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

OCTOBER 27, 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)

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)

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))

ITEM 8.01. OTHER EVENTS

On October 27, 2004, Discovery Laboratories, Inc. (the "Company") issued a press release to announce that the European Medicines Evaluation Agency has determined that the Marketing Authorization Application ("MAA") for Surfaxin(R) for the treatment and prevention of Respiratory Distress Syndrome in premature infants has been validated. Validation of the MAA indicates that the Company's application is complete and that the review process has begun. The full text of the press release is set forth in Exhibit 99.1 hereto.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits:

99.1 Press Release dated October 27, 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: October 27, 2004

EXHIBIT 99.1

EMEA VALIDATES DISCOVERY LABORATORIES MAA TO MARKET SURFAXIN(R) IN EUROPE

DOYLESTOWN, PA --OCTOBER 27, 2004 -- DISCOVERY LABORATORIES, INC. (NASDAQ: DSCO) today announced that the European Medicines Evaluation Agency (EMEA) has determined that the Marketing Authorization Application (MAA) for Surfaxin(R) for the treatment and prevention of Respiratory Distress Syndrome (RDS) in premature infants has been validated. Validation of the MAA indicates that Discovery's application is complete and that the review process has begun.

In the United States, Discovery has filed a New Drug Application (NDA) with the FDA for clearance to market Surfaxin for the prevention of RDS. The FDA has accepted the NDA filing and has established a target date of February 13, 2005 for completion of review of the NDA.

Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer of Discovery commented, "We believe the data included in the MAA as well as in our NDA, strongly supports the therapeutic benefit of Surfaxin for infants who suffer from RDS. Based on the positive results from our clinical trials, we are optimistic that Surfaxin will be favorably reviewed by the European regulatory authorities. We look forward to productive interactions with the EMEA and anticipate the review to be completed by the end of 2005. If approved, Surfaxin would represent the world's first engineered version of human lung surfactant."

The MAA submission was supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials. The first was a landmark, 1294 patient pivotal study that demonstrated Surfaxin's superiority to Exosurf(R), a non-protein containing synthetic surfactant. Survanta(R), a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the trial. The second trial was a 252 patient supportive study that demonstrated Surfaxin's non-inferiority to Curosurf(R), a pig-derived surfactant and the leading surfactant used in Europe.

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, is capable of being produced in virtually unlimited quantities, in consistent pharmaceutical grade quality, and has no risk of potential transmission of animal-associated diseases.

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 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 patients where there are few or no approved therapies available.

SRT in the neonatal intensive care unit: 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 Respiratory Distress Syndrome in premature infants. Additionally, Discovery is conducting a Phase 3 and Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants and is preparing to initiate a Phase 2 clinical trial for Neonatal Respiratory Failures utilizing an aerosolized surfactant formulation in combination with nasal continuous positive airway pressure (nasal CPAP).

SRT for critical care and other hospitalized patients: Discovery is conducting a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, and is preparing to initiate a Phase 2 clinical trial for severe asthma using its aerosolized surfactant replacement therapy (development name DSC-104).

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 aerosol and surfactant replacement therapies), risk of delay in the company's preparation and filing of applications for regulatory approval, 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
Kori Beer, IR and Communications
215-340-4699