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

June 15, 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)

Item 5. Other Events

On June 15, 2004, Discovery Laboratories, Inc. (the "Registrant"), issued a press release to announce the acceptance by the United States Food and Drug Administration (FDA) of the Registrant's new drug application (NDA) for the use of Surfaxin(R) in preventing Respiratory Distress Syndrome (RDS) in premature infants. The NDA was filed with the FDA in April 2004. The FDA has granted a standard review designation with respect to the NDA and has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA.

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

(c) Exhibits:

99.1 Press Release dated June 15, 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: June 15, 2004

Exhibit 99.1

DISCOVERY LABORATORIES ANNOUNCES FDA ACCEPTANCE OF SURFAXIN(R) NEW DRUG APPLICATION

Doylestown, PA -- June 15, 2004 -- Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that the United States Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) filing for Surfaxin(R) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has granted a Standard Review designation and has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA.

Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer of Discovery, stated, "We believe the data included in the NDA strongly supports the therapeutic benefit of Surfaxin for patients who suffer from RDS. Surfaxin, if approved, has the potential to set a new standard for the prevention of RDS and would begin a dramatic evolution in the use of engineered humanized surfactants for the treatment of serious and life-threatening respiratory diseases prevalent in the neonatal intensive care unit. Surfaxin serves as the cornerstone of our portfolio of Surfactant Replacement Therapies to treat various respiratory diseases. We will continue to work closely with the FDA to facilitate a thorough and proper review of our NDA."

The NDA filing was supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials. The first was a landmark, 1,294 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.

Discovery also is preparing a Marketing Authorization Application (MAA) to be filed with the European Medicines Evaluation Agency (EMEA) in the second half of 2004 for Surfaxin for the prevention and treatment of RDS.

ABOUT DISCOVERY LABORATORIES

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies 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 critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery has filed a New Drug Application with the FDA for clearance to market Surfaxin, the Company's lead product, for the prevention of Respiratory Distress Syndrome in premature infants. Discovery is also conducting a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, Phase 3 and Phase 2 clinical trials for Meconium Aspiration Syndrome in full-term infants and (with aerosolized surfactant) is preparing to initiate a Phase 2 trial for asthma (development name DSC-104) and a Phase 2 trial for Respiratory Dysfunction in premature infants.

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 approval of any applications filed by the Company, risks that the FDA will not approve the marketing and sale of a drug product even after the FDA has accepted the applications 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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