

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**

August 2, 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 2.02. Results of Operations and Financial Condition

On August 2, 2005, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended June 30, 2005, and providing selected updates on the Company’s progress since the end of first fiscal quarter in 2005. 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 August 2, 2005.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filings.

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: August 3, 2005

Discovery Labs Reports Second Quarter 2005 Financial Results
and Business Progress

Warrington, PA, August 2, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the three and six months ended June 30, 2005. The Company will host a conference call today at 10:00 AM EDT. The call in number is 866-332-5218.

For the quarter ended June 30, 2005, the Company reported a net loss of \$9.8 million, or \$0.18 per share, on 53.6 million weighted average common shares outstanding, compared to a net loss of \$8.9 million, or \$0.19 per share, on 46.7 million weighted average shares outstanding for the same period in 2004. For the six months ended June 30, 2005, the Company reported a net loss of \$19.1 million, or \$0.37 per share, on 52.0 million weighted average common shares outstanding, compared to a net loss of \$17.8 million, or \$0.39 per share, on 45.0 million weighted average shares outstanding for the same period in 2004. The Company currently has 53.7 million shares outstanding.

As of June 30, 2005, the Company had cash and marketable securities of \$42.9 million, a decrease of \$8.9 million from the prior quarter. Cash used in operating and investing activities during the quarter was \$9.3 million, offset by \$0.4 million received in proceeds from the exercise of stock options.

As of June 30, 2005, the Company had \$67.8 million available under the Committed Equity Financing Facility (CEFF), subject to certain conditions. During the three and six months ended June 30, 2005, the Company did not raise capital under the CEFF. Additionally, the Company has a \$9.0 million capital lease financing arrangement with General Electric Capital Corporation, of which \$5.5 remains available for use and \$2.5 million is outstanding. The Company's \$8.5 million credit facility with PharmaBio Development Inc., Quintiles strategic investment group, is fully outstanding and repayment is due in December 2006.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "Surfaxin[®] is the cornerstone of our precision-engineered Surfactant Replacement Therapy pipeline that holds the promise to revolutionize the treatment of respiratory diseases prevalent in the neonatal intensive care unit, critical care, and hospital settings. With the recent submission of our Response to the FDA Approvable Letter for Surfaxin, we are prepared for the FDA to complete its review of our NDA within the next six months. We believe that we are well positioned as a company based on the potential U.S. launch and European approval of Surfaxin in the first quarter of 2006, collaborative commercialization opportunities in Europe and Japan, potential financial resources of approximately \$110 million and a broad pipeline centered upon our SRT technology that, to date, has achieved significant milestones."

The Company reported a net loss of \$9.8 million and \$19.1 million for the three and six months ended June 30, 2005, respectively, an increase of \$0.9 million and \$1.4 million compared to the same prior year periods. The change in the net loss is primarily due to:

- (i) the Company building its own specialty pulmonary United States sales and marketing organization to focus initially on the commercial and medical promise of its Surfactant Replacement Therapy (SRT) to address respiratory therapies for the Neonatal Intensive Care Unit (NICU). Investments include pre-launch commercialization activities (included in general and administrative expenses) to support the potential approval and launch of Surfaxin for Respiratory Distress Syndrome (RDS) including, without limitation, sales, marketing and medical affairs management as well as medical science liaisons. For the three and six months ended June 30, 2005, costs associated with pre-launch commercialization activities were \$2.1 million and \$4.5 million, respectively, an increase of \$1.0 million and \$2.5 million compared to the same prior year period;
- (ii) manufacturing activities (included in research and development) to support the production of clinical and commercial drug supply for the Company's SRT programs, including Surfaxin, in conformance with current Good Manufacturing Practices (cGMPs). For the three and six months ended June 30, 2005, costs associated with these manufacturing activities were \$2.7 million and \$4.0 million, respectively, an increase of \$0.8 million and \$0.5 million compared to the same prior year period;
- (iii) research and development activities related to the advancement of the Company's SRT pipeline. For the three and six months ended June 30, 2005, costs associated with these activities, excluding manufacturing activities, were \$3.2 million and \$6.9 million, respectively, a decrease of \$1.3 million and \$2.6 million compared to the same prior year period. The decrease is primarily due to costs in 2004 associated with clinical and regulatory activities for Surfaxin for RDS, principally the NDA filing, a related milestone payment for the license of Surfaxin, and follow-up clinical activity for the related two Phase 3 clinical trials. For the three and six months ended June 30, 2005, research and development activities primarily reflect regulatory activities associated with Surfaxin for RDS (specifically the U.S. FDA Approvable Letter and the Marketing Authorization Application with the European Medicines Evaluation Agency) and clinical activities related to the Phase 2 clinical trials for ARDS in adults, BPD in premature infants, and aerosolized SRT administered through nasal nCPAP for Neonatal Respiratory Failures;
- (iv) general and administrative activities including financial and information technology capabilities in preparation for the potential approval and launch of Surfaxin for RDS, executive management and support infrastructure, legal activities related to the preparation and filing of patents in connection with the expansion of our SRT pipeline, facilities related costs to accommodate current and prepare for future growth, and corporate governance initiatives to comply with the Sarbanes-Oxley Act. For the three and six months ended June 30, 2005, costs associated with these related activities were \$2.0 million and \$3.9 million respectively, a decrease of \$0.1 million and an increase of \$0.4 million compared to the same period the prior year; and

- (v) the Company restructuring in December 2004 its strategic alliance with Laboratories del Dr. Esteve, S.A. to develop, market and sell Surfaxin in Southern Europe. For the three and six months ended June 30, 2005, revenues from this strategic alliance were \$24,000 and \$85,000, respectively, a decrease of \$0.7 million and \$0.8 million, compared to the same prior year period.

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 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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215-488-9490

Lisa Caperelli, Investor Relations

215-488-9413

Condensed Consolidated Statement of Operations
(in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	(unaudited)		(unaudited)	
	2005	2004	2005	2004
Revenues from collaborative agreements	\$ 24	\$ 697	\$ 85	\$ 839
Operating expenses:				
Research and development	5,864	6,373	10,984	13,083
General and administrative	4,095	3,175	8,365	5,456
Total expenses	9,959	9,548	19,349	18,539
Operating loss	(9,935)	(8,851)	(19,264)	(17,700)
Other income / (expense)	109	(46)	122	(69)
Net loss	<u>\$ (9,826)</u>	<u>\$ (8,897)</u>	<u>\$ (19,142)</u>	<u>\$ (17,769)</u>
Net loss per common share	\$ (0.18)	\$ (0.19)	\$ (0.37)	\$ (0.39)
Weighted average number of common shares outstanding	53,587	46,683	52,029	45,003

Condensed Consolidated Balance Sheets
(in thousands)

	<u>June 30,</u> 2005 (unaudited)	<u>December 31,</u> 2004
ASSETS		
Current Assets:		
Cash and marketable securities	\$ 42,946	\$ 32,654
Prepaid expenses and other current assets	784	688
Total Current Assets	<u>43,730</u>	<u>33,342</u>
Property and equipment, net	4,076	4,063
Other assets	220	232
Total Assets	<u>\$ 48,026</u>	<u>\$ 37,637</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	\$ 7,697	\$ 8,823
Long-Term Liabilities:		
Credit facility	8,500	5,929
Capitalized leases and other long-term liabilities	<u>1,632</u>	<u>1,788</u>
Total Liabilities	17,829	16,540
Stockholders' Equity	30,197	21,097
Total Liabilities and Stockholders' Equity	<u>\$ 48,026</u>	<u>\$ 37,637</u>

