

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**

**May 9, 2006**

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 May 9, 2006, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 31, 2006, and providing selected updates on the Company’s progress since the end of the fiscal year 2005. The full text of the press release is set forth in Exhibit 99.1 hereto.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 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.

**Item 2.05. Costs Associated with Exit or Disposal Activities.**

On May 4, 2006, the Company filed a Current Report on Form 8-K and issued a press release announcing that, in connection with the recent delay in U.S. regulatory approval and commercial launch of Surfaxin<sup>®</sup>, it had undertaken a staff reduction, with a primary emphasis on the commercial infrastructure, in order to lower its cost structure and appropriately align the Company’s operations with its business priorities. The Company indicated that, in the quarter ending June 30, 2006, it expects to take a one-time restructuring charge of approximately \$4.5 to \$5.0 million, related to the staff reductions and the wind-down of certain commercial programs. The Company expects that approximately \$2.5 million of the expected one-time charge will be comprised of one-time termination benefits related to the staff reduction and approximately \$2.0 to \$2.5 million of the expected one-time charge will be related to third-party contract termination costs associated with the wind-down of certain commercial programs.

**Item 8.01. Other Events.**

On May 10, 2006, the Company held a conference call to provide an update on its regulatory and manufacturing issues and to provide guidance with respect to its operating results and estimated cash burn in 2006. During the conference call, John G. Cooper, the Company’s Executive Vice President and Chief Financial Officer provided the following guidance regarding the Company’s operations through the remainder of fiscal year 2006:

- in the second quarter 2006, the Company expects (i) an operating loss of approximately \$11 million to \$12 million, excluding a charge for stock-based compensation associated with the adoption by the Company of Financial Accounting Standards No. 123(R) (“FAS 123(R)”) and the expected one-time charge associated with the recent staff reduction and the wind-down of certain commercial programs, and (ii) an estimated cash burn of approximately \$12 million to \$13 million;

- in each of the third and fourth quarters 2006, the Company expects an operating loss (excluding a charge for stock-based compensation associated with the adoption by the Company of FAS 123(R)) of approximately \$8 million to \$9 million; and
- the Company expects an estimated cash burn of approximately \$10 million to \$11 million in the third quarter 2006 and approximately \$8 million to \$9 million in the fourth quarter 2006.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

99.1 Press release dated May 9, 2006.

**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

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Robert J. Capetola, Ph.D.  
President and Chief Executive Officer

Date: May 15, 2006



## Discovery Labs Reports First Quarter 2006 Financial Results

**Warrington, PA — May 9, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO),** today announced financial results for the first quarter ended March 31, 2006. The Company will host a conference call on May 10, 2006 at 4:00 PM EDT. **The call in number is 866-332-5218.**

For the quarter ended March 31, 2006, the Company reported, on a GAAP basis, a net loss of \$15.8 million, or \$0.26 per share, on 61.2 million weighted average common shares outstanding, compared to a net loss of \$9.3 million, or \$0.18 per share, on 50.8 million weighted average shares outstanding for the same period in 2005. The GAAP net loss includes \$1.7 million, or \$0.03 per share, in stock-based compensation expenses as a result of our adoption, on January 1, 2006, of Financial Accounting Standards No. 123(R) ("FAS 123(R)"). Excluding this charge, the non-GAAP net loss for the quarter ended March 31, 2006 was \$14.1 million, or \$0.23 per share. As of March 31, 2006, the Company had 61.2 million shares outstanding.

As of March 31, 2006, the Company had cash and marketable securities of \$37.6 million, compared to \$50.9 million as of December 31, 2005, a decrease of \$13.3 million. The decrease is primarily due to cash used in operating and investing activities of \$13.9 million, offset by \$0.7 million of proceeds from the exercise of stock options and warrants.

As of March 31, 2006, the Company had \$47.6 million available under the 2004 Committed Equity Financing Facility (the "2004 CEFF"), subject to certain conditions. On April 19, 2006, the Company announced that it entered into a new CEFF ("2006 CEFF") with Kingsbridge Capital, Ltd., in which Kingsbridge committed to finance up to \$50 million of capital to support the Company's future growth through the purchase of newly-issued shares of its common stock. The CEFF allows Discovery to raise capital, subject to certain conditions, during a three-year period once the registration statement, which was filed on May 4, 2006, is declared effective by the SEC. Upon effectiveness of the registration statement, the Company's 2004 CEFF will automatically terminate. The Company believes the 2006 CEFF provides potential advantages over the 2004 CEFF, including an adjusted minimum stock purchase price and an extension of the term of the CEFF into 2009.

Under the Company's \$9.0 million capital lease financing arrangement with GECC, \$6.5 million has been used to date, \$4.7 million is outstanding (\$1.7 million classified as current liabilities and \$3.0 million as long-term liabilities) and \$2.5 million remains available for use. The Company's \$8.5 million credit facility with PharmaBio Development, Inc., Quintiles strategic investment group, is fully outstanding and due in December 2006.

### Recent Developments

In April 2006, the Company received a second Approvable Letter from the FDA relating to its New Drug Application (NDA) for Surfaxin<sup>®</sup> for Respiratory Distress Syndrome (RDS). Issues contained in the second Approvable Letter primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA and product labeling. The Company also announced that it anticipates a potentially significant delay in the U.S. regulatory approval for Surfaxin because analysis of ongoing stability data from Surfaxin process validation batches indicated that certain stability parameters had not been achieved and, therefore, additional process validation batches will likely have to be produced. These process validation batches were previously manufactured as a requirement for the Company's U.S. NDA regulatory approval and have been undergoing periodic stability testing. This delay does not arise out of any issues related to the clinical data from our multinational SELECT Study, which demonstrates that Surfaxin was significantly more effective in the prevention of RDS and also improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants.

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On May 4, 2006, the Company announced that it reduced its personnel from 160 to 105, or approximately 34% of the workforce, and reorganized corporate management in order to lower its cost structure and appropriately align operations with business priorities. These actions were based upon the potential financial impact of a delay in the regulatory approval and commercial launch of Surfaxin for RDS in premature infants. The Company expects to realize annual expense savings of approximately \$8.0 million from the reduction in workforce and related operating expenses. Additionally, commercial program expenses totaled approximately \$5.0 million over the past two fiscal quarters (Q4 '05 and Q1 '06), and these expenses will no longer be incurred. The Company expects to take a one-time restructuring charge of approximately \$4.5 to \$5.0 million in the second quarter ending June 30, 2006 related to the staff reductions and the wind down of certain commercial programs.

On May 9, 2006, with enrollment totaling approximately 130 patients, the Company determined to conclude early its Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants. This action is related to the potential financial impact of the Surfaxin manufacturing issues that are anticipated to significantly delay the regulatory approval of Surfaxin for RDS and may adversely affect the availability of Surfaxin drug product for this trial. This double-blind, controlled Phase 2 clinical trial was intended to enroll up to 210 very low birth weight premature infants born at risk for developing BPD. The study's objective is to determine the safety and tolerability of administering Surfaxin for the prevention and treatment of BPD. The Company plans to perform a comprehensive analysis of the clinical data from this trial, report top-line results, and submit these data for publication.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "Based on recent events, we have taken steps to control costs and maintain the human and capital resources to focus on the programs that potentially allow patients to experience the benefit of this important new class of respiratory medicine. Our highest priority is the actions necessary to gain Surfaxin regulatory approval. We are focused on investigating and remediating the Surfaxin manufacturing issues while maintaining the clinical and commercial manufacturing capabilities for Surfaxin and our SRT pipeline. Just as important is the development of our pipeline of SRT products, primarily our potentially revolutionary aerosolized SRT, Aerosurf™ for neonatal respiratory disorders, as well as exploring opportunities for strategic partnerships."

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## Review of Operating Results – Three Months Ended March 31, 2006

The Company reported, on a GAAP basis, a net loss of \$15.8 million for the three months ended March 31, 2006. Excluding a charge for stock-based compensation associated with FAS 123(R) of \$1.7 million (\$0.4 million classified as research and development and \$1.3 million classified as general and administrative), the non-GAAP net loss for the 2006 quarter was \$14.1 million, compared to \$9.3 million for the same period last year, an increase of \$4.8 million. This increase is primarily due to:

- (i) pre-launch commercialization activities (included in general and administrative expenses) related to the Company building a United States commercial infrastructure to market its SRT to address respiratory disorders in the Neonatal Intensive Care Unit (NICU). For the three months ended March 31, 2006, costs associated with pre-launch commercialization activities were \$4.7 million, an increase of \$2.3 million compared to the same period in 2005;
- (ii) manufacturing activities (included in research and development expenses) to support the production of clinical and commercial drug supply for the Company's SRT programs, including Surfaxin, other SRT formulations and aerosol development capabilities, in conformance with current Good Manufacturing Practices (cGMPs). For the three months ended March 31, 2006, costs associated with these activities were \$2.4 million, an increase of \$1.0 million compared to the same period in 2005. The increase in expenses is primarily associated with the ownership of our NJ manufacturing operations which we purchased from Laureate Pharma, Inc. (our contract manufacturer at that time) in December 2005;
- (iii) research and development activities related to the advancement of the Company's SRT pipeline. For the three months ended March 31, 2006, costs associated with these activities, excluding manufacturing activities, were \$4.8 million, an increase of \$1.1 million compared to the same period in 2005. The increase is primarily due to: (i) U.S. and European regulatory activities associated with Surfaxin for RDS; (ii) clinical activities for the Phase 2 trial for Acute Respiratory Distress Syndrome (ARDS) in adults and the Phase 2 trial for BPD in premature infants; and (iii) development activities related to Aerosurf for Neonatal Respiratory Disorders; and
- (iv) general and administrative activities to support long-term business plans. For the three months ended March 31, 2006, costs associated with these activities, excluding pre-launch commercialization activities, were \$2.7 million, an increase of \$0.8 million compared to the same period in 2005. The increase is predominantly due to legal activities (including the preparation and filing of patents in connection with our SRT pipeline and efforts to support business development for strategic collaborations) and corporate governance initiatives to comply with the Sarbanes-Oxley Act.

## Use of Non-GAAP Financial Measures

Discovery adopted FAS 123(R) on January 1, 2006 using the modified prospective method, which resulted in the recognition of stock compensation expenses in the statement of operations during the quarter ended March 31, 2006 without adjusting the prior year first quarter. Discovery uses non-GAAP net loss data to improve its analysis of operational results and trends. Discovery's management also uses these non-GAAP figures to make financial and operational decisions as these numbers exclude non-operational activities. These measures should not be considered an alternative to measurements required by GAAP, such as net loss and net loss per share, and should not be considered measures of our liquidity. A reconciliation between GAAP and non-GAAP financial measures is included in a footnote to the Statement of Operations accompanying this press release.

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## 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 lead product, Surfaxin<sup>®</sup>, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received two Approvable Letters from the FDA and is under review for approval in Europe by the EMEA.

Our proprietary SRT is also being developed in an aerosolized form under the name Aerosurf<sup>™</sup>, for the treatment of neonatal respiratory failure. We are preparing to conduct Phase 2 pilot studies with Aerosurf<sup>™</sup>, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP). In addition, also for premature infants, we have recently concluded early a Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), also known as Chronic Lung Disease. The Company recently completed and announced preliminary results of a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to potentially address Acute Lung Injury (ALI), cystic fibrosis and other respiratory conditions.

For more information, please visit our corporate website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

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*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 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 that approval by the FDA or other health regulatory authorities of any applications filed by Discovery may be withheld, delayed and/or limited by indications or other label limitations, 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 that Discovery's CMC will not satisfy the FDA, risk in the FDA review process generally, risks relating to the ability of Discovery's third party contract manufacturers and development partners to provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery's clinical studies, risks relating to drug manufacturing by Discovery, risks relating to the integration of manufacturing operations into Discovery's existing operations, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, risks relating to the ability of the Company and its collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements, 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:**

John G. Cooper, EVP and CFO  
215-488-9490

Lisa Caperelli, Investor Relations  
215-488-9413

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

	Three Months Ended March 31, (unaudited)	
	2006	2005
Revenues from collaborative agreements	\$ -	\$ 61
Operating expenses:		
Research and development (1)	7,613	5,120
General and administrative (1)	8,682	4,270
Total expenses	16,295	9,390
Operating loss	(16,295)	(9,329)
Other income / (expense)	500	13
Net loss	\$ (15,795)	\$ (9,316)
Net loss per common share	\$ (0.26)	\$ (0.18)
Weighted average number of common shares outstanding	61,170	50,784

- (1) Included in expenses for the quarter ended March 31, 2006 is a charge of \$1.7 million (\$0.4 million classified as research and development and \$1.3 million classified as general and administrative) associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123(R), which the Company adopted on January 1, 2006.

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

	March 31, 2006	December 31, 2005
<b><u>ASSETS</u></b>		
Current Assets:		
Cash and marketable securities	\$ 37,569	\$ 50,908
Prepaid expenses and other current assets	876	560
Total Current Assets	38,445	51,468
Property and equipment, net	4,798	4,322
Other assets	218	218
Total Assets	\$ 43,461	\$ 56,008
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 8,168	\$ 7,540
Credit facility	8,500	8,500
Capitalized leases and other liabilities, current portion	1,663	1,568
Total Current Liabilities	18,331	17,608
Long-Term Liabilities:		
Capitalized leases and other liabilities, long-term portion	3,282	3,562
Total Liabilities	21,613	21,170
Stockholders' Equity	21,848	34,838
Total Liabilities and Stockholders' Equity	\$ 43,461	\$ 56,008

