

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

April 27, 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 April 27, 2005, Discovery Laboratories, Inc. (the “Registrant”), issued a news release announcing financial results for the quarter ended March 31, 2004, and providing selected updates on the Registrant’s progress since the end of fiscal year 2004 (the “2005 First Quarter Financial Results News Release”). A copy of the press release is furnished pursuant to this Item 2.02 as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits:

99.1 The 2005 First Quarter Financial Results News Release.

The information in this Current Report on 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 may be expressly set forth 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: April 28, 2005

Discovery Labs Reports First Quarter 2005 Financial Results and Business Progress

Warrington, PA, April 27, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the three months ended March 31, 2005. The Company will host a conference call today at 4:30 PM EDT. **The call in number is 866-332-5218.**

For the quarter ended March 31, 2005, the Company reported a net loss of \$9.3 million, or \$0.18 per share, on 50.8 million weighted average common shares outstanding, compared to a net loss of \$8.9 million, or \$0.20 per share, on 43.3 million weighted average shares outstanding for the same period in 2004. The Company currently has 53.5 million shares outstanding.

As of March 31, 2005, the Company had cash and marketable securities of \$51.8 million. In February 2005, the Company received net proceeds of \$27.5 million from a registered direct public offering of 5,060,000 shares of the Company's common stock. Excluding proceeds from this public offering, net cash used in the first quarter was \$8.4 million. Cash used in operating and investing activities during the quarter was \$11.0 million, offset by \$2.6 million accessed under the Company's secured credit facility.

As of March 31, 2005, the Company had \$67.8 million available under the Committed Equity Financing Facility (CEFF), subject to certain conditions. Additionally, the Company had \$2.5 million outstanding under the Company's \$9.0 million capital lease financing arrangement with General Electric Capital Corporation. In February 2005, the Company accessed the remaining \$2.6 million available under the credit facility with PharmaBio Development Inc., Quintiles strategic investment group, and currently the entire \$8.5 million is outstanding and is due in December 2006.

Selected Updates on Discovery's progress in the first quarter of 2005:

§ Surfaxin[®] for Respiratory Distress Syndrome (RDS) in Premature Infants

In February 2005, the Company received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. The FDA has not requested any additional preclinical or clinical trials for final approval, however, the Company must primarily address manufacturing issues raised by the FDA and finalize labeling details for the product. The Company anticipates resolving the manufacturing issues by July 2005 and launching Surfaxin in the first quarter of 2006.

Scientific information pertaining to Surfaxin (lucinactant) for RDS has recently been published in the following publications:

Pediatrics (2005) **115**:1018-1029; A Multicenter, Randomized, Masked, Comparison Trial of Lucinactant, Colfosceril Palmitate, and Beractant for the Prevention of Respiratory Distress Syndrome Among Very Preterm Infants; Moya Fernando R., Gadzinowski Janusz, Bancalari Eduardo, *et al.*

Pediatrics (2005) **115**:1030-1038; A Multicenter, Randomized, Controlled Trial of Lucinactant Versus Poractant Alfa Among Very Premature Infants at High Risk for Respiratory Distress Syndrome; Sinha Sunil K., Lacaze-Masmonteil Thierry, Valls i Soler Adolf, *et al.*

Expert Opinion on Investigational Drugs (2005) **14**(3):329-334; Lucinactant: A Novel Synthetic Surfactant for the Treatment of Respiratory Distress Syndrome; Donn Steven M.

Treat Respir Med (2005) **4**(2):139-145; Lucinactant in Neonatal Respiratory Distress Syndrome; Moen Marit D., Perry Caroline M., Wellington Keri.

Pediatric Pulmonology (2005) **39**:167-177; Interaction of an Artificial Surfactant in Human Pulmonary Epithelial Cells; Romero Edgar J., Moya Fernando R., *et al.*

§ Surfactant Replacement Therapies (SRT) in the Neonatal Intensive Care Unit (NICU)

The Company broadened its SRT pipeline of therapeutic programs to address the most prevalent respiratory disorders with significant unmet medical needs for the neonatal community. In January 2005, a Phase 2 clinical trial was initiated to assess the safety and efficacy of delivering multiple doses of Surfaxin during the first two weeks of life for the prevention of Bronchopulmonary Dysplasia (BPD), a serious, chronic lung disease of newborn infants. Results from this trial are expected to be available in the first quarter of 2006. Also in January 2005, a Phase 2 pilot study was initiated to evaluate aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP) as a non-invasive means to potentially treat the broad range of Neonatal Respiratory Failures that occur in the NICU. Results from this trial are expected to be available in the third quarter of 2005.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, “Discovery’s mission is to advance to market a pipeline of Surfactant Replacement Therapies that will revolutionize the treatment of respiratory diseases prevalent in the neonatal intensive care unit, critical care, and hospital settings. Surfaxin is the cornerstone of our SRT pipeline and potentially sets a new standard for the prevention of RDS. With regards to the Approvable Letter we received from the FDA for Surfaxin, we are working diligently with our drug product contract manufacturer to address the manufacturing matters raised by the FDA. Due to our collaborative efforts, we remain on schedule to submit a Complete Response Letter to the FDA by July 2005. Our organization is committed to the anticipated commercial launch of our first precision-engineered surfactant product in the first quarter of 2006.”

Review of Operating Results - First Quarter 2005

The Company reported a net loss of \$9.3 million and \$8.9 million for the three months ended March 31, 2005 and 2004 respectively, an increase of \$0.4 million compared to the same prior year period. This increase 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 SRT to address respiratory therapies for the NICU. Investments include pre-launch commercialization activities (included in general and administrative expenses) to support the potential approval and launch of Surfaxin for RDS including, without limitation, sales and marketing management and medical affairs as well as medical science liaisons. For the three months ended March 31, 2005, costs associated with pre-launch commercialization activities were \$2.4 million, an increase of \$1.4 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 months ended March 31, 2005, costs associated with these manufacturing activities were \$1.4 million, a decrease of \$0.3 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 months ended March 31, 2005, costs associated with these activities, excluding manufacturing activities, were \$3.7 million, a decrease of \$1.2 million compared to the same prior year period. The costs for the first quarter of 2005 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 nCPAP for Neonatal Respiratory Failures. For the three months ended March 31, 2004, research and development activities were primarily associated with clinical and regulatory activities for Surfaxin for RDS (principally the NDA filing) and investment in the Company's SRT pipeline, including development of the aerosol SRT programs.
- (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 months ended March 31, 2005, costs associated with these related activities were \$1.9 million, an increase of \$0.6 million compared to the same period the prior year.

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 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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215-488-9413

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

	Three Months Ended March 31, (unaudited)	
	2005	2004
Revenues from collaborative agreements	\$ 61	\$ 142
Operating expenses:		
Research and development	5,120	6,710
General and administrative	4,270	2,281
Total expenses	9,390	8,991
Operating loss	(9,329)	(8,849)
Other income / (expense)	13	(23)
Net loss	\$ (9,316)	\$ (8,872)
Net loss per common share	\$ (0.18)	\$ (0.20)
Weighted average number of common shares outstanding	50,784	43,320

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2005	December 31, 2004
ASSETS		
Current Assets:		
Cash and marketable securities	\$ 51,827	\$ 32,654
Prepaid expenses and other current assets	739	688
Total Current Assets	52,566	33,342
Property and equipment, net	3,990	4,063
Other assets	220	232
Total Assets	\$ 56,776	\$ 37,637
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	7,090	8,823
Credit facility, non-current portion	8,500	5,929
Capitalized lease, non-current portion, and deferred revenue	1,702	1,788
Total Liabilities	17,292	16,540
Shareholders' Equity	39,484	21,097
Total Liabilities and Shareholders' Equity	\$ 56,776	\$ 37,637