

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**

March 22, 2011

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 March 22, 2011, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the year and quarter ended December 31, 2010, and providing an update on certain business matters. 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 relating to the announcement of the results of operations for the year and quarter ended December 31, 2010 and all other matters except for those discussed under Item 8.01 below 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.

On March 22, 2011, the Company issued a press release highlighting the results of operations for the year and quarter ended December 31, 2010, and providing an update on certain business matters. The Company announced that, for the first quarter of 2011, it projects cash outflow of \$5.2 million before taking into account financing activities. The Company also announced that it has been conducting a comprehensive preclinical program to validate its optimized biological activity test (BAT) for Surfaxin® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants, and that validating the BAT is a key remaining issue that must be addressed to potentially gain U.S. Food and Drug Administration (FDA) marketing approval for Surfaxin in the United States. The Company has had several interactions with the FDA intended to ensure that its comprehensive preclinical program for would satisfy the FDA, and in January 2011, announced that the FDA had directed the Company to increase the sample size of a specific data set by testing additional Surfaxin batches. To comply with the FDA's suggestion, the Company has successfully manufactured seven Surfaxin batches and plans to manufacture three additional Surfaxin batches for the comprehensive preclinical program. The Company continues to believe that it will be in a position to file a Surfaxin Complete Response in the third quarter of 2011, which could lead to potential approval of Surfaxin in the first quarter of 2012.

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 March 22, 2011

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: March 22, 2011

Discovery Labs Reports Fourth Quarter Financial Results and Provides an Update on Key Pipeline Programs

Warrington, PA — March 22, 2011 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biotechnology company developing surfactant therapies for respiratory disease, today reports financial results for the fourth quarter ended December 31, 2010 and provides an update on key pipeline programs. The Company will host a conference call this morning at 10:00 AM EDT. **The call-in number is 866-332-5218.**

Selected financial information, discussed in greater detail below, include:

- A net loss of \$5.7 million for the fourth quarter of 2010. Excluding non-cash items related to depreciation, stock-based compensation and the change in fair value of certain outstanding warrants accounted for as derivative liabilities, the fourth quarter 2010 loss was \$5.0 million.
- Net cash outflows of \$4.4 million for the fourth quarter of 2010, consisting of \$5.7 million of cash outflows partially offset by \$1.3 million net proceeds from financing activities.
- The Company began 2011 with pro-forma cash of \$32.8 million, consisting of \$10.2 million as of December 31, 2010, \$1.0 million of net proceeds from a January 2011 Committed Equity Financing Facility (CEFF) financing, and \$21.6 million of net proceeds from a February 2011 public offering of the Company's securities. For the first quarter of 2011, the Company projects cash outflow of \$5.2 million before taking into account financing activities.

Selected updates on pipeline programs include:

- Surfaxin[®] (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants – the Company is conducting a comprehensive preclinical program to validate its optimized biological activity test (BAT), a key remaining issue that must be addressed to potentially gain U.S. Food and Drug Administration (FDA) marketing approval for Surfaxin in the United States. The Company has had several interactions with the FDA intended to ensure that the comprehensive preclinical program would satisfy the FDA, and in January 2011, announced that the FDA had directed the Company to increase the sample size of a specific data set by testing additional Surfaxin batches. To comply with the FDA's suggestion, the Company has successfully manufactured seven Surfaxin batches and plans to manufacture three additional Surfaxin batches for the comprehensive preclinical program. The Company continues to believe that it will be in a position to file a Surfaxin Complete Response in the third quarter of 2011, which could lead to potential approval of Surfaxin in the first quarter of 2012.
 - Surfaxin LS[™] (lyophilized lucinactant) for neonatal RDS – the Company continues to advance this program and plans in 2011 to establish a commercial-scale manufacturing capability at a cGMP-compliant contract manufacturer with expertise in lyophilized formulations and to seek regulatory guidance from the FDA and the European Medicines Agency (EMA) for the planned development program.
 - Aerosurf[®] (aerosolized lucinactant) for neonatal RDS – the Company continues to advance this program and plans in 2011 to finalize the clinical and potential commercial design of its capillary aerosolization generator, finalize the clinical and potential commercial design for its novel disposable patient interface intended to increase the efficiency of pulmonary aerosol delivery, and to seek regulatory guidance from the FDA and EMA for the planned clinical development program.
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W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs commented, "We have made considerable progress in our comprehensive preclinical program intended to gain FDA approval for Surfaxin, while prudently advancing our Surfaxin LS and Aerosurf programs. We have also recently concluded a number of key corporate initiatives that we believe fundamentally strengthens our Company and provides sufficient capital to take us through the potential FDA approval of Surfaxin, which we believe could occur in the first quarter 2012."

Summary Financial Position and Results for the Quarter and Year ended December 31, 2010

As of December 31, 2010, the Company had cash and cash equivalents of \$10.2 million. In January 2011, the Company received aggregate proceeds of approximately \$1.0 million from the issuance of 314,179 shares of common stock pursuant to a financing under the 2010 CEFF. In February 2011, the Company completed a public offering that resulted in net proceeds of \$21.6 million through the issuance of 10.0 million shares of common stock, fifteen-month warrants to purchase 5.0 million shares of common stock, and five-year warrants to purchase 5.0 million shares of common stock. The shares and warrants were priced at \$2.35 per unit. The fifteen-month warrants have an exercise price of \$2.94 per share and the five-year warrants have an exercise price of \$3.20 per share, subject to certain provisions. The Company could realize up to an additional \$14.7 million in proceeds by May 2012 from the potential exercise of the fifteen-month warrants.

Additionally, the Company currently has two CEFFs that, subject to certain conditions, including price and volume limitations, may allow the Company in the future to raise additional capital to support its business plans. Under the 2010 CEFF (which expires in June 2013), there are 1.3 million shares available for potential future issuance. Under the May 2008 CEFF (which expires in June 2011), there are 0.9 million shares available for potential future issuance.

As of December 31, 2010, the Company had debt from loans payable and equipment loans of \$0.4 million compared to \$11.5 million for the same period in 2009. The reduction primarily reflects the satisfaction in full of all obligations related to a \$10.6 million loan with PharmaBio Development Inc. (PharmaBio), the former strategic investment subsidiary of Quintiles Transnational Corp. The \$0.4 million equipment loan balance primarily represents a 2008 loan with the Commonwealth of Pennsylvania Department of Economic Development that funded the purchase of equipment for our analytical and development laboratory.

For the quarter ended December 31, 2010, the Company reported a net loss of \$5.7 million (or \$0.42 per share) on 13.5 million weighted average common shares outstanding compared to a net loss of \$2.8 million (or \$0.33 per share) on 8.4 million weighted average common shares outstanding for the same period in 2009. Included in the net loss is income (non-cash) of \$38,000 and \$3.4 million for 2010 and 2009, respectively, representing the change in fair value of certain outstanding common stock warrants accounted for as derivative liabilities.

Net cash burn for the fourth quarter of 2010 was \$4.4 million, consisting of \$5.6 million used in operating activities and \$0.1 million used for debt service, partially offset by cash inflows in the fourth quarter from the following financing activities:

- PharmaBio, a shareholder of the Company, invested an incremental \$0.5 million to advance Surfaxin LS and Aerosurf regulatory and development activities. The Company issued 158,730 shares of its common stock and warrants to purchase approximately 79,365 shares of common stock to PharmaBio.
 - The Company received aggregate proceeds of approximately \$0.8 million from the issuance of 312,359 shares of common stock pursuant to financings under the 2010 CEFF.
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In addition, in the fourth quarter of 2010, the Company was awarded the following U.S. government grants, providing non-dilutive capital, to support the Company's program for aerosolized KL₄ surfactant for neonatal RDS.

- U.S. Internal Revenue Service's Qualifying Therapeutic Discovery Project grant of \$244,479 (funded and accounted for in the fourth quarter as other income). The award was based on program expenditures made in 2009.
- Phase I of a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health (NIH) providing \$581,000 to support development efforts in 2011. Following conclusion of the Phase I grant activities, the Company may receive from the NIH a Phase II grant which could provide up to an additional \$1.8 million. The Company anticipates recording revenue from the funding of the Phase I grant in the first half of 2011.

For the year ended December 31, 2010, the Company reported a net loss of \$19.2 million (or \$1.65 per share) on 11.6 million weighted average common shares outstanding compared to a net loss of \$29.9 million (or \$3.89 per share) on 7.7 million weighted average common shares outstanding for the same period in 2009. Included in the net loss is income (non-cash) of \$6.4 million and \$0.4 million in 2010 and 2009, respectively, representing the change in fair value of certain outstanding common stock warrants accounted for as derivative liabilities.

The Company had 8.4 million, 13.8 million, and 24.1 million common shares outstanding as of December 31, 2009, December 31, 2010 and March 18, 2011 respectively.

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 Annual Report on Form 10-K for the year ended December 31, 2010 to be filed with the Securities and Exchange Commission, which includes further detail on the above-referenced transactions and the Company's business plans and operations, financial condition and results of operations.

Surfaxin, Surfaxin LS, Aerosurf and the Company's other aerosolized KL₄ surfactant drug product candidates are investigational medications and are not approved by the FDA or any other world health regulatory authority for use in humans.

Conference Call Details

Discovery Labs will hold a conference call on Tuesday March 22, 2011 at 10:00 AM EDT to further discuss the foregoing. The call in number is 866-332-5218. The international call in number is 706-679-3237. This audio webcast will be available through a live broadcast on the Internet at http://us.meeting-stream.com/discoverylaboratories_032211 and www.discoverylabs.com. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 51155817.

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 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 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 other materials 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 compliance with The Nasdaq Capital Market listing requirements, 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, President and Chief Financial Officer
215-488-9490

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

	Three Months Ended December 31, (unaudited)		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Revenue from collaborative arrangement and grants	\$ -	\$ -	\$ -	\$ -
Operating expenses: ⁽¹⁾				
Research and development	3,913	3,888	17,136	19,077
General and administrative	2,119	2,015	8,392	10,120
Total expenses	<u>6,032</u>	<u>5,903</u>	<u>25,528</u>	<u>29,197</u>
Operating loss	(6,032)	(5,903)	(25,528)	(29,197)
Change in fair value of common stock warrant liability ⁽¹⁾	38	3,354	6,422	369
Other income / (expense), net	254	(238)	(69)	(1,043)
Net loss	<u>\$ (5,740)</u>	<u>\$ (2,787)</u>	<u>\$ (19,175)</u>	<u>\$ (29,871)</u>
Net loss per common share	<u>\$ (0.42)</u>	<u>\$ (0.33)</u>	<u>\$ (1.65)</u>	<u>\$ (3.89)</u>
Weighted avg. common shares outstanding	13,525	8,376	11,602	7,680

(1) Material non-cash items include the change in fair value of certain outstanding warrants accounted for as derivative liabilities, and in operating expenses, depreciation and stock-based compensation (in accordance with ASC Topic 718). For the three and twelve months ended December 31, 2010, the charges for depreciation and stock-based compensation were \$0.7 million (\$0.4 million in R&D and \$0.3 million in G&A) and \$2.8 million (\$1.7 million in R&D and \$1.1 million in G&A), respectively. For the three and twelve months ended December 31, 2009, the charges for depreciation and stock-based compensation were \$1.0 million (\$0.5 million in R&D and \$0.5 million in G&A) and \$4.1 million (\$1.9 million in R&D and \$2.2 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2010	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 10,211	\$ 15,741
Prepaid expenses and other current assets	285	233
Total current assets	<u>10,496</u>	<u>15,974</u>
Property and equipment, net	3,467	4,668
Restricted Cash	400	400
Other assets	174	361
Total Assets	<u>\$ 14,537</u>	<u>\$ 21,403</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,685	\$ 1,294
Accrued expenses	3,286	3,446
Common stock warrant liability	2,469	3,191
Loan payable, including accrued interest	-	10,461
Equipment loan and capitalized leases, current portion	136	597
Total Current Liabilities	<u>7,576</u>	<u>18,989</u>
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	935	1,118
Total Liabilities	<u>8,511</u>	<u>20,107</u>
Stockholders' Equity	6,026	1,296
Total Liabilities and Stockholders' Equity	<u>\$ 14,537</u>	<u>\$ 21,403</u>