

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**

March 13, 2009

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 March 13, 2009, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the year and quarter ended December 31, 2008. 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.

In connection with the release of its earnings for the quarter and year ended December 31, 2008, the Company provides an estimate of the anticipated net cash outflows for the first quarter of 2009 of approximately \$7.0 - \$8.0 million. Until the U.S. Food and Drug Administration (FDA) has completed its review of the new drug application (NDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS), which is anticipated in April 2009, the Company plans to conserve its financial resources by rigorously managing limited investments in research and development activities and other programs, while taking other actions, including potentially drawing down on its Committed Equity Financing Facilities (CEFFs).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated March 13, 2009

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: March 13, 2009



Discovery Labs Reports Fourth Quarter 2008 Financial Results

Warrington, PA — March 13, 2009 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced financial results for the fourth quarter ended December 31, 2008.

For the quarter ended December 31, 2008, the Company reported a net loss of \$8.5 million (or \$0.08 per share) on 100.5 million weighted average common shares outstanding compared to a net loss of \$12.0 million (or \$0.14 per share) on 88.5 million weighted average common shares outstanding for the same period in 2007. Net cash burn for the fourth quarter of 2008 was \$6.7 million, reflecting \$7.6 million used for operating activities and \$0.9 million used for debt service, offset by aggregate proceeds of \$1.8 million received from the issuance of 1.4 million shares of common stock pursuant to financings under the Company's Committed Equity Financing Facilities (CEFFs).

As of December 31, 2008, the Company had cash and marketable securities of \$24.8 million. Additionally, the Company has the ability (subject to certain conditions, including price and volume limitations) to raise capital under its existing CEFFs to support its business plans. As of December 31, 2008, there were approximately 15.0 million shares (not to exceed an aggregate of \$25.0 million) remaining available for issuance under the December 2008 CEFF, approximately 15.6 million shares (not to exceed an aggregate of \$54.9 million) under the May 2008 CEFF, and approximately 4.5 million shares under the 2006 CEFF, which will expire in May 2009. As of March 12, 2009, a maximum of \$34 million is available to the Company after giving effect to applicable discounts. The Company had 101.3 million common shares outstanding as of December 31, 2008.

The decrease in net loss for the fourth quarter of 2008 as compared to the fourth quarter of 2007 is primarily due to the Company's efforts during the fourth quarter of 2008 to conserve financial resources by limiting program development activities as we await April 17, 2009, the U.S. Food and Drug Administration's (FDA) target action date to complete its review of the NDA for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Additionally, in the fourth quarter of 2007, the Company incurred significant expenses related to the development of its Capillary Aerosolization Technology for the delivery of aerosolized KL₄ Surfactant.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "We believe our KL₄ Surfactant and Capillary Aerosolization Technology Platform has the potential to address multiple respiratory problems in a range of patient populations from premature infants to adults. Our top priority is to gain potential FDA marketing approval for Surfaxin for the prevention of RDS in premature infants. As we await the FDA's decision, we plan to continue to conserve our financial resources while simultaneously preparing to build a significant pediatric respiratory franchise around our lead pipeline programs, Surfaxin and Aerosurf[®]."

Selected Key Priorities for 2009 include:

- We are focused on potentially gaining FDA approval for Surfaxin for the prevention of RDS in premature infants. The FDA has established April 17, 2009 as its target action date to complete its review. If approved, Surfaxin will represent the first synthetic, peptide-containing surfactant for use in pediatric medicine and the first product from our technology platform.
- Initiate our Phase 2 clinical program for Aerosurf[®], our proprietary KL₄ Surfactant in aerosolized form, which we are developing using our Capillary Aerosolization Technology, initially for premature infants at risk for RDS. Aerosurf will potentially provide the neonatal medical community, for the first time, an ability to treat premature infants at risk for RDS without the risks generally associated with invasive endotracheal intubation and mechanical ventilation. We believe that Aerosurf holds the promise to significantly expand the use of surfactants in pediatric medicine.
- Advance our ongoing Phase 2 trial of Surfaxin for children up to 2 years of age with Acute Respiratory Failure, continue our support of a sponsor initiated Phase 2a trial at University of North Carolina that is using our aerosolized KL₄ surfactant in patients with Cystic Fibrosis, and continue development of our novel lyophilized KL₄ Surfactant, Surfaxin LS, which is manufactured in a dry powder form and reconstituted as a liquid just prior to administration. Surfaxin LS, among other things, may potentially simplify storage requirements and methods of administering surfactant.
- Following the potential approval of Surfaxin, we plan to establish our own specialty pulmonary commercial organization that will focus on creating a significant presence in the neonatal and pediatric intensive care units. Alternatively, we would also consider a strategic alliance or collaboration, assuming such a potential transaction would meet our business and strategic requirements.
- Secure strategic alliances to strengthen our financial position, support development and commercialization of our pediatric respiratory franchise in international markets and support development and commercialization of our adult respiratory programs in worldwide markets.

Readers are referred to, and encouraged to read in its entirety, the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, which includes full details on the Company's business plans and operations, financial condition and results of operations. The Company's audited financial statements for the year ending December 31, 2008, are accompanied by an unqualified audit opinion from Ernst & Young LLP, the Company's independent public accounting firm, which includes a "going concern" explanatory statement. The Company is providing this information to comply with Nasdaq Marketplace Rule 4350(b)(1)(B), which requires an issuer that receives an audit report containing a going concern explanatory statement to make a public announcement through the news media disclosing the receipt of such statement.

Additional Financial Information

For the year ended December 31, 2008, the Company reported a net loss of \$39.1 million (or \$0.40 per share) on 98.1 million weighted average common shares outstanding compared to a net loss of \$40.0 million (or \$0.49 per share) on 81.7 million weighted average common shares outstanding for the same period in 2007.

As of December 31, 2008, the Company had \$10.1 million outstanding under its long-term loan with PharmaBio Development Inc. d/b/a Novaquest (a strategic investment group of Quintiles Transnational Corp.). The outstanding principal, together with all accrued and unpaid interest is due and payable on April 30, 2010. Also, as of December 31, 2008, the Company had \$3.0 million outstanding under its secured credit facility with GE Business Financial Services Inc. and \$0.5 million outstanding under the Machinery and Equipment Loan with the Commonwealth of Pennsylvania Department of Community and Economic Development.

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 Labs' novel proprietary KL₄ Surfactant Technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant. In addition, our proprietary capillary aerosol generating technology produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL₄ Surfactant to the deep lung. Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery Labs' lead product from its KL₄ Surfactant pipeline is SURFAXIN[®] for the prevention of Respiratory Distress Syndrome in premature infants. The U.S. Food and Drug Administration (FDA) has established April 17, 2009 as its target action date to complete its review of this new drug application (NDA) and potentially grant marketing approval for SURFAXIN. SURFAXIN is also being developed for other neonatal and pediatric indications. AEROSURF[®], Discovery Labs' aerosolized KL₄ Surfactant, 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.

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. Examples of such risks and uncertainties are: risks relating to the rigorous regulatory requirements required for approval of any drug or drug-device combination products that the Company may develop, including that (i) the Complete Response to the May 2008 Approvable Letter for Surfaxin that the Company submitted to the U. S. Food and Drug Administration (FDA) in October 2008 will not satisfy the FDA, (ii) the FDA or other regulatory authorities may not accept or may withhold or delay consideration of any of the Company's applications, or may not approve or may limit approval of the Company's products to particular indications or impose unanticipated label limitations, and (iii) that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval; risks relating to the Company's research and development activities, including time-consuming and expensive pre-clinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or fail; risks relating to the Company's ability to develop and manufacture drug products and capillary aerosolization systems for clinical studies, and, if approved, for commercialization of drug and combination drug-device products, including risks of technology transfers to contract manufacturers and problems or delays encountered by the Company, its contract manufacturers or suppliers in manufacturing drug products, drug substances and capillary aerosolization systems on a timely basis or in an amount sufficient to support the Company's development efforts and, if approved, commercialization; risks that (a) market conditions, the competitive landscape or otherwise, may make it difficult to launch and profitably sell products, (b) the Company may be unable to build a successful sales and marketing organization to market its products, if approved, in a timely manner, if at all, and (c) the Company's products will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community; the risk that the Company or its strategic partners or collaborators will not be able to attract or maintain qualified personnel; the risk that the Company will not be able in a changing financial market to raise additional capital or enter into strategic alliances or collaboration agreements, or that the ongoing credit crisis will adversely affect the ability of the Company to fund its activities, or that additional financings could result in substantial equity dilution; the risk that the Company will not be able to access credit from its committed equity financing facilities, or that the share price at which the Company may access the facilities from time to time will not enable the Company to access the full dollar amount potentially available under the facilities; the risk that the Company will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of the Company's common stock to decline; the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten the Company's ability to continue as a going concern; the risks that the Company may be unable to maintain and protect the patents and licenses related to its products, or other companies may develop competing therapies and/or technologies, or health care reform may adversely affect the Company; risks of legal proceedings, including securities actions and product liability claims; risks relating to reimbursement and health care reform; and other risks and uncertainties 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.

Company Contact:

Lisa Caperelli, Investor Relations
215-488-9413

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

	Three Months Ended December 31, (unaudited)		Twelve Months Ended December 31,	
	2008	2007	2008	2007
	2008	2007	2008	2007
Revenue from collaborative arrangement and grants	\$ -	\$ -	\$ 4,600	\$ -
Operating expenses: ⁽¹⁾				
Research and development	5,170	7,800	26,566	26,200
General and administrative	3,121	4,381	16,428	13,747
Total expenses	<u>8,281</u>	<u>12,181</u>	<u>42,994</u>	<u>39,947</u>
Operating loss	(8,291)	(12,181)	(38,394)	(39,947)
Other income / (expense)	(246)	217	(712)	(58)
Net loss	<u>\$ (8,537)</u>	<u>\$ (11,964)</u>	<u>\$ (39,106)</u>	<u>\$ (40,005)</u>
Net loss per common share	\$ (0.08)	\$ (0.14)	\$ (0.40)	\$ (0.49)
Wghtd. Avg. number of common shares outstanding	100,474	88,469	98,116	81,731

(1) Expenses include a charge for stock-based employee compensation in accordance with the provisions of FAS 123(R). For the three and twelve months ended December 31, 2008, the charges associated with FAS 123(R) were \$1.2 million (\$0.4 million in R&D and \$0.8 million in G&A) and \$4.6 million (\$1.5 million in R&D and \$3.1 million in G&A), respectively. For the three and twelve months ended December 31, 2007, the charges associated with FAS 123(R) were \$1.8 million (\$0.6 million in R&D and \$1.2 million in G&A) and \$5.2 million (\$1.7 million in R&D and \$3.5 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2008	December 31, 2007
<u>ASSETS</u>		
Current Assets:		
Cash and marketable securities	\$ 24,792	\$ 53,007
Receivables, prepaid expenses and other current assets	625	611
Total Current Assets	<u>25,417</u>	<u>53,618</u>
Property and equipment, net	5,965	7,069
Restricted Cash	600	600
Other assets	907	1,457
Total Assets	<u>\$ 32,889</u>	<u>\$ 62,744</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 2,111	\$ 757
Accrued expenses	5,313	7,087
Equipment loan and other liabilities	<u>2,442</u>	<u>2,625</u>
Total Current Liabilities	9,866	10,469
Long-Term Liabilities:		
Loan payable, including accrued interest	10,128	9,633
Equipment loan and other liabilities	<u>1,962</u>	<u>3,861</u>
Total Liabilities	21,956	23,963

Stockholders' Equity	<u>10,933</u>	<u>38,781</u>
Total Liabilities and Stockholders' Equity	<u>\$ 32,889</u>	<u>\$ 62,744</u>