

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 1, 2007**

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 2, 2007, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the first quarter ended March 31, 2007, providing selected updates on the progress of regulatory and manufacturing activities associated with the Company’s lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and discussing the appointment of W. Thomas Amick as Chairman of the Company’s Board of Directors in March. The press release is attached as 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 8.01.            Other Events.**

On May 1, 2007, the United States District Court for the Eastern District of Pennsylvania dismissed, without prejudice, the consolidated shareholder derivative complaints initially filed in May and June 2006 and amended on December 29, 2006 against the Company and certain of its executive officers and directors. The plaintiffs were granted leave to file an amended complaint by May 15, 2007.

On May 3, 2007, the Company held a conference call to discuss the financial results for the first quarter. During the conference call, John G. Cooper, the Company’s Executive Vice President and Chief Financial Officer provided an estimate of aggregate cash outflows from operating and investing activities for the second quarter of approximately \$9.0 million to \$9.5 million. This estimate represents an increase of approximately \$0.5 million from the guidance provided for the first quarter of 2007, primarily as a result of activities associated with the development of Aerosurf™, the Company’s aerosolized surfactant platform.

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

(d)            Exhibits

99.1          Press release dated May 2, 2007

**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

Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

Date: May 3, 2007



## Discovery Labs Reports First Quarter 2007 Financial Results

**Warrington, PA — May 2, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO),** today announced financial results for the first quarter ended March 31, 2007. The Company will host a conference call on May 3, 2007 at 9:00 AM EDT. **The call in number is 866-332-5218.**

For the quarter ended March 31, 2007, the Company reported a net loss of \$8.3 million (or \$0.12 per share) on 70.0 million weighted average common shares outstanding compared to a net loss of \$15.8 million (or \$0.26 per share) on 61.2 million weighted average common shares outstanding for the same period in 2006.

As of March 31, 2007, the Company had cash and marketable securities of \$20.7 million. On April 5, 2007, the Company completed a registered direct offering to institutional investors resulting in gross proceeds of \$30.2 million (\$28.2 million net) from the issuance of 14,050,000 shares of common stock at \$2.15 per share. Additionally, under its existing Committed Equity Financing Facility (CEFF), the Company may issue up to approximately 7.1 million shares (not to exceed \$40.5 million in aggregate proceeds) in future financings. During the first quarter of 2007, the Company's cash and marketable securities decreased by \$6.3 million primarily due to \$8.3 million used in operating activities and debt payments, offset by proceeds of \$2.0 million from a financing pursuant to the CEFF.

Selected highlights include:

- At the Company's clarification meeting with the U.S. Food and Drug Administration (FDA), the Company obtained guidance regarding the steps necessary to potentially gain approval of Surfaxin<sup>®</sup> for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. This guidance provided the clarity needed to address key remaining issues identified in the April 2006 FDA Approvable Letter, which focused on the Chemistry, Manufacturing and Controls portion of the Company's New Drug Application (NDA). Consistent with the guidance obtained from the FDA and based on the progress made by the Company in its comprehensive investigation and manufacturing remediation activities related to the April 2006 process validation stability failure, the Company manufactured new Surfaxin process validation batches. The Company plans to file its formal response to the Surfaxin Approvable Letter in September or October 2007, followed by an anticipated six-month review cycle by the FDA for potential approval of the Surfaxin NDA.
  - In March, W. Thomas Amick was appointed Chairman of the Company's Board of Directors. Mr. Amick brings extensive pharmaceutical, strategic and operational leadership to Discovery Labs as the Company prepares for the potential FDA approval of Surfaxin<sup>®</sup> and advances its pipeline of Surfactant Replacement Therapies (SRT) for the treatment of various respiratory diseases. Mr. Amick enjoyed a highly successful 30-year career with Johnson & Johnson (J&J) where he led the launch of Procrit<sup>®</sup> (Epoetin alfa) and built J&J's oncology franchise into one of the most successful businesses in J&J history with annual revenues exceeding \$2.5 billion.
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Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, “We believe, with the clarity gained from the FDA meeting, with the continuing enhancements to our quality and manufacturing operations, and through strategic improvements to our financial position, we have significantly strengthened our Company over the last two quarters. Surfaxin potentially represents an opportunity to improve the standard of care for premature infants and is a base on which we plan to build an important respiratory franchise. Aerosurf™, our aerosolized SRT delivered through non-invasive methods, holds the promise to significantly expand the use of surfactants in neonatal and pediatric medicine. The Company’s top priority is to gain FDA approval of Surfaxin while advancing Aerosurf into Phase 2 clinical trials later this year.”

#### **First Quarter 2007 Operating Expenses:**

Total operating expenses for the quarter ended March 31, 2007 were \$8.2 million compared to \$16.3 million for the same period in 2006. The decrease in this quarter compared to the same period last year is primarily due to costs incurred in 2006 in anticipation of the potential approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. After the April 2006 Surfaxin process validation stability failure, the Company took immediate steps to lower its costs and suspended pre-launch commercial activities, reduced personnel and reorganized corporate management. For the first quarter of 2007, the components of the \$8.2 million operating expense include:

- manufacturing development expenses (included in research and development expenses) of \$2.3 million, including: (i) costs associated with operating the Company’s manufacturing facility to support the production of clinical and anticipated commercial drug supply for the Company’s SRT programs; (ii) continued investment in the Company’s quality assurance and analytical chemistry capabilities to ensure compliance with current good manufacturing practices (cGMP); (iii) activities associated with developing data and other information necessary for the Company’s formal response to the Surfaxin Approvable Letter; and (iv) activities to develop improved formulations of the Company’s SRT.
  - research and development expenses (excluding manufacturing development activities) of \$3.1 million, including: (i) costs associated with developing data and other information necessary for the Company’s formal response to the Surfaxin Approvable Letter; (ii) development activities related to Aerosurf™, the Company’s proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), to address premature infants at risk for respiratory failure; and (iii) activities to develop Surfaxin and aerosol SRT to address pediatric and adult patients with respiratory disorders.
  - general and administrative expenses of \$2.8 million, including costs associated with executive management, the defense of the securities class action and derivative proceedings (which have been dismissed), evaluation of various strategic business alternatives, financial and legal management and other administrative costs.
  - \$0.6 million (classified in the amounts above as \$0.2 million in research and development and \$0.4 million in general and administrative) associated with stock-based employee compensation resulting from Financial Accounting Standards No. 123(R).
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## Debt Arrangements at March 31, 2007:

The Company had \$9.1 million outstanding under its long-term loan with PharmaBio Development Inc., a strategic investment group of Quintiles Transnational Corp. The outstanding principal, together with all accrued interest from July 1, 2006, is due and payable on April 30, 2010. The Company may repay this loan in whole or in part at any time prior to April 2010 without prepayment penalty or premium.

The Company had \$4.2 million outstanding under a capital lease financing arrangement with General Electric Capital Corporation (GECC), of which \$2.0 million was classified as a current liability and \$2.2 million as a long-term liability.

## About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing 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 its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery's lead product candidate, Surfaxin<sup>®</sup>, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. Surfaxin is also being developed for other neonatal and pediatric indications. Aerosurf<sup>™</sup>, Discovery's aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

*To the extent that statements in this press release are not strictly historical, 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 Discovery may not profitably develop and market its products, the risk that financial market conditions may change, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements, the risk that Discovery will not be able to attract or retain qualified personnel or timely provide for a successful sales and marketing organization, risks relating to the progress of Discovery's research and development, risks in the FDA or other regulatory agency review process generally, including that such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application or that approval by such regulatory agency may be withheld, delayed and/or limited by indications or other label limitations, risks that the Chemical, Manufacturing and Controls section of Discovery's New Drug Application will not satisfy the FDA, risks relating to the ability of Discovery or Discovery's third party manufacturers and development partners to manufacture or provide Discovery with adequate supplies of drug substances and expertise for completion of any of Discovery's clinical studies, risks related to the ability of Discovery and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery's drug products with innovative aerosolization technologies, risks relating to drug manufacturing by Discovery, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval process for any products that Discovery may develop independently or with Discovery's collaboration arrangements, risks relating to the development by other companies of competing therapies and/or technologies, risks relating to reimbursement and health care reform, and risks relating to securities, product liability and other litigation. 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 Contact:

Lisa Caperelli, Investor Relations  
215-488-9413

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

	Three Months Ended March 31, (unaudited)	
	2007	2006
Revenue	\$ --	\$ --
<b>Operating expenses (1) :</b>		
Research and development	5,422	7,613
General and administrative	2,754	8,682
Total operating expenses	8,176	16,295
Operating loss	(8,176)	(16,295)
Other income / (expense)	(134)	500
Net loss	\$ (8,310)	\$ (15,795)
Net loss per common share	\$ (0.12)	\$ (0.26)
Weighted average number of common shares outstanding	69,989	61,170

(1) Included in expenses for the three months ended March 31, 2007 and 2006 are charges of \$0.6 million (\$0.2 million classified as research and development and \$0.4 million classified as general and administrative) and \$1.7 million (\$0.4 million classified as research and development and \$1.3 million classified as general and administrative), respectively, associated with stock-based employee compensation in accordance with the provisions of FAS No. 123(R), which the Company adopted on January 1, 2006.

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

	March 31, 2007	December 31, 2006
<b><u>ASSETS</u></b>		
<b>Current Assets:</b>		
Cash and marketable securities	\$ 20,748	\$ 27,002
Prepaid expenses and other current assets	216	565
Total Current Assets	20,964	27,567
Property and equipment, net	4,831	4,794
Other assets	1,902	2,039
Total Assets	\$ 27,697	\$ 34,400
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
<b>Current Liabilities:</b>		
Accounts payable and accrued expenses	\$ 5,119	\$ 5,953
Capitalized leases and other liabilities	1,970	2,015
Total Current Liabilities	7,089	7,968
<b>Long-Term Liabilities:</b>		
Loan payable, including accrued interest	9,086	8,907
Capitalized leases and other liabilities	2,754	3,203
Total Liabilities	18,929	20,078
Stockholders' Equity	8,768	14,322
Total Liabilities and Stockholders' Equity	\$ 27,697	\$ 34,400