

**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**

September 14, 2004

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)

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 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers

On September 14, 2004, Discovery Laboratories, Inc. (the “Company”) appointed W. Thomas Amick to its Board of Directors. Prior to his appointment as a member of the Board, Mr. Amick served as a commercialization strategist to the Company since March 1, 2004. In such role, Mr. Amick received cash compensation of \$60,000 and options to purchase 25,000 shares of common stock of the Company pursuant to the terms and conditions of the Company’s 1998 Amended and Restated Stock Incentive Plan. The Company issued a press release announcing Mr. Amick’s appointment on September 14, 2004. 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 September 14, 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: September 20, 2004

**W. THOMAS AMICK, FORMER J&J SENIOR EXECUTIVE,
APPOINTED TO
DISCOVERY LABS' BOARD OF DIRECTORS**

Doylestown, PA — September 14, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced the appointment of W. Thomas Amick to its Board of Directors. Mr. Amick adds global commercial and strategic expertise to Discovery as the Company prepares for the potential commercialization of its lead product, Surfaxin(r), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and advances its pipeline of Surfactant Replacement Therapies for the treatment of various respiratory diseases.

Mr. Amick brings more than 30 years of pharmaceutical and biotechnology experience as an executive with Johnson & Johnson, with specific expertise in building and leading commercial operations throughout North America and Europe. Mr. Amick's positions included President of Ortho Biotech Europe and Janssen-Ortho Canada and Worldwide Vice President of J&J's Oncology Group, where he created and managed the commercial organizations for J&J's first oncology franchise within Ortho Biotech. Mr. Amick was also responsible for building the organization that drove the growth of Procrit into a multibillion-dollar product.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Laboratories stated, "Tom brings to Discovery's Board extensive experience in the commercialization of several successfully-marketed products, many of which set new treatment standards or established new treatment paradigms within their therapeutic areas. This experience is beneficial to executing our commercialization strategy. If approved, Surfaxin will represent a significant opportunity to improve the standard of care for premature infants who suffer from RDS."

"Discovery's mission is to advance to market a pipeline of Surfactant Replacement Therapies which we believe will revolutionize the treatment of respiratory diseases. The introduction of Surfaxin has the potential to represent a dramatic evolution in the role surfactants play in the neonatology community and could become the first engineered humanized surfactant available throughout the world. Our strategy is to build a therapeutic portfolio that addresses the range of respiratory disorders treated in the NICU, critical care and hospital settings. Tom brings a wealth of operational experiences and pharmaceutical industry relationships that are essential to properly and carefully execute this strategy," continued Dr. Capetola.

Mr. Amick received a B.S. Degree in Business from Elon University. Additionally, he has completed graduate courses at the Darden Business School, University of Virginia, the Kellogg School of Business, Northwestern University, and the Harvard Business School.

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(r), the Company's lead product, for the prevention of Respiratory Distress Syndrome in premature infants. Discovery is currently 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. With aerosolized surfactant formulations, Discovery is preparing to initiate a Phase 2 trial for asthma (development name DSC-104) and a Phase 2 trial for Neonatal Pulmonary Disorders.

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 & Communications
215-340-4699