

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 11, 2005

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)

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:

- 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))
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Item 8.01. Other Events

On October 11, 2005, Discovery Laboratories, Inc. (the “Company”) issued a press release to announce that it had filed a universal shelf registration statement on Form S-3 (File No. 333-128929) (the “Registration Statement”) with the Securities and Exchange Commission (“SEC”) for the proposed offering from time to time of up to \$100 million of the Company’s debt or equity securities. The Company has no immediate plans to sell its securities under the Registration Statement. Once the Registration Statement is declared effective by the SEC, however, the Company will be able to issue the securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time. The full text of the press release is set forth in Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements, Pro Forma Financial Statements and Exhibits

(c) Exhibits:

99.1 Press Release dated October 11, 2005.

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K 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 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 Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such 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.

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 12, 2005

Discovery Labs Files Universal Shelf Registration Statement

Warrington, PA — October 11, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO) announced today that it has filed a universal shelf registration statement with the Securities Exchange Commission (SEC) relating to the possible issuance of up to \$100 million in securities. The filing should allow Discovery flexibility as to the type of security it could choose to sell, including common stock, preferred stock, and varying forms of debt securities, and is intended to enable Discovery to react to market opportunities as they arise.

Discovery has no immediate plans to sell its securities under this shelf registration. Once this registration statement is declared effective by the SEC, the Company will be able to issue these securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

A registration statement relating to the securities listed in the shelf registration statement has been filed with the SEC but has not yet become effective. These securities may not be sold nor may offers to buy be accepted before the registration statement becomes effective. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology 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 precision-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 address respiratory diseases where there are few or no approved therapies available.

Discovery's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the treatment of Chronic Lung Disease (CLD) in premature infants. Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), is in development to address neonatal respiratory failures.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

For more information, please visit our corporate website 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements 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 Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery 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 that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery'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 Discovery, 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 Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery'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 Discovery'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.

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