

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 27, 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))
-

Item 2.02. Results of Operations and Financial Condition.

On April 27, 2010, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 31, 2010. 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 April 27, 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
Chief Executive Officer

Date: April 28, 2010

Discovery Labs Provides Updates on Surfaxin[®], Other Key Programs and First Quarter 2010 Financial Results

Conference Call Wednesday, April 28, 2010 at 10:00 AM EDT

Warrington, PA —April 27, 2010 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biotechnology company developing its novel synthetic surfactant and aerosol technologies for respiratory diseases, today provides an update on Surfaxin[®] and key pipeline and business initiatives and reports financial results for the first quarter ended March 31, 2010. The Company will host a conference call on Wednesday, April 28, 2010, at 10:00 AM EDT. **The call-in number is 866-332-5218.**

Highlights, discussed in greater detail below, include:

- Progress on addressing sole remaining issue to gain potential FDA approval in 2011 of Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants. Re-validation of the optimized fetal rabbit Biological Activity Test (BAT) is 90% complete and currently meeting all pre-specified acceptance criteria. Feedback from the FDA on proposed Surfaxin preclinical program which employs the optimized and revalidated BAT is expected this May.
- The \$10.6 million loan with PharmaBio Development Inc., the former strategic investment subsidiary of Quintiles Transnational Corp., has been restructured. PharmaBio has agreed to purchase common stock and warrants for \$2.2 million. Quintiles, PharmaBio and the Company have also agreed to explore a potential strategic collaboration to develop Surfaxin LS[™] and/or Aerosurf[®].
- Enrollment completed for Phase 2 clinical trial of Surfaxin for Acute Respiratory Failure (ARF) with top-line results expected in June 2010.

Update on Surfaxin[®] for the prevention of RDS

In response to written guidance received in February 2010 from the U.S. Food and Drug Administration (FDA), the Company is focused on performing specified preclinical work as the way to potentially address the sole remaining issue necessary for Surfaxin approval, the final validation of a fetal rabbit Biological Activity Test (BAT, an important quality control release and stability test). A key component of the preclinical program is to first satisfactorily optimize and re-validate the BAT. The BAT has been optimized in accordance with previous review and comment from the FDA. Re-validation of the optimized BAT is approximately 90% complete and currently meeting all pre-specified acceptance criteria. The Company anticipates completing its efforts to revalidate the optimized BAT in May 2010.

Additionally, the Company has been interacting with the FDA regarding important aspects of the specified preclinical program, including its proposed study design and success criteria. The program calls for a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and a well-established preterm lamb model of RDS to address the sole remaining issue for Surfaxin approval. The Company expects written response from the FDA to its proposed program in May 2010.

Subject to satisfactory BAT revalidation and FDA feedback on the proposed preclinical program, the Company plans to promptly initiate the proposed preclinical protocol to address the sole remaining issue for Surfaxin approval. The Company believes it remains on track to complete the preclinical work and submit its Complete Response to the FDA in the first quarter of 2011.

Financial Update

For the quarter ended March 31, 2010, the Company reported a net loss of \$7.3 million (or \$0.05 per share) on 137.7 million weighted average common shares outstanding compared to a net loss of \$9.0 million (or \$0.09 per share) on 102.1 million weighted average common shares outstanding for the same period in 2009. Net cash burn before financings for the first quarter of 2010 consisted of \$5.4 million used for ongoing operating activities, a one-time payment of \$1.0 million to satisfy certain contractual severance obligations to the Company's former President and Chief Executive Officer, and \$0.2 million used for debt service. Also, in February 2010, the Company completed a public offering of common stock and warrants resulting in net proceeds to the Company of \$15.1 million.

As of March 31, 2010, the Company had cash and marketable securities of \$24.2 million. Additionally, the Company currently has two Committed Equity Financing Facilities (CEFFs) that, subject to certain conditions, may allow the Company to raise additional capital to support its business plans. As the current market price of the Company's common stock is below the minimum price (\$0.60 and \$1.15) required by the CEFFs, neither CEFF is currently available. The Company had 154.0 million common shares outstanding as of March 31, 2010.

On April 27, 2010, the Company and PharmaBio Development Inc. (PharmaBio), the former strategic investing subsidiary of Quintiles Transnational Corp. (Quintiles), agreed to restructure the Company's \$10.6 million outstanding loan due April 30, 2010. The Company will immediately pay PharmaBio \$6.6 million of the loan in cash. The remaining \$4.0 million balance of the loan will be due in payments of \$2.0 million on each of July 30th and September 30th of 2010. PharmaBio has also agreed to the cancellation of warrants held by it to purchase an aggregate of 2,393,612 shares of common stock.

Additionally, on April 27, 2010, PharmaBio agreed to purchase approximately 4.1 million shares of the Company's common stock and warrants to purchase approximately 2.0 million shares of common stock for gross proceeds of \$2.2 million. Each common share, together with a related warrant to purchase one half of a share of common stock, was sold at a unit price of \$0.5429. The offering is being made solely to PharmaBio. The securities will be issued under a previously filed registration statement that was declared effective by the Securities and Exchange Commission on June 18, 2008. The warrants are exercisable beginning on the date that is 181 days after the date of issuance until the fifth anniversary of such date at an exercise price of \$0.7058 per share of common stock. The transaction is expected to close on or about April 30, 2010, subject to satisfaction of customary closing conditions. This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities of Discovery Laboratories, Inc. nor shall there be any sale of the securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Quintiles, PharmaBio and the Company have also agreed to explore a long-term strategic collaboration for the development of Surfaxin LS and Aerosurf. While there can be no assurance regarding the terms of any such strategic collaboration, PharmaBio has, for example, provided other pharmaceutical companies with at-risk funding for product research, development, and commercialization in exchange for anticipated future financial returns, including fees based upon the attainment of success milestones or royalties on net product sales. The companies plan to continue related discussions and activities in connection with the above; however, there can be no assurances that any such arrangements will be entered into.

W. Thomas Amick, Chairman and interim Chief Executive Officer of Discovery Labs, commented, "A key priority for the Company in 2010 is to strengthen our long-term strategic and financial position and secure capital resources to meaningfully advance our promising KL₄ surfactant pipeline programs and maximize shareholder value. We continue to engage in discussions with potential strategic and financial partners that, if successful, will provide the financial resources needed to potentially advance our development programs."

Although a key priority for the Company is to secure strategic partners and capital to support its ongoing research and development activities and assure its future growth and financial stability, there can be no assurance that any strategic alliance will be successfully identified or other financing alternatives will be successfully concluded.

Other Key Pipeline Programs

- 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 now completed and top-line results are expected to be available in June 2010.
 - Surfaxin LS™ (lyophilized dry powder formulation of KL₄ surfactant) and Aerosurf® (aerosolized formulation of KL₄ surfactant) 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 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 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 conducting important preclinical activities for both Surfaxin LS and Aerosurf as well as advancing development of its capillary aerosolization device to support regulatory requirements for its planned clinical programs. The Company is preparing to further engage the FDA and international regulatory agencies with respect to its planned Phase 3 clinical program for Surfaxin LS and Phase 2 clinical program for Aerosurf. The Company intends to initiate these clinical programs upon determining final regulatory strategy and after securing appropriate strategic alliances and necessary capital.
 - Aerosolized KL₄ surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in Cystic Fibrosis (CF) patients. The trial is being conducted at a leading research center, The University of North Carolina, and is further supported by the Cystic Fibrosis Foundation. 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. Enrollment is approximately 70% complete and top-line results are now expected in the third quarter of 2010.
-

The descriptions of the transactions agreed to with PharmBio are entirely modified by the transaction documents, which are attached as exhibits to the Form 8-K to be filed by the Company with the Securities and Exchange Commission ("SEC"). Readers are referred to, and encouraged to read in their entirety, the Form 8-K, including the exhibits attached thereto, and the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 to be filed with the SEC, which includes further detail on the Company's business plans and operations, financial condition and results of operations.

Conference Call Details

Discovery Labs will hold a conference call on Wednesday, April 28, 2010 at 10:00 AM EDT to further discuss the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 71846778.

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 eventually result in delisting of Discovery Labs' common stock and 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 March 31, (unaudited)	
	2010	2009
Revenue	\$ -	\$ -
Operating expenses: ⁽¹⁾		
Research and development	4,133	5,607
General and administrative	2,932	3,096
Total expenses	<u>7,065</u>	<u>8,703</u>
Operating loss	(7,065)	(8,703)
Other income / (expense)	<u>(223)</u>	<u>(297)</u>
Net loss	<u>\$ (7,288)</u>	<u>\$ (9,000)</u>
Net loss per common share	\$ (0.05)	\$ (0.09)
Wghtd. Avg. number of common shares outstanding	137,699	102,093

⁽¹⁾ Expenses include a charge for stock-based compensation in accordance with ASC Topic 718. For the three months ended March 31, 2010 and 2009, the charges associated with stock-based compensation were \$0.4 million (\$0.2 million in R&D and \$0.2 million in G&A) and \$0.9 million (\$0.2 million in R&D and \$0.7 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2010 (unaudited)	December 31, 2009
<u>ASSETS</u>		
Current Assets:		
Cash and marketable securities	\$ 24,172	\$ 15,741
Receivables, prepaid expenses and other current assets	<u>270</u>	<u>233</u>
Total Current Assets	24,442	15,974
Property and equipment, net	4,444	4,668
Restricted Cash	400	400
Other assets	<u>223</u>	<u>361</u>
Total Assets	<u>\$ 29,509</u>	<u>\$ 21,403</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payable	\$ 1,147	\$ 1,294
Accrued expenses	3,531	3,446
Loan payable, including accrued interest	10,545	10,461
Equipment loan and other liabilities	<u>472</u>	<u>597</u>
Total Current Liabilities	15,695	15,798
Long-Term Liabilities:		
Equipment loan and other liabilities	<u>1,078</u>	<u>1,118</u>
Total Liabilities	16,773	16,916

Stockholders' Equity	<u>12,736</u>	<u>4,487</u>
Total Liabilities and Stockholders' Equity	<u>\$ 29,509</u>	<u>\$ 21,403</u>
