

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**

February 28, 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 February 28, 2007, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the fourth quarter and fiscal year ended December 31, 2006, and 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. 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 February 28, 2007, the Company held a conference call to discuss the financial results for the fourth quarter and fiscal year ended December 31, 2006. On the call, the Company provided an estimate of aggregate cash outflows from operating and investing activities for the first fiscal quarter of 2007 of approximately \$8.5 million to \$9.0 million. This figure represents an increase of approximately \$1.0 - \$1.5 million from the fourth quarter of 2006, 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 February 28, 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: February 28, 2007



Discovery Labs Reports Fourth Quarter 2006 Financial Results

Warrington, PA — February 28, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the fourth quarter and year ended December 31, 2006. The Company will host a conference call on Wednesday, February 28, 2007 at 10:00 AM EST. **The call in number is 866-332-5218.**

For the quarter ended December 31, 2006, the Company is reporting a net loss of \$7.8 million (or \$0.12 per share) on 66.2 million weighted average common shares outstanding compared to a net loss of \$29.4 million (or \$0.51 per share) on 57.8 million weighted average common shares outstanding for the same period in 2005. Included in the net loss for the fourth quarter of 2006 is a charge of \$1.3 million (or \$0.02 per share) associated with stock-based employee compensation resulting from the adoption of Financial Accounting Standards No. 123(R) (FAS 123(R)) in 2006. Included in the net loss for the fourth quarter of 2005 was a charge of \$16.8 million (or \$0.29 per share) for the purchase of our then contracted manufacturing operation in Totowa, New Jersey. Excluding these charges, the non-GAAP net loss for the quarters ended December 31, 2006 and 2005 were \$6.5 million (or \$0.10 per share) and \$12.6 million (or \$0.22 per share), respectively. As of December 31, 2006, the Company had 69.6 million common shares outstanding.

As of December 31, 2006, the Company had cash and marketable securities of \$27.0 million and approximately 8.0 million shares available for issuance under the Company's Committed Equity Financing Facility (CEFF) for future financings (not to exceed \$42.5 million). Cash and marketable securities increased by \$7.3 million in the fourth quarter primarily due to: (i) aggregate cash outflows of \$7.5 million used in operating and investing activities, (ii) a financing with one selected institutional investor resulting in gross proceeds of \$10.0 million (net proceeds of \$9.5 million) from the sale of approximately 4.6 million shares of common stock and issued a warrant with a five-year term exercisable for approximately 2.3 million shares of common stock at an exercise price of \$3.18 per share; and (iii) two CEFF financings that generated proceeds of approximately \$5.3 million from the issuance of approximately 2.6 million shares of common stock. Use of the CEFF is subject to certain conditions, including that the volume weighted average price of the Company's common stock during a draw down must be at least \$2.00 per share.

As of December 31, 2006, the Company had \$8.9 million outstanding (classified as a long-term liability - loan payable) under its loan with PharmaBio Development Inc. (PharmaBio), an investment group of Quintiles Transnational Corp. In the fourth quarter of 2006, the Company restructured this loan with PharmaBio to provide, among other things, that the principal amount of \$8.5 million originally scheduled to mature on December 31, 2006 and all interest is now due on April 30, 2010. In connection with the restructuring, Discovery and PharmaBio entered into a Warrant Agreement, pursuant to which PharmaBio has the right to purchase during a seven-year term 1.5 million shares of the Company's common stock at an exercise price of \$3.58 per share. Also as of December 31, 2006, the Company had \$4.7 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 \$2.7 million as a long-term liability.

In addition, 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) include:

- On December 21, 2006, at a meeting with the U.S. Food and Drug Administration (FDA) the Company received guidance regarding the key remaining steps necessary for potential approval of Surfaxin for the prevention of RDS in premature infants. This guidance provides the clarity and the defined pathway that the Company believes is necessary to address key remaining issues identified in the April 2006 FDA Approvable Letter. The Company remains on-track 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 New Drug Application.
- Following the December 2006 FDA meeting and based on the progress the Company has made in its comprehensive manufacturing investigation and remediation activities to date, the Company recently completed the manufacture of new Surfaxin process validation batches. These batches are currently undergoing release and ongoing stability testing. This stability data will support the Company's forthcoming formal response to the Surfaxin Approvable Letter. Additionally, the FDA indicated that Surfaxin shelf-life will be determined based upon comparative stability data from historical Surfaxin batches, including previously manufactured clinical, technology transfer, and investigational batches, as well as the new process validation batches.

Review of Operating Results - Three Months Ended December 31, 2006

The Company is reporting a net loss of \$7.8 million for the quarter ended December 31, 2006 compared to a net loss of \$29.4 million for the same period in 2005. Included in the net loss for the fourth quarter of 2006 is a charge of \$1.3 million associated with stock-based employee compensation resulting from the adoption of FAS 123(R) on January 1, 2006. Included in the net loss for the fourth quarter of 2005 was a charge of \$16.8 million for the purchase of our then contracted manufacturing operation in Totowa, New Jersey. Excluding these charges, the non-GAAP net loss for the quarters ended December 31, 2006 and 2005 were \$6.5 million and \$12.6 million, respectively, a decrease of \$6.1 million. The primary components of the fourth quarter 2006 loss include:

- (i) manufacturing development expenses (included in research and development expenses) for the quarter ended December 31, 2006 were \$2.2 million, a decrease of \$2.2 million compared to the same period in 2005. Manufacturing development includes (1) costs associated with operating the Company's manufacturing facility in Totowa, New Jersey (which the Company acquired from its then contract manufacturer, Laureate Pharma, Inc. (Laureate), in December 2005), to support the production of clinical and anticipated commercial drug supply for the Company's SRT programs; (2) continued investment in the Company's quality assurance and analytical chemistry capabilities to ensure current good manufacturing practices (cGMP); and (3) costs associated with the comprehensive investigation, analysis and remediation of the April 2006 Surfaxin process validation stability failure and related manufacturing issues. Expenditures in the quarter ended December 31, 2005 primarily represented manufacturing charges from Laureate, service charges and costs for the manufacture of Surfaxin, as well as, approximately \$2.0 million of improvements and enhancements to the manufacturing operation in New Jersey prior to the acquisition by the Company;
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- (ii) research and development expenses (excluding manufacturing development activities) for the quarter ended December 31, 2006 were \$2.4 million, a decrease of \$0.6 million compared to the same period in 2005. Expenditures in the fourth quarter of 2006 were primarily associated with costs incurred for (1) regulatory activities related to the April 2006 Approvable Letter for Surfaxin for the prevention of RDS and the process validation stability failure; (2) engineering and development activities (in conjunction with our strategic alliance with Chrysalis Technologies, Inc., a division of Philip Morris USA) related to Aerosurf™, the Company's proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), for the prevention and treatment of infants at risk for respiratory failure; and (3) research and development activities to explore improved formulations and expand the application of the Company's technology in other respiratory conditions; and
- (iii) general and administrative expenses for the quarter ended December 31, 2006 were \$2.0 million, a decrease of \$3.3 million compared to the same period in 2005. Expenses in the fourth quarter of 2006 include, but are not limited to, the costs of executive management, defense costs related to pending securities class actions and derivative litigation, evaluation of various strategic business alternatives, financial and legal management and other administrative costs. Included in the fourth quarter of 2005 are costs associated with building a United States commercial infrastructure. The decrease compared to last year primarily reflects the Company's decision, in response to the April 2006 Approvable Letter and the Surfaxin process validation stability failure, to discontinue this commercial capability.

Financial Results for the Year Ended December 31, 2006

For the twelve months ended December 31, 2006, the Company reported a net loss of \$46.3 million (or \$0.74 per share) on 62.8 million weighted average common shares outstanding compared to a net loss of \$58.9 million (or \$1.09 per share) on 54.1 million weighted average common shares outstanding for the same period in 2005. Included in the net loss for the twelve months ended December 31, 2006 is a charge of \$5.5 million (or \$0.09 per share) for stock-based compensation associated with FAS 123(R), which the Company adopted effective January 1, 2006, and 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 following receipt of the April 2006 Approvable Letter and the Surfaxin process validation stability failure. Included in the net loss for the twelve months ended December 31, 2005 is a charge of \$16.8 million (or \$0.31 per share) for the purchase of our manufacturing operation in Totowa, New Jersey. Excluding these charges, the non-GAAP net loss for the twelve months ended December 31, 2006 was \$36.0 million (or \$0.57 per share) compared to \$42.1 million (or \$0.78 per share) for the same period in 2005.

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 statements of operations for the three and twelve months ended December 31, 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 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 premature infants, children and adults.

Discovery's lead product candidate, Surfaxin[®], 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 the prevention and treatment of Bronchopulmonary Dysplasia in premature infants. Aerosurf[™], Discovery's aerosolized SRT, is being developed initially to treat premature infants suffering from respiratory disorders and is intended to obviate the need for intubation and conventional mechanical ventilation. Discovery's SRT pipeline also includes programs potentially addressing Acute Lung Injury, Acute Respiratory Failure, Cystic Fibrosis, Acute Respiratory Distress Syndrome, and other respiratory conditions. For more information, please visit our corporate website 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 potentially conditioned upon 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 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 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 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 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.

Company Contact:

Lisa Caperelli, Investor Relations
215-488-9413

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	(unaudited)			
	2006	2005	2006	2005
Revenues from collaborative agreements	\$ --	\$ 29	\$ --	\$ 134
Operating expenses:				
Research and development (1)	4,988	7,477	23,716	24,137
General and administrative (1)	2,957	5,323	18,386	18,505
Restructuring charge	--	--	4,805	--
In-process research & development	--	16,787	--	16,787
Total operating expenses	7,945	29,587	46,907	59,429
Operating loss	(7,945)	(29,558)	(46,907)	(59,295)
Other income / (expense)	100	202	574	391
Net loss	\$ (7,845)	\$ (29,356)	\$ (46,333)	\$ (58,904)
Net loss per common share	\$ (0.12)	\$ (0.51)	\$ (0.74)	\$ (1.09)
Weighted average # of common shares outstanding	66,195	57,843	62,767	54,094

- (1) Included in expenses for the three and twelve months ended December 31, 2006 are charges of \$1.3 million (\$0.4 million classified as research and development and \$0.9 million classified as general and administrative) (or \$0.02 per share) and \$5.5 million (\$1.6 million classified as research and development and \$3.9 million classified as general and administrative) (or \$0.09 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)

	December 31,	December 31,
	2006	2005
<u>ASSETS</u>		
Current Assets:		
Cash and marketable securities	\$ 27,002	\$ 50,908
Prepaid expenses and other current assets	565	560
Total Current Assets	27,567	51,468
Property and equipment, net	4,794	4,322
Other assets	2,039	218
Total Assets	\$ 34,400	\$ 56,008
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,953	\$ 7,540
Loan payable	--	8,500
Capitalized leases and other liabilities	2,015	1,568
Total Current Liabilities	7,968	17,608
Long-Term Liabilities:		
Loan payable, including accrued interest	8,907	--
Capitalized leases and other liabilities	3,203	3,562
Total Liabilities	20,078	21,170
Stockholders' Equity	14,322	34,838
Total Liabilities and Stockholders' Equity	\$ 34,400	\$ 56,008