

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 8, 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 November 9, 2010, Discovery Laboratories, Inc. (the "Company") issued a press release highlighting the results of operations for the quarter ended September 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 relating to the announcement of the results of operations for the quarter ended September 30, 2010 and all other matters except for those discussed under the heading "Restatement of Financial Statements" 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 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.**

In connection with a review of the Company's Annual Report on 2009 Form 10-K among the Audit Committee of the Company's Board of Directors (the "Audit Committee"), and the Company's management, with the assistance of Ernst & Young LLP ("Ernst & Young"), the Company's independent registered public accounting firm, and the Company's outside legal advisors, the Audit Committee has reassessed the accounting classification of certain warrants issued by the Company in May 2009 and February 2010 with respect to ASC 815 "Derivatives and Hedging — Contracts in Entity's Own Equity" ("ASC 815," formerly known as Emerging Issues Task Force Issue 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock"). The review was conducted to respond to certain comments raised by the Staff of the Securities and Exchange Commission ("SEC") following its periodic review of the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

The warrants under review are:

- Warrants to purchase 7,000,000 shares of common stock issued in May 2009 in connection with a registered equity offering. The warrants expire in May 2014 and are exercisable, subject to an aggregate share ownership limitation, at an exercise price of \$1.15 per share; and
- Warrants to purchase 13,750,000 shares of our common stock issued in February 2010 in connection with a registered equity offering. The warrants expire in February 2015 and are exercisable, subject to an aggregate share ownership limitation, at a price of \$0.85 per share.

The Company has historically accounted for its warrants, which prior to May 2009 were issued in private transactions, as equity instruments. The Company's warrants generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, notwithstanding the availability of cashless exercise, ASC 815, as interpreted, appears to establish a presumption that, in the absence of express language to the contrary, registered warrants may be subject to net cash settlement, as it is not within the absolute control of the Company to provide freely-tradable shares in all circumstances. After extensive discussion, the Company's management, Ernst & Young, and the Company's outside legal advisors concluded that, although the interpretation and applicability of ASC 815 as it relates to registered warrants is complex and subject to varying interpretations, it should be applied based on a strict reading of the authoritative literature without respect to any evaluation of remoteness or probability.

Applying such a strict reading, the Audit Committee, together with management and in consultation with Ernst & Young and the Company's outside legal advisors, determined that, notwithstanding the highly-remote and theoretical possibility of net cash settlement, the warrants identified above should have been recorded as liabilities, measured at fair value on the date of issue, with changes in the fair values recognized in the Company's quarterly statement of operations in its quarterly financial reports. Accordingly, the Audit Committee has also concluded on November 8, 2010 that the Company's previously-filed consolidated financial statements for the fiscal year ended December 31, 2009 on Form 10-K; Ernst & Young's reports on the financial statements and the effectiveness of internal control over financial reporting for the fiscal year ended December 31, 2009; each of the consolidated financial statements included in the Company's Quarterly Reports on Form 10-Q for the periods ended June 30, 2009, September 30, 2009, March 31, 2010 and June 30, 2010; and all related earnings releases and similar communications issued by the Company with respect to the foregoing, should no longer be relied upon. The Company's management and the Audit Committee are assessing the effect of the pending restatements on the Company's internal control over financial reporting and its disclosure controls and procedures.

On or before November 15, 2010, the Company anticipates filing an amended Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and amended Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2010 and June 30, 2010, each with restated financial statements reflecting the reclassification of the warrants identified above, together with the Quarterly Report on Form 10-Q for the period ended September 30, 2010. The Company does not expect to amend its previously-filed Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009.

The restatements that are being implemented will reflect the reclassification of the warrants from equity to a liability in an amount equal to the fair value of the warrants, as of the dates of issuance, calculated using the Black Scholes option pricing model. The restatements will have no impact on amounts previously reported for Assets; Revenues; Operating Expenses; Cash Flows; Loans, Equipment Loan and Accounts Payables; and Contractual Obligations. The restatements will have no effect on the Company's development programs, including Surfaxin®, anticipated development milestones, or business strategy.

#### **Item 8.01. Other Events.**

On November 9, 2010, the Company issued a press release announcing the restatement and related matters referred to in Item 4.02 to this Current Report on Form 8-K. Subject to the note relating to the press release in Item 2.02 to this Current Report on Form 8-K, the press release is attached as Exhibit 99.1 hereto.

#### **Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press release dated November 9, 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/ John G. Cooper

Name: John G. Cooper

Title: President, Chief Financial Officer and Treasurer

Date: November 9, 2010

## Discovery Labs Provides a Third Quarter 2010 Business and Financial Update

Warrington, PA — November 9, 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 a financial update for the third quarter ended September 30, 2010. The Company will host a conference call this morning at 10:00 AM EST. **The call-in number is 866-332-5218.**

Selected highlights, discussed in greater detail below, include:

- **Surfaxin® (lucinactant)** – Discovery Labs has now completed studies proposed to the FDA relating to its comprehensive preclinical program intended to gain regulatory approval for Surfaxin for the prevention of respiratory distress syndrome (RDS) in premature infants. In conducting the preclinical program, Discovery Labs has taken into account guidance from the U.S. FDA and anticipates further FDA feedback in advance of filing a complete response. The Company believes it remains on track for the potential filing of a complete response in the first quarter of 2011.
- **Surfaxin Phase 2 Acute Respiratory Failure (ARF) Trial** – New analyses from this trial demonstrate that, based on patient stratification by severity of lung injury, Surfaxin treatment significantly reduced time on mechanical ventilation in the least severe patient segment ( $p < 0.01$ ). Furthermore, the data demonstrated that Surfaxin intervention reduced the need for a second dose ( $p < 0.05$ ), suggesting a decrease in disease severity following surfactant treatment.
- **Aerosolized KL<sub>4</sub> Surfactant (lucinactant) for Cystic Fibrosis (CF)** – results from the recently-completed Phase 2a, investigator-initiated trial concluded that aerosolized KL<sub>4</sub> surfactant delivery to CF patients was feasible, generally safe and well tolerated, and demonstrated evidence of pharmacologic response via improvement in mucociliary clearance (MCC) versus patient baseline. Additionally, the FDA recently granted orphan drug designation to Discovery Labs' KL<sub>4</sub> surfactant for the treatment of CF.
- **3Q10 Financial Update** - cash burn from operations was \$5.0 million, before financings and debt service. Additionally, the Company paid \$4.0 million to fully satisfy its loan obligations with PharmaBio. Discovery Labs ended the third quarter of 2010 with cash and cash equivalents of \$14.7 million. In addition, the Company's 2010 Committed Equity Financing Facility (2010 CEFF) may, subject to certain conditions and limitations, allow the Company to raise additional capital. For the fourth quarter of 2010, Discovery projects a net cash burn of \$4.0 million. The Company recently received a non-dilutive grant to advance the aerosolized KL<sub>4</sub> surfactant program for prevention of neonatal RDS awarded under the Patient Protection and Affordable Care Act of 2010.

W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs commented, "We are at an important transition point for our Company and the third quarter has been very productive for Discovery Labs. We have solidified our Company's leadership, significantly progressed the Surfaxin complete response initiative and have begun to understand the potential role of KL<sub>4</sub> surfactant in two new disease targets – cystic fibrosis and acute respiratory failure. As we move towards the end of 2010, Discovery Labs will be focused on remaining activities to support the Surfaxin complete response filing and ongoing strategic alliance initiatives while diligently managing our financial resources."

---

## **Selected Updates on KL<sub>4</sub> Surfactant Pipeline Development**

**Surfaxin for Neonatal RDS:** If approved, Surfaxin would become the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine. 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).

In this respect, Discovery Labs conducted a comprehensive preclinical program intended to satisfy the FDA. The comprehensive preclinical program, as proposed to the FDA, involved the optimization and subsequent revalidation of the BAT, which was then employed in a series of prospectively-designed, side-by-side preclinical studies with the well-established preterm lamb model of RDS. Discovery Labs has taken into account the FDA's guidance in conducting its comprehensive program. These proposed studies were recently completed. The resulting dataset is undergoing final review and compilation in preparation for submission to the FDA.

Throughout this process, Discovery Labs has had multiple 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. Previously, Discovery Labs provided additional analysis to the FDA 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 is awaiting FDA feedback regarding this analysis and anticipates further interactions in advance of the pending complete response. Such 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 remains on track to submit a complete response to the FDA in the first quarter of 2011, potentially leading to Surfaxin approval later in the year.

**Surfaxin LS™ and Aerosurf® Neonatal RDS Programs:** Surfaxin LS (lyophilized lucinactant) is an important life-cycle initiative, intended to further improve on the Surfaxin product profile and provide access to international markets. Discovery Labs has contracted with a leading pharmaceutical contract manufacturing organization to establish a Surfaxin LS clinical supply manufacturing capability that is compliant with current good manufacturing practices (cGMP). Preparation for the manufacture of process validation lots of lyophilized lucinactant has initiated in the fourth quarter of 2010. Additionally, the Company intends to seek regulatory guidance for its planned development program, first with the FDA in the fourth quarter of 2010 and then with the EMA in early 2011.

Aerosurf is a novel drug/device combination therapy intended to allow early administration of aerosolized surfactant to address neonatal RDS. Aerosurf holds the promise to significantly expand the use of surfactant therapy by providing neonatologists with a less invasive means of delivering KL<sub>4</sub> surfactant without the current requirement of invasive endotracheal intubation and mechanical ventilation. The Company is preparing to engage the FDA and EMA in the first half of 2011 for regulatory guidance with respect to the planned Aerosurf development program. Discovery Labs, working with a leading technology company with expertise in biomedical device development, is optimizing the design of the capillary aerosolization device to potentially reduce development risk and satisfy regulatory and development requirements for Aerosurf.

---

**Surfaxin Phase 2 trial for ARF:** Discovery Labs recently completed a comprehensive analysis of its Phase 2 clinical trial of Surfaxin in children with ARF, a critical condition often caused in children by severe respiratory infections. The study was a multicenter, randomized, masked trial that enrolled 165 children under the age of two and compared Surfaxin treatment to standard of care alone. The objective was to evaluate the safety and tolerability of intratracheal administration of Surfaxin and to assess whether Surfaxin treatment could decrease the duration of mechanical ventilation in children with ARF. The trial was designed as an estimation trial, intended to evaluate multiple, potentially clinically-relevant endpoints, as this was the first ever exposure of Surfaxin in a pediatric ARF patient population. The previously reported preliminary analysis indicated that Surfaxin treatment was generally safe and well tolerated in the ARF patient population in this trial. Additionally, Surfaxin treatment reduced time on mechanical ventilation by approximately 10% compared with standard of care alone, although this observation was not statistically significant.

The recently completed comprehensive analysis demonstrated that, based on patient stratification by severity of lung injury, Surfaxin treatment significantly reduced time on mechanical ventilation in the least severe patient segment ( $p < 0.01$ ) when compared with standard of care alone. Furthermore, the data demonstrated that Surfaxin intervention reduced the need for a second dose ( $p < 0.05$ ), suggesting a decrease in disease severity following surfactant treatment. The comprehensive analysis of the ARF trial has been submitted for presentation at several medical congresses in 2011.

Data from this trial are supportive of Discovery Labs belief that intervention with aerosolized KL<sub>4</sub> surfactant earlier in the disease progression may provide for a better clinical outcome in patients at risk for severe respiratory compromise. As a next step in development, Discovery Labs has entered into a collaboration with a leading academic center to evaluate the potential advantage of aerosolized KL<sub>4</sub> surfactant intervention in a pre-clinical model of acute lung injury and expects this study to conclude in early 2011.

**Aerosolized KL<sub>4</sub> Surfactant (lucinactant) for CF:** Aerosolized KL<sub>4</sub> surfactant was evaluated in a Phase 2a investigator-initiated clinical trial as a single center, pilot study to evaluate the effect of aerosolized KL<sub>4</sub> surfactant in patients with mild to moderate CF. The study was designed to assess the safety, tolerability and preliminary effectiveness of short term administration of aerosolized KL<sub>4</sub> surfactant on MCC.

Discovery recently announced the completion of this study and that the trial was presented at the 2010 North American Cystic Fibrosis Conference. Dr. Scott H. Donaldson (University of North Carolina), the study's principle investigator, concluded that aerosolized KL<sub>4</sub> surfactant delivery to CF patients was feasible, generally safe and well tolerated, was not associated with serious adverse events, and demonstrated evidence of pharmacologic response via improvement in MCC versus patient baseline. Discovery Labs believes that this Phase 2a trial supports the rationale for further development of aerosolized KL<sub>4</sub> surfactant in CF and other diseases associated with mucociliary compromise and also represents the first meaningful assessment of feasibility relating to the therapeutic use of aerosolized KL<sub>4</sub> surfactant in an ambulatory setting.

Recently, the Office of Orphan Products Development of the FDA granted orphan drug designation to Discovery Labs' KL<sub>4</sub> surfactant for the treatment of CF. Orphan designation provides for up to seven years of U.S. market drug product exclusivity for the designated indication following marketing authorization.

Surfaxin, Surfaxin LS, Aerosurf and the Company's other Aerosolized KL<sub>4</sub> surfactant drug product candidates 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 September 30, 2010**

For the quarter ended September 30, 2010, the Company reported a net operating loss of \$6.2 million (or \$0.03 per share) on 194.2 million weighted average common shares outstanding. For the nine months ended September 30, 2010, the Company reported a net operating loss of \$19.5 million (or \$0.12 per share) on 164.3 million weighted average common shares outstanding. As of September 30, 2010, the Company had 198.9 million common shares outstanding.

For the third quarter of 2010, net cash burn from ongoing operating activities (before financing and debt service activities) was \$5.0 million. Additionally, the Company made \$4.0 million of repayments under its previously restructured \$10.6 million loan with PharmaBio Development Inc. (PharmaBio), the former strategic investing subsidiary of Quintiles Transnational Corp. (Quintiles). As of September 30, 2010, all amounts owed under this loan obligation have been paid in full. During September 2010, the Company received aggregate proceeds of \$0.6 million from the issuance of 3.1 million shares of common stock pursuant to a financing under the 2010 CEFF.

As of September 30, 2010, the Company had cash and cash equivalents of \$14.7 million. Additionally, under the 2010 CEFF, there were approximately 28.5 million shares (not to exceed an aggregate of \$34.4 million) available for issuance, (subject to certain conditions and limitations, including a minimum share price requirement of \$0.20) which may allow the Company to raise additional capital to support its business plans.

The Company anticipates that its net cash burn for the fourth quarter of 2010 will be approximately \$4.0 million consisting of \$5.5 million of cash used primarily for operating activities offset by cash inflows to date in the fourth quarter from the following financing activities:

- The Company has been awarded a grant of \$244,479, administered through the U.S. Internal Revenue Service's Qualifying Therapeutic Discovery Project, to advance its project for aerosolized KL<sub>4</sub> surfactant for prevention of neonatal RDS. The award payments are expected in the fourth quarter of 2010 and will provide non-dilutive capital to support the program based on expenditures made in 2009.
- PharmaBio invested an incremental \$0.5 million to advance Surfaxin LS and Aerosurf regulatory and development activities. Discovery issued to PharmaBio approximately 2.4 million shares of the Company's common stock and warrants to purchase approximately 1.2 million shares of common stock.
- The Company received aggregate proceeds of approximately \$0.8 million from the issuance of 4.7 million shares of common stock pursuant to financings under the 2010 CEFF.

## **Restatement of Financial Statements**

In connection with a review of our Annual Report on 2009 Form 10-K by the Audit Committee of the Company's Board of Directors (the "Audit Committee"), and the Company's management, conducted with the assistance of Ernst & Young LLP ("Ernst & Young"), the Company's independent registered public accounting firm, and the Company's outside legal advisors, the Audit Committee has reassessed the accounting classification of certain warrants issued by the Company in May 2009 and February 2010 with respect to ASC 815 "Derivatives and Hedging — Contracts in Entity's Own Equity" ("ASC 815," formerly known as Emerging Issues Task Force Issue 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock"). The review was conducted to respond to certain comments raised by the Staff of the Securities and Exchange Commission ("SEC") following its periodic review of the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

---



The warrants under review are:

- Warrants to purchase 7,000,000 shares of common stock issued in May 2009 in connection with a registered equity offering. The warrants expire in May 2014 and are exercisable, subject to an aggregate share ownership limitation, at an exercise price of \$1.15 per share; and
- Warrants to purchase 13,750,000 shares of our common stock issued in February 2010 in connection with a registered equity offering. The warrants expire in February 2015 and are exercisable, subject to an aggregate share ownership limitation, at a price of \$0.85 per share.

The Company has historically accounted for its warrants, which prior to May 2009 were issued in private transactions, as equity instruments. The Company's warrants generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, notwithstanding the availability of cashless exercise, ASC 815, as interpreted, appears to establish a presumption that, in the absence of express language to the contrary, registered warrants may be subject to net cash settlement, as it is not within the absolute control of the Company to provide freely-tradable shares in all circumstances. After extensive discussion, the Company's management, Ernst & Young, and the Company's outside legal advisors concluded that, although the interpretation and applicability of ASC 815 as it relates to registered warrants is complex and subject to varying interpretations, it should be applied based on a strict reading of the authoritative literature without respect to any evaluation of remoteness or probability.

Applying such a strict reading, the Audit Committee, together with management and in consultation with Ernst & Young and the Company's outside legal advisors, determined that, notwithstanding the highly-remote and theoretical possibility of net cash settlement, the warrants identified above should have been recorded as liabilities, measured at fair value on the date of issue, with changes in the fair values recognized in the Company's quarterly statement of operations in its quarterly financial reports. Accordingly, the Audit Committee has also concluded on November 8, 2010 that the Company's previously-filed consolidated financial statements for the fiscal year ended December 31, 2009 on Form 10-K; Ernst & Young's reports on the financial statements and the effectiveness of internal control over financial reporting for the fiscal year ended December 31, 2009; each of the consolidated financial statements included in the Company's Quarterly Reports on Form 10-Q for the periods ended June 30, 2009, September 30, 2009, March 31, 2010 and June 30, 2010; and all related earnings releases and similar communications issued by the Company with respect to the foregoing, should no longer be relied upon. The Company's management and the Audit Committee are assessing the effect of the pending restatements on the Company's internal control over financial reporting and its disclosure controls and procedures.

On or before November 15, 2010, the Company anticipates filing an amended Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and amended Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2010 and June 30, 2010, each with restated financial statements reflecting the reclassification of the warrants identified above, together with the Quarterly Report on Form 10-Q for the period ended September 30, 2010. The Company does not expect to amend its previously-filed Quarterly Reports on Form 10-Q for the periods ended June 30, 2009 and September 30, 2009.

---

The restatements that are being implemented will reflect the reclassification of the warrants from equity to a liability in an amount equal to the fair value of the warrants, as of the dates of issuance, calculated using the Black Scholes option pricing model. The restatements will have no impact on amounts previously reported for Assets; Revenues; Operating Expenses; Cash Flows; Loans, Equipment Loan and Accounts Payables; and Contractual Obligations. The restatements will have no effect on the Company's development programs, including Surfaxin, anticipated development milestones, or business strategy.

Readers are referred to, and encouraged to read in their entirety, the Forms 8-K regarding the matters referred to herein, including any exhibits attached thereto, and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 to be filed with the Securities and Exchange Commission, which includes further detail on above-referenced transactions and the Company's business plans and operations, financial condition and results of operations.

#### **Conference Call Details**

Discovery Labs will hold a conference call on Tuesday November 9, 2010 at 10:00 AM EST 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://us.meeting-stream.com/discoverylabs\\_110910](http://us.meeting-stream.com/discoverylabs_110910) and [www.discoverylabs.com](http://www.discoverylabs.com). The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 22279770.

#### **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<sub>4</sub> 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<sub>4</sub> 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](http://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 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:**

Media relations:

Michelle Linn, Linnden Communications  
508-362-3087

Investor relations:

John G. Cooper, President and Chief Financial Officer  
215-488-9490