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

August 4, 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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 August 4, 2010, Discovery Laboratories, Inc. (the "Company") issued a press release announcing financial results for the quarter ended June 30, 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. <u>Financial Statements and Exhibits</u>.

- (d) Exhibits
- 99.1 Press release dated August 4, 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: August 4, 2010



Discovery Labs Provides Business Update and Reports Second Quarter 2010 Financial Results

Warrington, PA — August 4, 2010 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biotechnology company developing its novel, synthetic, peptide-containing surfactant and related aerosolization technologies as first in class therapies for severe respiratory diseases, today provides an update on key pipeline and business initiatives and reports financial results for the second quarter ended June 30, 2010. The Company will host a conference call this morning at 8:45 AM EDT. The call-in number is 866-332-5218.

Highlights and upcoming milestones, discussed further below, include:

- Surfaxin® Discovery Labs continues to advance its program to gain regulatory approval for Surfaxin for the prevention of respiratory distress syndrome (RDS) in premature infants. Discovery has taken into account recently-received guidance from the U.S. FDA in the conduct of its ongoing comprehensive preclinical program, continues to interact with the FDA, and believes it remains on track for the potential filing of a complete response in the first quarter of 2011.
- Surfaxin LS™ (next-generation, lyophilized formulation of Surfaxin) Discovery Labs is preparing the Surfaxin LS program for planned clinical activities. Fourth quarter 2010 milestones include establishing a commercial-scale Surfaxin LS manufacturing capability at a cGMP-compliant contract manufacturer with expertise in lyophilized formulations; producing necessary process validation batches. Additionally, Discovery Labs is intending to seek regulatory and scientific guidance with respect to its planned Surfaxin LS development program, first with the FDA in the fourth quarter of 2010 and then with the European Medicines Agency (EMA) in the first quarter of 2011.
- Aerosurf[®] (drug/device combination for noninvasive administration of aerosolized KL₄ surfactant to address neonatal RDS) Discovery Labs and industry-leading engineers are optimizing the design of the novel capillary aerosolization device to potentially reduce development risk and satisfy the regulatory and clinical requirements for Aerosurf. First half 2011 milestones include finalizing Aerosurf clinical device design, producing a sufficient number of devices to conduct design verification testing, and seeking regulatory guidance from the FDA and EMA for the planned Aerosurf development program.
- Phase 2a trial assessing safety and tolerability of aerosolized KL₄ surfactant for cystic fibrosis Top-line results anticipated to be available in the third quarter of 2010.
- · Discovery Labs ended the second quarter of 2010 with \$23.3 million in cash and marketable securities and a new Committed Equity Financing Facility which, subject to certain conditions, could allow the Company to raise up to \$35 million in additional capital. Second quarter 2010 cash burn from operations (before financings and debt service) was \$5.3 million. For the second half of 2010, Discovery Labs is providing guidance of projected cash burn from operations (before financings and debt service) of \$12.0 million which includes investments to advance the Surfaxin, Surfaxin LS and Aerosurf programs.

W. Thomas Amick, Chairman and interim Chief Executive Officer of Discovery Labs, commented "Discovery's ongoing program to gain potential Surfaxin approval in 2011 continues to benefit from the FDA's direction and willingness to continue to interact with our team. While remaining focused on Surfaxin, we are advancing our Surfaxin LS and Aerosurf programs in a resource-effective way intended to reduce development risk for these promising, high-value programs.

Discovery Labs has made progress in securing additional capital while exploring potential strategic alliances to adequately support our promising pipeline programs. On the financial front, we have streamlined our operating plans, significantly reduced debt and secured additional financial resources intended to advance Surfaxin to approval and move Surfaxin LS and Aerosurf towards clinical trials. Additionally, we are continuing discussions with several potential strategic alliance partners that clearly recognize the medical and commercial opportunity that Surfaxin, Surfaxin LS and Aerosurf may represent as a valuable RDS franchise. We believe that success in entering into meaningful strategic alliances will likely parallel success in advancing Surfaxin towards a complete response and positioning Surfaxin LS and Aerosurf for initiation of clinical trials."

Although a key priority for Discovery Labs is to secure strategic partners to support ongoing research and development activities and future progress, there can be no assurances that any strategic alliance will be successfully identified or concluded.

Selected Updates on KL4 Surfactant Pipeline Development

Surfaxin® for neonatal RDS: The safety and efficacy of Surfaxin for neonatal RDS has been previously demonstrated in a large, multinational Phase 3 clinical program. Discovery Labs believes that the last remaining step necessary to potentially gain FDA marketing approval for Surfaxin for the prevention of RDS is to satisfy the FDA as to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit biological activity test (BAT). Discovery Labs is currently conducting a comprehensive preclinical program that is intended to satisfy the FDA in this respect. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine.

The ongoing comprehensive preclinical program has involved the optimization and revalidation of the BAT which is now being employed in a series of prospectively-designed, side-by-side preclinical studies with the well-established preterm lamb model of RDS. In June 2010, Discovery Labs received written guidance from the FDA regarding the comprehensive preclinical program that is consistent with its ongoing program. Also in June 2010, Discovery Labs submitted data and analysis from its program to optimize and revalidate the BAT.

In July 2010, Discovery Labs took the opportunity to further interact with the FDA via a conference call regarding several important aspects of the ongoing comprehensive preclinical program. The FDA's comments support the activities undertaken by Discovery Labs to optimize and revalidate the BAT. Also during the meeting, the FDA requested that Discovery Labs provide additional data and analysis regarding the revalidation of the BAT intended to aid the FDA in its final determination of whether the BAT is appropriately validated for use as an ongoing quality control release and stability test for Surfaxin, if approved. Discovery Labs also obtained further FDA guidance regarding certain aspects of the ongoing side-by-side preclinical studies involving the BAT and preterm lamb model of RDS.

Discovery Labs has taken into account the FDA's guidance into ongoing activities, including the planned submission of the additional BAT-related data and analysis requested by the FDA. During the July teleconference, the FDA reiterated its willingness to provide continued guidance on plans to gain Surfaxin approval. Since then, Discovery Labs has continued interactions with the FDA intended to ensure that the comprehensive preclinical program satisfies the FDA as to the final validation of the BAT and its ultimate appropriateness as a release and stability test for Surfaxin, upon potential approval. However, future interactions with the FDA could affect the ultimate timing, conduct and outcomes of remaining steps necessary to gain Surfaxin approval, including the potential filing of the complete response. Discovery Labs believes it can provide the data and analysis requested by the FDA and remain on track to submit a complete response to the FDA in the first quarter of 2011, potentially leading to Surfaxin approval that year.

Surfaxin LSTM for neonatal RDS: Discovery Labs' development strategy for Surfaxin LS is to build upon the Surfaxin clinical experience to create a best-in-class surfactant therapy with improved preparation and administration flexibility and the potential to further improve clinical performance. Data presented at the May 2010 *Pediatric Academic Societies Meeting* indicate that Surfaxin LS, when compared to currently marketed, animal-derived surfactant products, favorably improved lung function and oxygenation while attenuating lung inflammation in an animal model of RDS.

To support plans for finalizing the intended development pathway for Surfaxin LS, the Company is currently conducting a series of key chemistry, manufacturing and control (CMC) activities. The Company has determined that clinical and commercial manufacturing requirements for Surfaxin LS would be most efficiently met by collaborating with a world-class contract manufacturing organization (CMO) with a successful, multi-national regulatory track record and established expertise in current good manufacturing practices (cGMP) and lyophilized formulations. In that regard, Discovery Labs has contracted with a leading pharmaceutical CMO to establish a cGMP-compliant clinical and commercial Surfaxin LS manufacturing capability. The production of required process validation batches is anticipated to be initiated in the fourth quarter of 2010.

Additionally, the Company intends to seek regulatory and scientific guidance with respect to its planned development program, first with the FDA in the fourth quarter of 2010 and then with the EMA in the first quarter of 2011.

Aerosurf® for neonatal RDS: Aerosurf is a novel drug/device combination therapy incorporating Discovery Labs' synthetic surfactant and unique capillary aerosolization technology to allow early administration of aerosolized surfactant to prevent neonatal RDS. Aerosurf holds the promise to significantly expand the use of surfactant therapy by providing neonatologists with a less-invasive means of delivering KL₄ surfactant without the current requirement of invasive endotracheal intubation and mechanical ventilation.

Through the conduct of the Aerosurf program, the Company's aerosol engineers and scientists have meaningfully improved the design of the capillary aerosolization device and patient interface for neonatal application, employing a flexible design strategy to support potential downstream applications of aerosolized KL₄surfactant in other respiratory disorders. The Company has recently engaged a leading global technology company with expertise in biomedical devices to assist in incorporating design improvements into the capillary aerosolization device. The design of the capillary aerosolization device is being optimized to potentially reduce development risk and satisfy regulatory and clinical requirements for Aerosurf. The Company anticipates finalizing the clinical Aerosurf device design and producing a sufficient number of Aerosurf devices to complete required design verification testing in the first half of 2011.

Additionally, the Company is preparing to engage the FDA and EMA in the first half of 2011 for regulatory and scientific guidance with respect to the planned Aerosurf clinical development program. In preparation, the Company is currently conducting important CMC activities for Aerosurf, including doseranging experiments conducted in a well-established animal model of RDS and comprehensive aerosol characterization studies.

Phase 2a trial for cystic fibrosis: Aerosolized KL₄ surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial as a single center, pilot study to evaluate the effects of aerosolized KL₄ surfactant in patients with mild to moderate cystic fibrosis (CF). The study is designed to assess the safety, tolerability and potential effect on mucociliary clearance from short term administration of aerosolized KL₄ surfactant. Enrollment has been completed and top-line results are expected to be available in the third quarter of 2010.

Surfaxin, Surfaxin LS and Aerosurf are investigational products and are not approved by the FDA or any other world health regulatory authority for use in humans.

Selected Financial Results for the Quarter Ended June 30, 2010

For the quarter ended June 30, 2010, the Company reported a net loss of \$6.3 million (or \$0.04 per share) on 160.4 million weighted average common shares outstanding compared to a net loss of \$7.9 million (or \$0.07 per share) on 112.7 million weighted average common shares outstanding for the same period in 2009. As of June 30, 2010, the Company had 194.1 million common shares outstanding.

As of June 30, 2010, the Company had cash and marketable securities of \$23.3 million. Additionally in June, the Company secured a new Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited, a private investment group, in which Kingsbridge has committed to provide up to \$35 million of capital over a three-year period through the purchase of up to approximately 31.6 million newly-issued shares of Discovery Labs' common stock. Under the terms of the CEFF agreement, Discovery Labs will be able determine the exact timing and amount of any financings, subject to certain conditions and limitations (including price and share limitations). In connection with the CEFF, Discovery Labs issued a five-year warrant to Kingsbridge to purchase up to 1,250,000 shares of common stock at an exercise price of \$0.4459 per share.

On June 22, 2010, the Company completed a public offering of common stock and warrants resulting in gross proceeds of \$10.0 million from the issuance of 35.7 million shares of common stock, 17.9 million five-year warrants and 17.9 million short-term (9-month) warrants. The shares and warrants were priced at \$0.28 per unit. The five-year warrants have an exercise price of \$0.40 per share and the short-term warrants have an exercise price of \$0.28 per share. Net proceeds from the offering, after underwriting discounts and commissions and other fees and expenses, were \$9.1 million. The Company could realize up to an additional \$5.0 million in proceeds by March 22, 2011, from the potential exercise of the short-term warrants.

Net cash burn from ongoing operating activities (before financing and debt service activities) for the second quarter of 2010 was \$5.3 million. The Company anticipates that its net cash burn for operating activities (before any financing and debt service activities) for the second half of 2010 will be approximately \$12.0 million.

In April 2010, the Company restructured its \$10.6 million loan with PharmaBio Development Inc. (PharmaBio), the former strategic investment subsidiary of Quintiles Transnational Corp. (Quintiles). The Company satisfied \$6.6 million of the loan in cash. As of June 30, 2010, \$4.0 million remained as the short-term outstanding balance of the loan. On July 30, 2010, \$2.0 of the loan was paid and the remaining balance of \$2.0 million is due on September 30, 2010. Additionally, contemporaneously with the restructuring, PharmaBio purchased Discovery Labs common stock and warrants resulting in net proceeds of \$2.1 million to Discovery Labs. Quintiles, PharmaBio and the Company have also agreed to explore a long-term strategic collaboration for the development of Surfaxin LS and Aerosurf, however, there can be no assurance that any such arrangements will be achieved.

The descriptions of the transactions referred to herein with respect to Kingsbridge, the recently completed public offering and the PharmaBio loan restructuring and the PharmaBio investment in Discovery Labs' common stock are entirely qualified by reference to the transaction documents, which are attached as exhibits to each related Form 8-K filed by the Company with the Securities and Exchange Commission ("SEC"). Readers are referred to, and encouraged to read in their entirety, the Forms 8-K, including the exhibits attached thereto, and the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 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, August 4, 2010 at 8:45 AM EDT to further discuss the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available through a live broadcast on the Internet at http://intercallus.stream57.com/DiscoveryLaboratories 080410 and http://intercallus.stream57.com/DiscoveryLaboratories 080410 and www.discoverylabs.com. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 89526041.

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 KL_4 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 KL_4 surfactant to the 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 Capital Market listing requirements prior to the expiration of the additional 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 June 30, (unaudited)				Six Months Ended June 30, (unaudited)			
	2010		2009		2010		2009	
Revenue	\$ 	\$		\$		\$		
Operating expenses: (1)								
Research and development	4,363		5,052		8,496		10,659	
General and administrative	 1,865		2,592		4,797		5,688	
Total expenses	6,228		7,644		13,293		16,347	
Operating loss	 (6,228)		(7,644)		(13,293)		(16,347)	
Other income / (expense)	(84)		(264)		(307)		(561)	
Net loss	\$ (6,312)	\$	(7,908)	\$	(13,600)	\$	(16,908)	
Net loss per common share	\$ (0.04)	\$	(0.07)	\$	(0.09)	\$	(0.16)	
Weighted average number of common shares outstanding	160,425		112,712		149,133		107,433	

Expenses include a charge for stock-based compensation in accordance with ASC Topic 718. For the three and six months ended June 30, 2010, the charges associated with stock-based compensation were \$0.4 million (\$0.1 million in R&D and \$0.3 million in G&A) and \$0.8 million (\$0.3 million in R&D and \$0.5 million in G&A), respectively. For the three and six months ended June 30, 2009, the charges associated with stock-based compensation were \$1.0 million (\$0.3 million in R&D and \$0.7 million in G&A) and \$1.8 million (\$0.4 million in R&D and \$1.4 million in G&A), respectively.

Condensed Consolidated Balance Sheets

(in thousands)

ASSETS	June 30, 2010 (unaudited)		December 31, 2009	
Current Assets:	(ui	addited		
Cash and marketable securities	\$	23,320	\$	15,741
Receivables, prepaid expenses and other current assets		383		233
Total Current Assets		23,703		15,974
Property and equipment, net		4,116		4,668
Restricted Cash		400		400
Other assets		184		361
Total Assets	\$	28,403	\$	21,403
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	\$	1,235	\$	1,294
Accrued expenses		3,766		3,446
Loan payable, including accrued interest		4,000		10,461
Equipment loan and other liabilities		331		597
Total Current Liabilities		9,332		15,798
Long-Term Liabilities:				
Equipment loan and other liabilities		1,022		1,118
Total Liabilities		10,354		16,916
Stockholders' Equity		18,049		4,487
Total Liabilities and Stockholders' Equity	\$	28,403	\$	21,403
	-			