

**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**

February 18, 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))

Item 8.01 Other Events.

On February 18, 2005, Discovery Laboratories, Inc. issued a press release announcing that it has entered into commitments to sell approximately 450,000 shares of its common stock, par value \$.001 per share, for \$5.75 per share to a select institutional investor. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits:

99.1 Press release, dated February 18, 2005

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: February 22, 2005



Warrington, PA — February 18, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), has announced that in response to additional interest, the previously reported Registered Direct Offering with purchase commitments totaling approximately \$26.5 million has been extended to include an additional commitment to purchase approximately \$2.6 million of its common stock in a registered direct offering. Under the terms of the additional transaction, Discovery will sell approximately 450,000 shares of its common stock to a select institutional investor. The closing of the offering is expected to take place on February 24, 2005, subject to the satisfaction of customary closing conditions. All of the shares of common stock are being offered by Discovery pursuant to an effective registration statement previously filed with the Securities and Exchange Commission. SG Cowen & Co., LLC acted as exclusive placement agent for the transaction.

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 the securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. The shares of common stock may only be offered by means of a prospectus. Copies of the final prospectus supplement and accompanying base prospectus can be obtained from SG Cowen & Co., LLC, 1221 Avenue of the Americas, New York, NY 10020 (212-278-6000).

About Discovery Labs

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 received an Approvable Letter from the FDA for Surfaxin[®], the Company's lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and has filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome (MAS) in full-term 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 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.

Company Contacts:

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