

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 10, 2010

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 10, 2010, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the year and quarter ended December 31, 2009. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated March 10, 2010

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/ W. Thomas Amick

Name: W. Thomas Amick

Title: Chairman of the Board and interim
Chief Executive Officer

Date: March 12, 2010

Discovery Labs Reports Fourth Quarter 2009 Financial Results and Provides Business Update

Warrington, PA — March 10, 2010 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announces financial results for the fourth quarter ended December 31, 2009 and provides a business update.

For the quarter ended December 31, 2009, the Company reported a net loss of \$6.1 million (or \$0.05 per share) on 125.6 million weighted average common shares outstanding compared to a net loss of \$8.5 million (or \$0.08 per share) on 100.5 million weighted average common shares outstanding for the same period in 2008. Net cash burn for the fourth quarter of 2009 was \$1.9 million as a result of \$6.0 million used for operating activities and \$0.2 million used for debt service, partially offset by aggregate proceeds of \$4.3 million from the issuance of 4.6 million shares of common stock pursuant to financings under the Company's Committed Equity Financing Facilities (CEFFs).

For the year ended December 31, 2009, the Company reported a net loss of \$30.2 million (or \$0.26 per share) on 115.2 million weighted average common shares outstanding compared to a net loss of \$39.1 million (or \$0.40 per share) on 98.1 million weighted average common shares outstanding for the same period in 2008.

As of December 31, 2009, the Company had cash and marketable securities of \$15.7 million. In February 2010 the Company completed a public offering of common stock and warrants resulting in net proceeds of \$15.1 million. Additionally, the Company currently has two CEFFs that, subject to certain conditions, including price and volume limitations, may allow the Company in the future to raise additional capital to support its business plans. Relevant details regarding the recent financing and the CEFF arrangements are included in the "Additional Financial Information" section of this release. The Company had 126.4 and 153.9 million common shares outstanding as of December 31, 2009 and March 10, 2010 respectively.

W. Thomas Amick, the Company's Chairman and interim Chief Executive Officer, commented, "We believe that our proprietary KL₄ surfactant technology has the potential to significantly improve the medical outcomes of patients, from premature infants to adults, suffering from debilitating respiratory disorders. Our near term priorities are to satisfy the FDA's remaining requirements and potentially gain approval of Surfaxin for RDS in 2011, advance the development of Aerosurf[®], which we believe holds the promise to significantly advance neonatal respiratory medicine, and continue to strengthen the long-term financial position of our company. We continue to be engaged in discussions with potential strategic and financial partners that, if successful, will provide the financial resources needed to potentially advance the development our KL₄ surfactant pipeline and maximize shareholder value."

Selected key initiatives and anticipated milestones include:

- **Surfaxin for RDS:** In response to written guidance recently received from the U.S. Food and Drug Administration (FDA), the Company will now focus on a pathway that would entail solely performing additional preclinical work to potentially address the sole remaining Chemistry, Manufacturing & Control issue regarding the final validation of a fetal rabbit Biological Activity Test (BAT, an important quality control release and stability test) necessary for Surfaxin approval. A key component of this approach is to first satisfactorily optimize and revalidate the BAT and those efforts are currently underway and presently meeting all pre-specified acceptance criteria. The Company believes that the optimization and revalidation of the BAT will be completed in the second quarter of 2010. Upon successful completion, the Company anticipates conducting a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and a well-established preterm lamb model of RDS. The Company plans to seek FDA advice regarding important aspects of the preclinical program, including study design and appropriate success criteria. We believe a Complete Response could be submitted to the FDA in the first quarter of 2011.
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- Our neonatal pipeline programs, Surfaxin[®], Surfaxin LS[™] and Aerosurf[®], have the potential to greatly improve the management of RDS and represent the opportunity, over time, to expand the current RDS estimated worldwide annual market of \$200 million to a \$1 billion opportunity. Surfaxin LS is a lyophilized (dry powder) formulation of KL₄ surfactant intended to improve product ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and potentially further improve product clinical performance. Aerosurf, our aerosolized KL₄ surfactant, holds the promise to significantly expand the use of surfactant therapy in pediatric respiratory medicine by providing neonatologists with a means of delivering KL₄ surfactant while potentially avoiding the risks associated with invasive endotracheal intubation and mechanical ventilation. The Company is currently advancing its preclinical development activities and preparing to further engage the FDA and foreign regulators with respect to a planned Phase 3 clinical program for Surfaxin LS and a Phase 2 clinical program for Aerosurf and intends to initiate these programs upon final determination of the regulatory strategy and after securing appropriate strategic alliances and necessary capital.
 - Discovery Labs is conducting a Phase 2 clinical trial to determine whether Surfaxin improves lung function and reduces the duration and related risk-exposure of mechanical ventilation in children up to two years of age diagnosed with Acute Respiratory Failure (ARF). ARF is a severe respiratory disorder associated with lung injury, often entailing surfactant dysfunction. ARF occurs after patients have been exposed to serious respiratory infections, such as influenza (including the type A serotype referred to as H1N1) or respiratory syncytial virus (RSV). Hospitalization following influenza or other viral infection is associated with high morbidity and significant healthcare costs. Enrollment is expected to be complete in March 2010 with top-line results becoming available in the second quarter of 2010.
 - Aerosolized KL₄ surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in Cystic Fibrosis (CF) patients. The trial has been designed to assess the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL₄ surfactant in CF patients. The trial is being conducted at The University of North Carolina and supported by the Cystic Fibrosis Foundation. Results are anticipated in the second quarter of 2010.
 - An important business initiative for the Company in 2010 is to strengthen its long-term strategic and financial position in order to meaningfully advance its promising KL₄ surfactant pipeline and maximize shareholder value. The Company continues to assess various strategic and financial alternatives to secure the necessary resources to potentially advance its development programs. Although a key priority for the Company is to secure strategic partners and capital to potentially support its ongoing research and development activities and its future financial condition, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded.
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Additionally, as of December 31, 2009 the Company had \$10.5 million outstanding under its loan with Quintiles (formerly Novaquest). The outstanding principal and all accrued interest is due and payable on April 30, 2010. The Company's plans include pursuing a potential strategic restructuring of this loan with Quintiles and assessing alternative means of financing its payment; however, there can be no assurance that any such restructuring will occur or financing alternatives will be obtained.

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, 2009, 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, 2009, 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 Selected Financial Information

On February 23, 2010, the Company completed a public offering of common stock and warrants resulting in gross proceeds of \$16,500,000 from the issuance of 27,500,000 shares of common stock and warrants to purchase 13,750,000 shares. The shares and warrants were priced at \$0.60 per unit and the warrants are exercisable for cash, except in certain circumstances provided therein, for a period of five years at an exercise price of \$0.85 per share of common stock. Net proceeds, after underwriting discounts and commissions and other fees and expenses, were \$15.1 million.

The Company currently has two CEFFs that (subject to certain conditions, including price and volume limitations) may allow the Company to raise additional capital to support its business plans. Under the December 2008 CEFF, currently there are approximately 7.1 million shares (not to exceed an aggregate \$17.7 million) available for issuance, provided that the volume-weighted average price per share on each trading day in the draw-down period must be at least equal to the greater of \$0.60 or 90% of the closing market price on the trading day immediately preceding the draw-down period. The expiration date of the December 2008 CEFF is February 2011. Under the May 2008 CEFF, currently there are approximately 12.8 million shares (not to exceed an aggregate of \$51.7 million) available for issuance, provided that the average price on each trading day in the draw-down period must be at least equal to the greater of \$1.15 or 90% of the closing market price on the trading day immediately preceding the draw-down period. The expiration date of the May 2008 CEFF is June 2011.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Therapies 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 and is being developed in liquid, aerosol or lyophilized formulations. In addition, Discovery Labs' proprietary Capillary Aerosolization Technology produces a dense aerosol, with a defined particle size that is capable of potentially delivering aerosolized KL₄ surfactant to the deep lung without the complications currently associated with liquid surfactant administration. Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at www.Discoverylabs.com.

Forward-Looking Statements

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 Discovery Labs may develop, including that: (a) Discovery Labs and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on the matters raised during regulatory reviews, or Discovery Labs may be required to conduct significant additional activities to potentially gain approval of its product candidates, if ever; (b) the FDA or other regulatory authorities may not accept or may withhold or delay consideration of any of Discovery Labs' applications, or may not approve or may limit approval of Discovery Labs' products to particular indications or impose unanticipated label limitations, and (c) 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 Discovery Labs' research and development activities, including (i) 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, and (ii) the need for sophisticated and extensive analytical methodologies, including an acceptable biological activity test, if required, as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities; risks relating to Discovery Labs' 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 Discovery Labs, 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 Discovery Labs' development efforts and, if approved, commercialization; the risk that Discovery Labs may be unable to identify potential strategic partners or collaborators to develop and commercialize its products, if approved, in a timely manner, if at all; the risk that Discovery Labs 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 Discovery Labs to fund its activities, or that additional financings could result in substantial equity dilution; the risk that Discovery Labs will not be able to access credit from its committed equity financing facilities (CEFFs), or that the minimum share price at which Discovery Labs may access the CEFFs from time to time will prevent Discovery Labs from accessing the full dollar amount potentially available under the CEFFs; the risk that Discovery Labs or its strategic partners or collaborators will not be able to retain, or attract, qualified personnel; the risk that Discovery Labs will be unable to regain compliance with The Nasdaq Global Market listing requirements prior to the expiration of the grace period currently in effect, which could cause the price of Discovery Labs' common stock to decline; the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten Discovery Labs' ability to continue as a going concern; the risks that Discovery Labs 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 Discovery Labs; risks of legal proceedings, including securities actions and product liability claims; risks relating to health care reform; and other risks and uncertainties described in Discovery Labs' 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.

Contact Information:

John G. Cooper, EVP and Chief Financial Officer
215-488-9300

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

	Three Months Ended December 31, (unaudited)		Twelve Months Ended December 31,	
	2009	2008	2009	2008
	2009	2008	2009	2008
Revenue from collaborative arrangement and grants	\$ -	\$ -	\$ -	\$ 4,600
Operating expenses: ⁽¹⁾				
Research and development	3,888	5,170	19,077	26,566
General and administrative	2,015	3,121	10,120	16,428
Total expenses	<u>5,903</u>	<u>8,291</u>	<u>29,197</u>	<u>42,994</u>
Operating loss	(5,903)	(8,291)	(29,197)	(38,394)
Other income / (expense)	<u>(238)</u>	<u>(246)</u>	<u>(1,043)</u>	<u>(712)</u>
Net loss	<u>\$ (6,141)</u>	<u>\$ (8,537)</u>	<u>\$ (30,240)</u>	<u>\$ (39,106)</u>
Net loss per common share	\$ (0.05)	\$ (0.08)	\$ (0.26)	\$ (0.40)
Wghtd. Avg. number of common shares outstanding	125,638	100,474	115,200	98,116

⁽¹⁾ Expenses include a charge for stock-based employee compensation in accordance with ASC Topic 718. For the three and twelve months ended December 31, 2009, the charges associated with ASC Topic 718 were \$0.7 million (\$0.2 million in R&D and \$0.5 million in G&A) and \$2.7 million (\$0.7 million in R&D and \$2.0 million in G&A), respectively. For the three and twelve months ended December 31, 2008, the charges associated with ASC Topic 718 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

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2009	December 31, 2008
<u>ASSETS</u>		
Current Assets:		
Cash and marketable securities	\$ 15,741	\$ 24,792
Receivables, prepaid expenses and other current assets	233	625
Total Current Assets	<u>15,974</u>	<u>25,417</u>
Property and equipment, net	4,668	5,965
Restricted Cash	400	600
Other assets	361	907
Total Assets	<u>\$ 21,403</u>	<u>\$ 32,889</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,294	\$ 2,111
Accrued expenses	3,446	5,313
Loan payable, including accrued interest	10,461	-
Equipment loan and other liabilities	597	2,442
Total Current Liabilities	<u>15,798</u>	<u>9,866</u>
Long-Term Liabilities:		
Loan payable, including accrued interest	-	10,128
Equipment loan and other liabilities	1,118	1,962
Total Liabilities	<u>16,916</u>	<u>21,956</u>
Stockholders' Equity	4,487	10,933
Total Liabilities and Stockholders' Equity	<u>\$ 21,403</u>	<u>\$ 32,889</u>