

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**

April 28, 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 April 28, 2009, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 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 8.01. Other Events.

In its press release dated April 28, 2009, the Company also announced that, following receipt on April 17, 2009 of a Complete Response letter from the U.S. Food and Drug Administration (FDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, the Company has been analyzing all aspects of its business with an immediate intention to conserve cash. The Company has re-evaluated its plans to establish its own specialty pulmonary organization to commercialize its potential pediatric products, including Surfaxin, in the United States. (The Company had previously estimated that establishing its own commercial organization in the United States would require an investment per annum of approximately \$20 - \$25 million.) The Company now believes it is in its best interest financially to commercialize in the United States, as well as internationally, with a strategic partner or collaboration arrangement.

In addition, the Company has implemented cost containment measures and recently reduced its workforce from 115 to 91 employees. The Company has retained its core capabilities to support development of its KL₄ surfactant technology, including quality, manufacturing and research and development resources. The workforce reduction was focused primarily on commercial and corporate personnel. The Company expects to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction.

In connection with the release of its earnings for the first quarter ended March 31, 2009, the Company provides an estimate of the anticipated net cash outflows for the second and third quarters of 2009 of approximately \$8.0 and \$7.0 million, respectfully.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated April 28, 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: April 28, 2009



Discovery Labs Reports First Quarter 2009 Financial Results

Company now plans to partner Pediatric Franchise in both U.S. and international markets - --- and implements cost containment measures

Warrington, PA — April 28, 2009 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced financial results for the first quarter ended March 31, 2009.

For the quarter ended March 31, 2009, the Company reported a net loss of \$9.0 million (or \$0.09 per share) on 102.1 million weighted average common shares outstanding compared to a net loss of \$9.7 million (or \$0.10 per share) on 96.6 million weighted average common shares outstanding for the same period in 2008. Net cash burn for the first quarter 2009 was \$5.7 million, consisting of \$7.6 million used for operating activities and \$0.9 million used for debt service, offset by aggregate proceeds of \$2.8 million received from the issuance of 2.3 million shares of common stock pursuant to financings under the Company's Committed Equity Financing Facilities (CEFFs).

As of March 31, 2009, the Company had cash and marketable securities of \$19.1 million. In April, the Company received an additional \$1.0 million from the issuance of 0.8 million shares of common stock under the December 2008 CEFF. In addition, as of April 28, 2009, the Company has the ability under its December 2008 CEFF to raise, after applicable discount, up to approximately \$10.5 million additional capital.

On April 17, 2009 the Company received a Complete Response letter from the U.S. Food and Drug Administration (FDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In its letter, the FDA focused primarily on certain aspects of a Surfaxin biological activity test (BAT, a quality control stability and release test) that must be addressed before the Surfaxin application can be approved. The Company believes that it has already submitted data that is responsive to the questions raised by the FDA in the Complete Response letter and that the questions raised by the FDA can be resolved within a reasonable time. The Company is seeking an end of review meeting with the FDA.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "We are very confident in our KL₄ surfactant technology and our ability to resolve the remaining questions raised by the FDA in the Surfaxin Complete Response letter. The pharmacology of our synthetic KL₄ surfactant technology has been validated through our pivotal Surfaxin phase 3 clinical trials and post-hoc analyses, as well as, numerous clinical and preclinical studies. With Surfaxin, Surfaxin LS[™], our lyophilized formulation, and Aerosurf[®], our aerosolized surfactant, we plan to develop a pediatric franchise which could greatly improve the quality of RDS management in the NICU (neonatal intensive care unit) and support a greatly expanded and potentially significant market opportunity."

Following receipt of the Complete Response letter, the Company has been analyzing all aspects of its business with an immediate intention to conserve cash. The Company has re-evaluated its plans to establish its own specialty pulmonary organization to commercialize its potential pediatric products, including Surfaxin, in the United States. The Company now believes it is in its best interest financially to commercialize in the United States, as well as internationally, with a strategic partner or collaboration arrangement.

In addition, the Company has implemented cost containment measures and recently reduced its workforce from 115 to 91 employees. The Company now anticipates that its net cash outflows, before any financings, for the second and third quarter of 2009 will be approximately \$8.0 million and \$7.0 million, respectively. The Company has retained its core capabilities to support development of its KL₄ surfactant technology, including quality, manufacturing and research and development resources. The workforce reduction was focused primarily on commercial and corporate personnel and the Company expects to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction.

Additional Financial Information for First Quarter 2009:

The primary components of the first quarter 2009 operating loss of \$9.0 million included:

- research and development expenses of \$5.6 million primarily for (a) development of the lyophilized KL₄ surfactant and the Capillary Aerosolization Technology for the delivery of aerosolized surfactant, (b) the planned Surfaxin LS and Aerosurf clinical programs, (c) the Phase 2 clinical trials of Surfaxin for children with Acute Respiratory Failure (ARF) and aerosolized surfactant for Cystic Fibrosis, and (d) manufacturing development, including quality assurance and analytical activities, to support the Company's KL₄ Surfactant Technology pipeline.
- general and administrative expenses of \$3.1 million, including \$0.6 million associated with stock-based compensation under FAS123R. As the reduction in workforce predominantly affected this area, general and administrative expenses are expected to decrease beginning late in the second quarter.

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. As of March 31, 2009, there were approximately 15.0 million shares (not to exceed an aggregate of \$25.0 million) available for issuance under the December 2008 CEFF, 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. Under the May 2008 CEFF, as of March 31, 2009, there were approximately 13.3 million shares (not to exceed an aggregate of \$52.3 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.

As of March 31, 2009, the Company had \$10.2 million outstanding under its long-term loan with Novaquest, a strategic investment group of Quintiles Transnational Corp. The outstanding principal and all accrued interest is due and payable on April 30, 2010. Also, as of March 31, 2009, the company had \$2.2 million outstanding under its secured credit facility with GE Business Financial Services Inc., and \$0.5 million outstanding under the Machinery and Equipment Loan Fund with the Commonwealth of Pennsylvania Department of Community and Economic Development.

KL₄ Surfactant Pipeline Updates

In addition to receiving the Complete Response letter from the FDA in April, 2009, the Company has noted the following progress in the first quarter of 2009:

- The Company has further advanced the development of a lyophilized formulation of its KL₄ surfactant. Lyophilized KL₄ will potentially be the basis for future development of the Company's pipeline of KL₄ surfactant-based therapies. Lyophilized KL₄ surfactant is manufactured as a dry powder formulation and reconstituted as a liquid prior to use. It may provide certain clinical and other benefits, including elimination of continuous cold chain storage and refrigeration and greatly improving product flexibility and ease of use for healthcare practitioners. The Company is planning to meet with regulatory authorities this year with a view towards initiating a worldwide late-stage clinical development program in 2010 for Surfaxin LS for the prevention of RDS.
- The Company has made significant progress in developing its proprietary Capillary Aerosolization Technology, including, successfully advancing the fundamental design and improving the reliability and performance of the capillary aerosol generating systems. The Capillary Aerosolization Technology is designed to produce a consistent, high capacity aerosol with a defined particle size, intended to deliver aerosolized KL₄ surfactant to the deep lung. The Company believes that its novel Capillary Aerosolization Technology will support delivery of surfactant therapy without the risk associated with invasive endotracheal intubation and mechanical ventilation. The Company also believes that aerosolized KL₄ surfactant will potentially address a broad range of respiratory disorders associated with surfactant dysfunction, in a wide range of patient populations and for which current treatment options are limited.

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. Discovery Labs is focused initially on developing its KL₄ surfactant pipeline to build a pediatric franchise that will potentially address several respiratory conditions affecting neonates and young children. 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: (i) Discovery Labs and the U.S. Food and Drug Administration (FDA) will not be able to agree on the matters raised by the FDA in its Complete Response letter dated April 17, 2009, or the FDA may require Discovery Labs to conduct significant additional activities to potentially gain approval of Surfaxin, if ever (ii) 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 (iii) 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 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 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; risks that (a) market conditions, the competitive landscape or otherwise, may make it difficult to launch and profitably sell products, (b) Discovery Labs may be unable to identify potential strategic partners or collaborators to market its products, if approved, in a timely manner, if at all, and (c) Discovery Labs' products will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community; the risk that Discovery Labs or its strategic partners or collaborators will not be able to attract or maintain qualified personnel; 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, or that the share price at which Discovery Labs may access the facilities from time to time will not enable Discovery Labs to access the full dollar amount potentially available under the facilities; the risk that Discovery Labs will be unable to maintain The Nasdaq Global Market listing requirements, causing 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 reimbursement and 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:

Lisa Caperelli, Investor Relations
215-488-9413

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

	Three Months Ended	
	March 31,	
	(unaudited)	
	2009	2008
Revenue from collaborative arrangements and grants	\$ --	\$ 2,050
Operating expenses ⁽¹⁾ :		
Research and development	5,607	7,232
General and administrative	3,096	4,505
Total operating expenses	8,703	11,737
Operating loss	(8,703)	(9,687)
Other income / (expense)	(297)	(27)
Net loss	\$ (9,000)	\$ (9,714)
Net loss per common share	\$ (0.09)	\$ (0.10)
Wghtd. Avg. number of common shares outstanding	102,093	96,649

(1) Expenses include a charge for stock-based employee compensation in accordance with the provisions of FAS 123(R). For the three months ended March 31, 2009 and 2008, the charges associated with FAS 123(R) were \$0.8 million (\$0.2 million in R&D and \$0.6 million in G&A) and \$1.1 million (\$0.4 million in R&D and \$0.7 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	March 31,	December 31,
	2009	2008
	(unaudited)	
<u>ASSETS</u>		
Current Assets:		
Cash and marketable securities	\$ 19,125	\$ 24,792
Receivables, prepaid expenses and other current assets	338	625
Total Current Assets	19,463	25,417
Property and equipment, net	5,639	5,965
Restricted Cash	400	600
Other assets	769	907
Total Assets	\$ 26,271	\$ 32,889
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,881	\$ 2,111
Accrued expenses	5,153	5,313
Equipment loan and other liabilities	1,810	2,442
Total Current Liabilities	8,844	9,866
Long-Term Liabilities:		
Loan payable, including accrued interest	10,209	10,128
Equipment loan and other liabilities	1,779	1,962
Total Liabilities	20,832	21,956
Stockholders' Equity	5,439	10,933
Total Liabilities and Stockholders' Equity	\$ 26,271	\$ 32,889