart to strengthen the signal in the Phase 2 trial to more accurately design and power the Phase 3 clinical program.”

The Phase 2 trial is an open-label, controlled, randomized, dose-ranging, multicenter trial comparing the safety and efficacy of Surfaxin to Standard of Care in up to 160 ARDS patients. Patients on mechanical ventilation are randomized to receive Surfaxin or to continue to be managed on mechanical ventilation alone, which is the current standard of care for this patient population. The objective is to restore functional surfactant levels in the lung, in order to keep these critically ill patients alive and get them off costly mechanical ventilation as soon as possible. The primary endpoint of this trial is the incidence rate of patients being alive and off mechanical ventilation at Day 28. Key secondary endpoints include mortality at the end of Day 28, and safety and tolerability of Surfaxin and the bronchoscopic lavage procedure.

Surfaxin is administered via a proprietary sequential bronchopulmonary segmental lavage technique (a “lung wash” where Surfaxin is delivered through a tube, called a bronchoscope, to each of the 19 to 20 segments of the lung), which is intended to cleanse and remove inflammatory substances from the lungs, while approximately one-half of the Surfaxin remains to help re-establish the lung’s capacity to absorb oxygen.

Acute Respiratory Distress Syndrome

ARDS is a life-threatening respiratory disorder for which there are currently no approved therapies anywhere in the world. It is estimated that there are between 150,000 and 250,000 ARDS patients per year in each of the U.S. and Europe. The mortality rate for ARDS patients can range from 30% to 50%. The current standard of care includes placing patients on mechanical ventilators in intensive care units at an average estimated cost of approximately $8,500 per day. ARDS is characterized by an excess of fluid, inflammatory cells and debris in the lungs that leads to decreased oxygen levels in the patient's blood. One prominent characteristic is the destruction of the lung's natural surfactant that is essential to the ability to absorb oxygen. These conditions are caused by events such as pneumonia, aspiration of gastric contents, smoke inhalation, near drowning, industrial accidents, sepsis and other traumas.

Conference Call Details

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 http://www.irconnect.com/primecast/dsco/474/ and 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.

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More information about Discovery is available on the Company's Web site 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, 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 Surfactant Replacement Therapies), risk that the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that the Company's internal sales and marketing organization will not succeed in developing market awareness of the Company's products, risk that the Company's internal sales and marketing organization will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by the Company, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by the Company for any such drug product, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with adequate supplies of drug substance and drug products for completion of any of the Company's clinical studies, other risks relating to the lack of adequate supplies of drug substance and 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-Q and 8-K, and any amendments thereto.

Company Contacts:
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