

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

July 28, 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 July 28, 2006, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended June 30, 2006, and providing selected updates on the Company’s progress since the end of the first fiscal quarter in 2006. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press release dated July 28, 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

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

Date: August 2, 2006



Discovery Labs Reports Second Quarter 2006 Financial Results

Warrington, PA — July 28, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the second quarter ended June 30, 2006. 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, 2006, the Company reported, on a GAAP basis, a net loss of \$14.7 million, or \$0.24 per share, on 61.7 million weighted average shares of common stock outstanding. Included in the GAAP net loss for the quarter ended June 30, 2006 is a restructuring charge of \$4.8 million, or \$0.08 per share, related to the staff reductions and the close-out of certain commercial programs as a result of the adjusted timeline for the regulatory approval and commercial launch of Surfaxin[®] for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Also included in the GAAP net loss for the quarter ended June 30, 2006 is a charge of \$1.6 million (or \$0.03 per share) associated with stock-based compensation as a result of our adoption of Financial Accounting Standards No. 123(R) ("FAS 123(R)") on January 1, 2006. Excluding these charges, the net loss for the quarter ended June 30, 2006 was \$8.3 million (or \$0.13 per share), compared to a net loss of \$9.8 million (or \$0.18 per share), on 53.6 million weighted average shares outstanding for the same period in 2005. As of June 30, 2006, the Company had 62.3 million shares outstanding.

For the six months ended June 30, 2006, the Company reported, on a GAAP basis, a net loss of \$30.5 million, or \$0.50 per share, on 61.4 million weighted average shares outstanding. Included in the GAAP net loss for the six months ended June 30, 2006 is the second quarter restructuring charge of \$4.8 million (or \$0.08 per share) and a charge of \$3.2 million (or \$0.05 per share) associated with FAS 123(R). Excluding these charges, the non-GAAP net loss for the six months ended June 30, 2006 was \$22.5 million (or \$0.37 per share), compared to a net loss of \$19.1 million (or \$0.37 per share) on 52.0 million weighted average shares outstanding for the same period in 2005.

As of June 30, 2006, the Company had cash and marketable securities of \$27.3 million, compared to \$37.6 million as of March 31, 2006, a decrease of \$10.3 million. The decrease is primarily due to net cash used in operating and investing activities of \$12.5 million, offset by \$2.2 million of proceeds from a financing pursuant to the Company's Committed Equity Financing Facility (CEFF). Under the Company's \$9.0 million capital lease financing arrangement with General Electric Capital Corporation, \$5.2 million is outstanding (\$1.9 million classified as current liabilities and \$3.3 million as long-term liabilities) and \$1.6 million remains available for use. The Company's \$8.5 million secured revolving credit facility with an affiliate of Quintiles Transnational Corp. is fully outstanding and due in December 2006.

Under the CEFF, the Company has up to \$47.8 million potentially available to May 2009. Use of the CEFF is subject to certain conditions, including a share limitation (currently approximately 10.6 million shares) and the volume weighted average price of the Company's common stock on each trading day must be at least \$2.00.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "The highest priority for Discovery Labs is to gain U.S. regulatory approval for Surfaxin. Our focus is on remediating the Surfaxin manufacturing issues to achieve this goal. Based upon what we have learned to date from our comprehensive investigation, including the manufacture of two Surfaxin investigation batches, we believe we are on target to meet with the FDA and manufacture new process validation batches in the fourth quarter of 2006. Of equal importance is the development of our pipeline of SRT products, primarily Aerosurf™, our potentially revolutionary aerosolized SRT for neonatal respiratory disorders, as well as other novel formulations and the exploration of various strategic alternatives."

Review of Operating Results - Three and Six Months Ended June 30, 2006

The Company reported, on a GAAP basis, a net loss of \$14.7 million and \$30.5 million for the three and six months ended June 30, 2006, respectively, an increase of \$4.9 million and \$11.4 million compared to the same prior year periods. Included in the GAAP net loss is a charge for stock-based compensation associated with FAS 123(R) of \$1.6 million and \$3.2 million for the three and six months ended June 30, 2006, respectively. Excluding these charges, the non-GAAP net loss for the three and six months ended June 30, 2006 was \$13.1 million and \$27.3 million, respectively, an increase of \$3.3 million and \$8.2 million compared to the same prior year periods. This change is primarily due to:

- (i) a restructuring charge of \$4.8 million in the second quarter of 2006 associated with staff reductions and the close-out of certain commercial programs as a result of the Company receiving a second Approvable Letter and experiencing manufacturing issues that adjusted the timeline for the regulatory approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. This charge includes \$2.5 million of severance and benefits related to staff reductions and \$2.3 million for the termination of certain commercial programs;
 - (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, SRT formulations and aerosol development capabilities, in conformance with current Good Manufacturing Practices (cGMPs). For the three and six months ended June 30, 2006, costs associated with these activities were \$2.7 million and \$5.1 million, respectively, no change and an increase of \$1.1 million compared to the same prior year periods. The increase in expenses is primarily associated with the ownership of our manufacturing operation in Totowa, New Jersey, which we purchased in December 2005; and
 - (iii) general and administrative expenses, primarily Surfaxin pre-launch commercial activities to build a United States commercial infrastructure in preparation for the previously anticipated commercial launch of Surfaxin in the second quarter of 2006. For the three and six months ended June 30, 2006, costs associated with these activities were \$0.8 million and \$5.5 million, respectively, a decrease of \$1.3 million and an increase of \$1.0 million, compared to the same prior year periods. In April 2006, in connection with the second Approvable Letter and failure of Surfaxin process validation batches to achieve certain stability parameters, which resulted in an adjusted timeline for regulatory approval of Surfaxin, the Company discontinued pre-launch and commercial activities, resulting in a restructuring of the commercial infrastructure. The cost associated with the discontinuance of such activities are a component of the Q2 2006 restructuring charge.
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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 for the three and six months ended June 30, 2006 without adjusting the same prior year periods. 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. Discovery believes that presentation of results excluding non-cash compensation expense and restructuring charges may provide meaningful supplemental information to both management and investors. 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 non-GAAP financial measures and GAAP financial measures is included in a footnote to the Statement of Operations accompanying this press release.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing proprietary 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 pulmonary surfactant platform has the potential to address a variety of respiratory diseases where there are few or no approved therapies available.

Discovery's lead product, Surfaxin[®], has received two Approvable Letters from the FDA for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In addition, Discovery recently concluded patient enrollment for its Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants.

Discovery is also developing Aerosurf[™], its proprietary SRT administered in aerosolized form, for the treatment of premature infants with multiple respiratory disorders. Discovery is preparing to initiate Phase 2 clinical studies with Aerosurf administered through nasal continuous positive airway pressure (nCPAP), potentially obviating the need for intubation and conventional mechanical ventilation. Discovery is also developing its SRT to potentially address Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), cystic fibrosis and other respiratory conditions.

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), the risk that Discovery will not be able to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all, the 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, the risk 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 the Chemistry, Manufacturing and Controls (CMC) section of Discovery's New Drug Application will not satisfy the FDA, risk in the FDA or other regulatory agency review process generally, risks relating to the ability of Discovery or Discovery's third party contract manufacturers and development partners to manufacture or 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 Discovery and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery's 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 Discovery's 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.

For more information, please visit our corporate website at www.Discoverylabs.com.

Company Contact:

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)	
	2006	2005	2006	2005
Revenues from collaborative agreements	\$ -	\$ 24	\$ -	\$ 85
Operating expenses:				
Research and development (1)	5,911	5,864	13,524	10,984
General and administrative (1)	4,024	4,095	12,706	8,365
Restructuring charge	4,805	--	4,805	--
Total expenses	14,740	9,959	31,035	19,349
Operating loss	(14,740)	(9,935)	(31,035)	(19,264)
Other income / (expense)	45	109	545	122
Net loss	\$ (14,695)	\$ (9,826)	\$ (30,490)	\$ (19,142)
Net loss per share	\$ (0.24)	\$ (0.18)	\$ (0.50)	\$ (0.37)
Weighted average number of shares outstanding	61,652	53,587	61,411	52,029

(1) Included in expenses for the three and six months ended June 30, 2006 are charges of \$1.6 million (\$0.5 million classified as research and development and \$1.1 million classified as general and administrative) (or \$0.03 per share) and \$3.2 million (\$0.9 million classified as research and development and \$2.3 million classified as general and administrative) (or \$0.05 per share), respectively, 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)

	June 30,	December 31,
	2006	2005
	(unaudited)	
ASSETS		
Current Assets:		
Cash and marketable securities	\$ 27,289	\$ 50,908
Prepaid expenses and other current assets	348	560
Total Current Assets	27,637	51,468
Property and equipment, net	4,583	4,322
Other assets	217	218
Total Assets	\$ 32,437	\$ 56,008
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 7,203	\$ 7,540
Credit facility	8,500	8,500
Capitalized leases and other liabilities, current portion	1,883	1,568
Total Current Liabilities	17,586	17,608
Long-Term Liabilities:		
Capitalized leases and other liabilities, long-term portion	3,961	3,562
Total Liabilities	21,547	21,170
Stockholders' Equity	10,890	34,838
Total Liabilities and Stockholders' Equity	\$ 32,437	\$ 56,008