

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**

November 4, 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 November 4, 2009, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended September 30, 2009. The press release is attached as Exhibit 99.1 hereto.

For the three and nine months ended September 30, 2009, the Company reported a net loss of \$7.2 million (or \$0.06 per share) and \$24.1 million (or \$0.22 per share), respectively on 120.0 million and 111.7 million weighted average common shares outstanding, respectively. As of September 30, 2009, the Company had cash and marketable securities of \$17.7 million. In October 2009, the Company received an additional \$4.3 million of aggregate proceeds from the issuance of 4.6 million shares of common stock under the Company’s Committed Equity Financing Facilities (CEFFs).

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.

Also on November 4, 2009, the Company issued a press release providing a business and pipeline development status update. The second press release is attached as Exhibit 99.2 hereto.

As of September 30, 2009, the Company had \$10.4 million outstanding under its 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. The Company’s plans to seek a potential strategic restructuring of this loan with Novaquest and is 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.

The Company has taken steps to conserve its financial resources, predominantly by curtailing investments in its pipeline programs. As a result of these efforts, the Company anticipates that its estimated net cash outflow for the fourth quarter of 2009 will be \$2.7 million (\$7.0 million of cash outflow for operating activities and debt service offset by \$4.3 million aggregate proceeds received from the CEFF financings in October), before taking into account any further use of the CEFFs, any strategic alliances or other financing alternatives.

Estimates of H1N1 infection and hospitalization rates included in the press release are based in part on information obtained from the World Health Organization website (at http://www.who.int/csr/don/2009_10_30/en/index.html) and the U.S. Government Center for Disease Control (at http://www.cdc.gov/h1n1/images/qa_hospitalizations.gif). Estimates of RDS market size and business opportunities included in the press release are based on the Company’s analysis of data derived from the following sources, among others: IMS Midas Data MAT, September 2008 (IMS Data); Vermont Oxford Network Data, 2005/2006 (VON Data); Soll, Cochrane Database of Systematic Reviews, 1997, Issue 4 (SC Data); CDC National Vital Statistics, 2005 (CDC NVS); UNICEF Online Data Set, 2005 (UNICEF Data); ZD Associates Primary Market Research, 2009 (ZDA Research); Gdovin, *J Peds Pharm & Therapeutics*, 2006 (PP&T). In addition, the Company’s analysis and assumptions take into account estimated patient populations, expected adoption rates of our products, current pricing, economics and anticipated potential pharmaco-economic benefits of the Company’s drug products, if approved.

The Company's top priority is to secure sources of capital, preferably through strategic alliances, to advance its KL₄ surfactant pipeline for respiratory diseases and support its future financial condition. The Company is actively evaluating several potential strategic and financial alternatives. To further extend its resources, the Company has also taken operational steps to conserve existing capital. Although the Company is presently actively engaged in discussions regarding several potential strategic alliances, there can be no assurance that any such strategic alliance or other financing alternatives can be successfully concluded.

The Company's lead KL₄ surfactant pipeline programs (Surfaxin, Surfaxin LSTM and Aerosurf[®]) are intended to address the most significant respiratory conditions affecting pediatric populations. 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. Discovery Labs is planning to meet with U.S. and European regulatory authorities to present a development program entailing the conduct of a single Phase 3 clinical trial for global registration. Discovery Labs intends to initiate the Surfaxin LS clinical program upon securing appropriate strategic alliances and necessary capital.

Aerosurf holds the promise to significantly expand the use of KL₄ surfactant therapy by providing neonatologists with a novel means of administering surfactant without invasive endotracheal intubation and mechanical ventilation. Discovery Labs has met with and received guidance from the FDA with respect to the design of its planned Phase 2 clinical program using Aerosurf for RDS, and intends to initiate such program upon securing appropriate strategic alliances and necessary capital.

Acute Respiratory Failure 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 mortality, morbidity and significant healthcare cost. No medications are currently approved for this debilitating condition.

Aerosolized KL₄ surfactant is also being evaluated in an investigator-initiated Phase 2a clinical trial in CF patients. The trial is being conducted at The University of North Carolina and is funded primarily through a grant provided 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. The results from this trial are anticipated in the first half of 2010.

Surfaxin, Surfaxin LS and Aerosurf are investigational drugs currently under development and are subject to all of the risks and uncertainties associated with development-stage drug product candidates, including whether regulatory development and marketing approvals can be successfully obtained. Examples of these and other risks and uncertainties are included 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated November 4, 2009

99.2 Press release dated November 4, 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, market opportunities, 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: November 4, 2009



Discovery Labs' Third Quarter 2009 Financial Update

Warrington, PA — November 4, 2009 — Discovery Laboratories, Inc. (Nasdaq: DSCO) is providing financial results for the third quarter ended September 30, 2009. The Company will host a conference call today at 4:00 PM EST. **The call-in number is 866-332-5218.**

For the quarter ended September 30, 2009, the Company reported a net loss of \$7.2 million (or \$0.06 per share) on 120.0 million weighted average common shares outstanding, compared to a net loss of \$10.6 million (or \$0.11 per share) on 98.6 million weighted average common shares outstanding for the same period in 2008. For the nine months ended September 30, 2009, the Company reported a net loss of \$24.1 million (or \$0.22 per share) on 111.7 million weighted average common shares outstanding compared to a net loss of \$30.6 million (or \$0.31 per share) on 97.3 million weighted average common shares outstanding for the same period in 2008.

As of September 30, 2009, the Company had cash and marketable securities of \$17.7 million, representing a net decrease of \$5.7 million from the previous quarter ended June 30, 2009, primarily due to: (i) \$6.6 million used for operating activities and \$0.7 million used for debt service, partially offset by (ii) aggregate proceeds of \$1.6 million from the issuance of 1.8 million shares of common stock pursuant to financings under the Company's Committed Equity Financing Facilities (CEFFs). During October 2009, the Company received an additional \$4.3 million of aggregate proceeds from the issuance of 4.6 million shares of common stock under the CEFFs. The Company had 121.7 million and 126.3 million common shares outstanding as of September 30, 2009 and November 3, 2009, respectively.

W. Thomas Amick, the Company's Chairman and interim Chief Executive Officer, commented, "Our top priority is to secure sources of capital, preferably through strategic alliances, to advance our KL₄ surfactant pipeline for respiratory diseases and to support our future financial condition. We are evaluating several potential strategic and financial alternatives. Simultaneously, to further extend our resources, we have also taken operational steps to conserve our existing capital. I am encouraged that active discussions with several potential strategic and financial partners are continuing and, if successful, will allow us to advance our KL₄ surfactant pipeline, drive our company forward and maximize shareholder value."

Although the Company is presently actively engaged in discussions regarding several potential strategic alliances, there can be no assurance that any such strategic alliance or other financing alternatives can be successfully concluded. While pursuing such a transaction, the Company has taken steps to conserve its financial resources, predominantly by curtailing investments in its pipeline programs. As a result of these efforts, the Company anticipates that its estimated net cash outflow for the fourth quarter of 2009 will be \$2.7 million (\$7.0 million of cash outflow for operating activities and debt service offset by \$4.3 million aggregate proceeds received from the CEFF financings in October), before taking into account any further use of the CEFFs, any strategic alliances or other financing alternatives.

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 November 3, 2009, under the December 2008 CEFF, there were 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. As of November 3, 2009, under the May 2008 CEFF, there were 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.

As of September 30, 2009, the Company had \$10.4 million outstanding under its 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. The Company's plans include pursuing a potential strategic restructuring of this loan with Novaquest 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.

Debt service for the third quarter 2009 was \$0.7 million and will decrease to \$0.3 million in the fourth quarter. As of September 30, 2009, the company had \$0.8 million outstanding under its secured credit facility with GE Business Financial Services Inc., and \$0.4 million outstanding under the Machinery and Equipment Loan Fund (MELF) with the Commonwealth of Pennsylvania Department of Community and Economic Development. Of this \$1.2 million outstanding debt, \$0.7 million was classified as a current liability and \$0.5 million as a long-term liability. After giving effect to fourth quarter principal payments, the loan balance outstanding with GE is expected to be \$0.6 million at the end of 2009.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009 to be filed with the Securities and Exchange Commission, which includes further detail on the Company's business plans and operations, financial condition and results of operations.

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, including without limitation, any relating to the potential financial results for the current fiscal year, 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 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 Statement of Operations
(in thousands, except per share data)

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2009	2008	2009	2008
Revenue	\$ --	\$ 50	\$ --	\$ 4,600
Operating expenses: ⁽¹⁾				
Research and development	4,530	6,724	15,189	21,395
General and administrative	2,417	3,726	8,105	13,307
Total expenses	6,947	10,450	23,294	34,702
Operating loss	(6,947)	(10,400)	(23,294)	(30,102)
Other income / (expense)	(244)	(239)	(805)	(466)
Net loss	\$ (7,191)	\$ (10,639)	\$ (24,099)	\$ (30,568)
Net loss per common share	\$ (0.06)	\$ (0.11)	\$ (0.22)	\$ (0.31)
Weighted average number of common shares outstanding	119,993	98,619	111,683	97,324

⁽¹⁾ Expenses include a charge for stock-based employee compensation. For the three and nine months ended September 30, 2009, the charges were \$0.4 million (\$0.1 million in R&D and \$0.3 million in G&A) and \$2.2 million (\$0.5 million in R&D and \$1.7 million in G&A), respectively. For the three and nine months ended September 30, 2008, the charges were \$1.2 million (\$0.4 million in R&D and \$0.8 million in G&A) and \$3.4 million (\$1.1 million in R&D and \$2.3 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

ASSETS	September 30, 2009 (unaudited)	December 31, 2008
Current Assets:		
Cash and marketable securities	\$ 17,683	\$ 24,792
Receivables, prepaid expenses and other current assets	272	625
Total Current Assets	17,955	25,417
Property and equipment, net	4,960	5,965
Restricted Cash	400	600
Other assets	494	907
Total Assets	\$ 23,809	\$ 32,889
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,559	\$ 2,111
Accrued expenses	4,319	5,313
Loan payable, including accrued interest ⁽²⁾	10,375	-
Equipment loan and other liabilities	690	2,442
Total Current Liabilities	16,943	9,866
Long-Term Liabilities:		
Loan payable, including accrued interest	-	10,128
Equipment loan and other liabilities	1,242	1,962
Total Liabilities	18,185	21,956
Stockholders' Equity		
Total Liabilities and Stockholders' Equity	\$ 23,809	\$ 32,889

⁽²⁾ The loan from NovaQuest is due and payable on April 30, 2010.



Discovery Labs Provides Business and Pipeline Development Update

Conference Call today at 4:00 PM EST

Warrington, PA — November 4, 2009 — Discovery Laboratories, Inc. (Nasdaq: DSCO) is providing an update on its strategic business activities and its KL₄ surfactant pipeline clinical development programs. Discovery Labs is developing its proprietary KL₄ surfactant technology platform to potentially significantly improve the medical outcomes of patients, from premature infants to adults, suffering debilitating respiratory diseases and conditions. Discovery Labs is actively assessing various strategic and financial alternatives to secure the necessary capital to potentially advance its development programs.

W. Thomas Amick, Discovery Labs Chairman and interim Chief Executive Officer, commented, “We are developing a robust pipeline of KL₄ surfactant products to potentially address a broad range of respiratory diseases, such as respiratory distress syndrome (RDS), acute respiratory failure, acute lung injury and cystic fibrosis. Our most advanced 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. Our efforts with potential strategic and financial partners are centered on building an RDS franchise for the U.S. and international markets.

We are encouraged that discussions, related due diligence activities and valuation assessments are progressing with several interested strategic and financial parties. Our Board of Directors and management are focused on securing the strategic resources necessary to potentially advance our KL₄ surfactant pipeline, drive our company forward and maximize shareholder value.”

Although Discovery Labs believes that it will be successful in securing strategic partners and capital to 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. Furthermore, until any such strategic alliances or other financing alternatives are successfully secured, Discovery Labs will continue to conserve its financial resources by predominantly curtailing investments in its pipeline programs.

The following are selected updates on Discovery Labs’ KL₄ surfactant pipeline.

Respiratory Distress Syndrome (RDS) – RDS is one of the most common, potentially life-threatening pediatric respiratory disorders, with more than 500,000 low-birth-weight premature infants at risk globally each year. However, today fewer than 200,000 infants receive the currently-approved, animal-derived surfactants. Discovery Labs’ portfolio of programs focusing on RDS has the potential to redefine the management of RDS and expand the use of surfactants in the neonatal intensive care unit (NICU). Discovery Labs’ advanced-staged RDS programs include:

Surfaxin®

Surfaxin, Discovery Labs' first KL₄ surfactant product candidate, has demonstrated clinically meaningful survival and morbidity-lessening advantages versus comparator surfactants (the current standard of care). Discovery Labs participated in a September 29, 2009 meeting with the FDA to discuss the key remaining issue that must be addressed to potentially gain U.S. marketing approval of Surfaxin for the prevention of RDS in premature infants, as well as Discovery Labs' plans regarding optimization and final method validation of its fetal rabbit Biological Activity Test (BAT, a quality control and stability release test) and a proposed limited clinical trial. The trial would be designed to primarily assess a pharmacodynamic (PD) response following Surfaxin administration in premature infants diagnosed with RDS. During the conduct of this trial, the newly-optimized BAT would be employed as a quality test of the Surfaxin drug product used in the proposed clinical trial. As a result of this meeting, Discovery Labs believes that it has reached an understanding with the FDA and that it will be able to optimize the BAT to the satisfaction of the FDA. The FDA has indicated that a PD-based approach is consistent with their expectation for a limited clinical trial and also provided direction regarding trial design specifics. Discovery Labs has been collaborating with leading academic neonatologists to finalize the clinical trial design and remains on-track to submit the protocol to the FDA, for their review and comment, in the mid-fourth quarter of 2009.

Surfaxin LS™

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. Discovery Labs is planning to meet with U.S. and European regulatory authorities to present a development program entailing the conduct of a single Phase 3 clinical trial for global registration. Discovery Labs intends to initiate the Surfaxin LS clinical program upon securing appropriate strategic alliances and necessary capital.

Aerosurf®

Aerosurf holds the promise to significantly expand the use of KL₄ surfactant therapy by providing neonatologists with a novel means of administering surfactant without invasive endotracheal intubation and mechanical ventilation. Discovery Labs has met with and received guidance from the FDA with respect to the design of its planned Phase 2 clinical program using Aerosurf for RDS, and intends to initiate such program upon securing appropriate strategic alliances and necessary capital.

Acute Respiratory Failure (ARF) – ARF is a severe respiratory disorder associated with lung injury, often entailing surfactant dysfunction. Patient management typically includes prolonged critical care intervention, including mechanical ventilation. No medications are currently approved for this debilitating condition. 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 mortality, morbidity and significant healthcare cost.

Discovery Labs is conducting a Phase 2 clinical trial to determine whether Surfaxin improves lung function and reduces duration and related risk-exposure of mechanical ventilation in children up to two years of age diagnosed with ARF. Trial enrollment was conducted in the northern and southern hemispheres to track with viral season peaks. As H1N1-influenza has spread to pandemic levels, participating trial centers have observed an escalating frequency of this specific diagnosis and H1N1-confirmed patients have been enrolled in this trial. Presently, enrollment is approximately 90% complete with full enrollment expected in the first quarter of 2010 and top-line results becoming available shortly thereafter.

Discovery Labs believes that its KL₄ surfactant technology, whether administered as a rescue therapy into the endotracheal tube or as a less-invasive surfactant aerosol earlier in the course of respiratory compromise to prevent the progression of disease, may provide for a series of novel solutions for patients that require critical care intervention following exposure to viral pathogens. As of last week, separate from typical annual influenza, the World Health Organization reported more than 440,000 confirmed H1N1 cases with more than 5,700 attributable deaths while acknowledging that its reporting methodology underestimates true frequency. In the United States to date, 45% of H1N1-related hospitalizations have occurred in the pediatric population. Discovery Labs has met with U.S. Government officials to explore whether funding can be obtained for programs to address respiratory disease following exposure to viral pathogens.

Cystic Fibrosis (CF)

Aerosolized KL₄ surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in CF patients. The trial is being conducted at The University of North Carolina and is funded primarily through a grant provided 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. The results from this trial are anticipated in the first half of 2010.

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 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:

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215-488-9413
