

**SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**November 3, 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 2.02. Results of Operations and Financial Condition**

On November 3, 2005, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended September 30, 2005, and providing selected updates on the Company’s progress since the end of the second 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 November 3, 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: November 3, 2005

## Discovery Labs' Reports Third Quarter 2005 Financial Results and Business Progress

Warrington, PA, November 3, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the three and nine months ended September 30, 2005 and other business progress. The Company will host a conference call on Thursday, November 3, 2005 at 10:00 AM EST. The call in number is 866-332-5218.

For the quarter ended September 30, 2005, the Company reported a net loss of \$10.4 million, or \$0.19 per share, on 54.5 million weighted average common shares outstanding, compared to a net loss of \$8.4 million, or \$0.18 per share, on 47.0 million weighted average shares outstanding for the same period in 2004. For the nine months ended September 30, 2005, the Company reported a net loss of \$29.5 million, or \$0.56 per share, on 52.8 million weighted average common shares outstanding, compared to a net loss of \$26.2 million, or \$0.57 per share, on 45.7 million weighted average shares outstanding for the same period in 2004.

As of September 30, 2005, the Company had cash and marketable securities of \$50.3 million, an increase of \$7.4 million from the prior quarter. Cash used in operating and investing activities during the quarter was \$10.0 million, offset by \$0.4 million received in proceeds from the exercise of stock options and warrants. In September 2005, the Company completed a financing pursuant to its Committed Equity Financing Facility (CEFF) resulting in proceeds of \$17.0 million from the issuance of approximately 3.0 million shares of common stock at an average price of \$5.64 per share (\$6.27 per share less the applicable discount rate provided for by the CEFF). The Company intends to use these proceeds to acquire a dedicated manufacturing operation as a strategic investment for the manufacture of Surfaxin<sup>®</sup> and the development of its Surfactant Replacement Therapy (SRT) pipeline or for general corporate purposes.

As of September 30, 2005, the Company had \$50.8 million available under the CEFF, subject to certain conditions. Additionally, the Company had a \$9.0 million capital lease financing arrangement with General Electric Capital Corporation, of which \$5.2 million remains available for use and \$2.6 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.

Additionally, on October 26, 2005, Laboratorios del Dr. Esteve S.A. (Esteve), the Company's partner in Southern Europe, agreed to purchase 650,000 shares of the Company's common stock, at a price per share of \$6.88, for an aggregate purchase price of approximately \$4.5 million. After taking into account this transaction and the financing from the CEFF, the Company currently has 57.5 million shares outstanding.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "Surfaxin, our lead product with an FDA Approvable Letter, is now under a six month review by the FDA that began on October 5, 2005. We are preparing our organization for the potential approval of Surfaxin in April 2006, followed by the commercial launch in the second quarter of 2006. Surfaxin is the cornerstone of our precision-engineered Surfactant Replacement Therapy pipeline that promises to revolutionize the treatment of respiratory diseases prevalent in the neonatal intensive care unit, critical care, and hospital settings. We believe that with the potential of our SRT pipeline it is strategically important to manage our own manufacturing and commercial operations and we are making steady progress towards achieving this goal."

#### Review of Operating Results – Three and Nine Months Ended September 30, 2005

The Company reported a net loss of \$10.4 million and \$29.5 million for the three and nine months ended September 30, 2005, respectively, an increase of \$2.0 million and \$3.4 million compared to the same prior year periods. The change in the net loss is primarily due to:

- (i) sales, marketing and medical affairs activities (included in general and administrative expenses) related to the Company building its own specialty pulmonary United States commercial organization to focus initially on the commercial and medical promise of its SRT to address respiratory therapies for the Neonatal Intensive Care Unit (NICU). Expenditures are for the pre-launch activities in anticipation of the potential approval and launch of Surfaxin for Respiratory Distress Syndrome (RDS) in the second quarter of 2006. For the three and nine months ended September 30, 2005, costs associated with pre-launch commercialization activities were \$2.7 million and \$7.2 million, respectively, an increase of \$1.4 million and \$3.9 million compared to the same prior year periods;
- (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 nine months ended September 30, 2005, costs associated with these manufacturing activities were \$3.0 million and \$7.0 million, respectively, an increase of \$1.9 million and \$2.4 million compared to the same prior year period. Expenditures in 2005 for manufacturing activities include, but are not limited to, the implementation of enhancements to quality controls, process assurances and documentation requirements that support the clinical and commercial production process at the Company's contract manufacturer, Laureate Pharma, Inc., in response to the FDA 483 inspectional observations;
- (iii) research and development activities related to the advancement of the Company's SRT pipeline. For the three and nine months ended September 30, 2005, costs associated with

these activities, excluding manufacturing activities, were \$2.7 million and \$9.7 million, respectively, a decrease of \$1.9 million and \$4.5 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 nine months ended September 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 Acute Respiratory Distress Syndrome (ARDS) in adults, Chronic Lung Disease (CLD, also known as Bronchopulmonary Dysplasia) in premature infants, and Aerosurf™ for Neonatal Respiratory Failures;

- (iv) general and administrative activities in preparation for managing a fully-integrated commercial biotechnology organization. For the three and nine months ended September 30, 2005, costs associated with these activities, excluding sales and marketing activities, were \$2.1 million and \$6.0 million respectively, an increase of \$0.5 million and \$0.9 million compared to the same prior year period. These expenditures include financial and information technology capabilities, business development activities related to potential strategic collaborations, legal activities related to the preparation and filing of patents in connection with the expansion of our SRT pipeline, facilities expansion activities to accommodate existing and future growth, and corporate governance initiatives to comply with the Sarbanes-Oxley Act; and
- (v) the restructuring, in December 2004, of the strategic alliance with Esteve to develop, market and sell Surfaxin in Southern Europe. Revenues from this alliance decreased by \$0.2 million and \$1.0 million for the three and nine months ended September 30, 2005, respectively, compared to the same prior year period.

#### Selective Updates on Discovery's SRT Programs

##### Surfaxin for RDS

- The U.S. Food and Drug Administration (FDA) accepted the Company's resubmission of October 5, 2005 as a complete response to the Approvable Letter for Surfaxin for the prevention of RDS in premature infants. The FDA has established April 2006 as its target to complete its review of the Surfaxin NDA.

Additionally, at the European Society for Paediatric Research 46<sup>th</sup> Annual Meeting in September, the Company presented the results from a comparative pharmacoeconomic analysis of Surfaxin versus leading animal-derived surfactants (Survanta<sup>®</sup> and Curosurf<sup>®</sup>) in the prevention of RDS in premature infants. Conclusions indicated that babies treated with Surfaxin showed a reduction in overall cost of care, spent fewer days in the NICU, and fewer total days on mechanical ventilation as compared to the animal-derived surfactants.

##### Surfaxin for CLD

- In October, the Office of Orphan Products Development of the FDA granted orphan drug designation to Surfaxin, for the treatment of Bronchopulmonary Dysplasia in premature infants.

Currently the Company is conducting a Phase 2 trial to determine the safety and tolerability of administering up to 5 total doses of Surfaxin in the first 10 days of life as a therapeutic approach for the prevention and treatment of CLD. The Company has recently amended the protocol associated with conducting this trial and now anticipates results in the third quarter of 2006.

### Aerosurf for Neonatal Respiratory Failures

- In September, the Company completed its first pilot Phase 2 feasibility study of Aerosurf™, the Company's precision-engineered aerosolized SRT administered via nasal continuous positive airway pressure (nCPAP) intended to treat premature infants at risk for RDS. This pilot clinical trial serves as the first step in the development of a revolutionary technology that has the potential to treat infants with a wide array of respiratory failures who typically would require mechanical ventilation.

### 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. Our technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. We believe that through our technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. Our lead product, Surfaxin® (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) and is under review for approval in Europe by the European Medical Evaluation Agency (EMA). Surfaxin is also being developed for the treatment of Chronic Lung Disease (CLD, also known as Bronchopulmonary Dysplasia) in premature infants. In addition, we are developing Aerosurf™, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for neonatal respiratory failures.

Our SRT technology is also being developed to address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings. We are

conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and are also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disorder (COPD), and other respiratory conditions.

For more information, please visit our corporate website at [www.Discoverylabs.com](http://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		Nine Months Ended	
	September 30,		September 30,	
	(unaudited)		(unaudited)	
	2005	2004	2005	2004
Revenues from collaborative agreements	\$ 20	\$ 236	\$ 105	\$ 1,075
Operating expenses:				
Research and development	5,676	5,673	16,660	18,757
General and administrative	4,817	2,908	13,182	8,363
Total expenses	10,493	8,581	29,842	27,120
Operating loss	(10,473)	(8,345)	(29,737)	(26,045)
Other income / (expense)	67	(37)	189	(106)
Net loss	\$ (10,406)	\$ (8,382)	\$ (29,548)	\$ (26,151)
Net loss per common share	\$ (0.19)	\$ (0.18)	\$ (0.56)	\$ (0.57)
Weighted average number of common shares outstanding	54,476	46,988	52,844	45,659

**Condensed Consolidated Balance Sheets**  
(in thousands)

	September 30, 2005 <u>(unaudited)</u>	December 31, 2004 <u></u>
<b>ASSETS</b>		
Current Assets:		
Cash and marketable securities	\$ 50,340	\$ 32,654
Prepaid expenses and other current assets	<u>723</u>	<u>688</u>
Total Current Assets	51,063	33,342
Property and equipment, net	4,129	4,063
Other assets	<u>219</u>	<u>232</u>
Total Assets	<u><u>\$ 55,411</u></u>	<u><u>\$ 37,637</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities	\$ 7,878	\$ 8,823
Long-Term Liabilities:		
Credit facility	8,500	5,929
Capitalized leases and other long-term liabilities	<u>1,616</u>	<u>1,788</u>
Total Liabilities	17,994	16,540
Stockholders' Equity	<u>37,417</u>	<u>21,097</u>
Total Liabilities and Stockholders' Equity	<u><u>\$ 55,411</u></u>	<u><u>\$ 37,637</u></u>