

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**

May 11, 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))
-

Item 2.02. Results of Operations and Financial Condition.

On May 11, 2011, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended March 31, 2011, 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 hereto relating to the announcement of the results of operations for the quarter ended March 31, 2011 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 May 11, 2011, the Company issued a press release highlighting the results of operations for the quarter ended March 31, 2011, and providing an update on its pipeline development as follows:

- 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 ultimately satisfy the FDA. In January 2011, the Company announced that the FDA had provided guidance 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 eight Surfaxin batches and presently plans to manufacture two additional Surfaxin batches for use in the comprehensive preclinical program. The Company presently plans to complete all related analytical testing and concordance studies, and be in a position to file a Surfaxin Complete Response in the third quarter of 2011.
- Surfaxin LSTM (lyophilized lucinactant) for neonatal RDS: The Company continues to advance this program. Its plans for 2011 include establishing a commercial-scale manufacturing capability at a cGMP-compliant contract manufacturer with expertise in lyophilized formulations and seeking regulatory guidance from the FDA and the European Medicines Agency (EMA) for the planned clinical development program.
- Aerosolization Technology: Recently, at the 2011 Pediatric Academic Societies Annual Meeting (PAS), new data was presented including: (i) a collaborative study indicating that aerosolized KL4 surfactant significantly improved lung function and survival when treating Acute Lung Injury in a well established preclinical model of this severe respiratory condition, (ii) a dose-ranging assessment of aerosolized KL4 surfactant in a widely recognized preclinical model of RDS, demonstrating significant improvement in lung function, lung structural integrity and pulmonary inflammatory mediator profile following treatment with aerosolized KL4 surfactant versus controls, and (iii) a study highlighting the Company’s novel patient interface technology intended to increase the efficiency of pulmonary aerosol drug delivery to patients requiring positive pressure ventilatory support.

Regarding the Company's lead aerosolized KL4 surfactant program, Aerosurf® (aerosolized lucinactant for neonatal RDS), data from the preclinical dose ranging assessment study presented at PAS mentioned above suggests that, out of several doses tested, KL4 surfactant delivered via the Company's proprietary capillary aerosol generator during a 20 to 30 minute dosing interval results in the most favorable physiologic outcomes. This study provides guidance for future clinical dosing strategies for this program. The Company's plans for 2011 include finalizing the clinical and potential commercial design of the capillary aerosol generator, finalizing the clinical and potential commercial design for the novel patient interface, and seeking regulatory guidance in the U.S. and Europe for the planned development program.

For the quarter ending June 30, 2011, the Company projects cash outflow of \$5.8 million.

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 May 11, 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: May 11, 2011



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

Warrington, PA — May 11, 2011 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today reports financial results for the first quarter ended March 31, 2011 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 includes:

- For the quarter ended March 31, 2011, the Company reported a net loss of \$3.8 million. Excluding accounting for 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 first quarter 2011 loss was \$5.4 million.
- For the first quarter of 2011, net cash outflows, before financing activities, was \$5.1 million. Financing activities included a public offering of the Company's securities in February 2011, which resulted in net proceeds of \$21.6 million, and a financing in January 2011 under the Company's June 2010 Committed Equity Financing Facility (2010 CEFF), which resulted in net proceeds of \$1 million.
- As of March 31, 2011 the Company had cash and cash equivalents of \$27.7 million. The Company also has two Committed Equity Financing Facilities (CEFFs) that, subject to certain conditions, may allow the Company in the future to raise additional capital to support its business plans.

W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs commented, "In the first quarter, we concluded a number of key corporate initiatives that we believe fundamentally strengthen our Company and provides sufficient capital to take us through the potential FDA approval of Surfaxin, our first priority, which we believe could occur in the first quarter of 2012. Additionally, we are prudently advancing and are very encouraged by our aerosolization technology, which we believe has the potential to address the substantial unmet medical need for an aerosolized surfactant for several respiratory disorders. We are also pleased to have recently presented a series of related, new data to the pediatric critical care community at the prestigious PAS Annual Meeting."

Selected Pipeline Development Updates 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 ultimately satisfy the FDA. In January 2011, the Company announced that the FDA had provided guidance 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 eight Surfaxin batches and presently plans to manufacture two additional Surfaxin batches for use in the comprehensive preclinical program. The Company presently plans to complete all related analytical testing and concordance studies, and be in a position to file a Surfaxin Complete Response in the third quarter of 2011.
-

- **Surfaxin LS™ (lyophilized lucinactant) for neonatal RDS:** The Company continues to advance this program. Our plans for 2011 include establishing a commercial-scale manufacturing capability at a cGMP-compliant contract manufacturer with expertise in lyophilized formulations and seeking regulatory guidance from the FDA and the European Medicines Agency (EMA) for the planned clinical development program.
- **Aerosolization Technology:** Recently, at the 2011 Pediatric Academic Societies Annual Meeting (PAS), new data was presented including: (i) a collaborative study indicating that aerosolized KL₄ surfactant significantly improved lung function and survival when treating Acute Lung Injury in a well established preclinical model of this severe respiratory condition, (ii) a dose-ranging assessment of aerosolized KL₄ surfactant in a widely recognized preclinical model of RDS, demonstrating significant improvement in lung function, lung structural integrity and pulmonary inflammatory mediator profile following treatment with aerosolized KL₄ surfactant versus controls, and (iii) a study highlighting the Company's novel patient interface technology intended to increase the efficiency of pulmonary aerosol drug delivery to patients requiring positive pressure ventilatory support.

Regarding our lead aerosolized KL₄ surfactant program, Aerosurf® (aerosolized lucinactant for neonatal RDS), data from the preclinical dose ranging assessment study presented at PAS mentioned above suggests that, out of several doses tested, KL₄ surfactant delivered via the Company's proprietary capillary aerosol generator during a 20 to 30 minute dosing interval results in the most favorable physiologic outcomes. This study provides guidance for future clinical dosing strategies for this program. The Company's plans for 2011 include finalizing the clinical and potential commercial design of the capillary aerosol generator, finalizing the clinical and potential commercial design for the novel patient interface, and seeking regulatory guidance in the U.S. and Europe for the planned development program.

Summary Financial Position and Results for the Quarter ended March 31, 2011

For the quarter ended March 31, 2011, the Company reported a net loss of \$3.8 million (or \$0.21 per share) on 18.1 million weighted-average common shares outstanding, compared to a net loss of \$6.1 million (or \$0.66 per share) on 9.2 million weighted-average common shares outstanding for the same period in 2010. Included in the net loss is non-cash income of \$2.2 million and \$1.2 million for the three months ended March 31, 2011 and 2010, respectively, representing the change in fair value of certain common stock warrants classified as derivative liabilities.

For the quarter ended March 31, 2011, the Company reported an operating loss of \$6.1 million, compared to \$7.1 million for the same period last year. Excluding non-cash items related to depreciation and stock-based compensation, the first quarter 2011 operating loss was \$5.4 million, compared to \$6.3 million for the same period last year. Included in the first quarter of 2011 is \$0.4 million of revenue recognized under our grant from the National Institutes of Health (NIH) to support the development of the Company's program for aerosolized KL₄ surfactant for RDS.

As of March 31, 2011 the Company had cash and cash equivalents of \$27.7 million compared to \$10.2 million as of December 31, 2010. Net cash outflows from ongoing operating activities, before financings, for the first quarter of 2011 was \$5.1 million. Financing activities in the first quarter of 2011 included: (i) in January 2011, the Company received net proceeds of approximately \$1.0 million from the issuance of 314,179 shares of common stock pursuant to a financing under the 2010 CEFF; and (ii) in February 2011, the Company completed a public offering that resulted in net proceeds of \$21.6 million from the issuance of 10 million shares of common stock and warrants to purchase 10 million shares. The shares and warrants were priced at \$2.35 per unit, with each unit consisting of one share of common stock, one 15-month warrant to purchase 0.5 share of common stock and one five-year warrant to purchase 0.5 share of common stock. The 15-month warrants have an exercise price of \$2.94 per share, the five-year warrants have an exercise price of \$3.20 per share, subject to certain anti-dilution provisions. If the market price of the Company's common stock were to exceed \$2.94 at any time prior to May 2012, the Company may potentially realize up to an additional \$14.7 million in proceeds from the potential exercise of the 15-month warrants.

Additionally, the Company currently has two Committed Equity Financing Facilities (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 March 31, 2011, the Company reported common stock warrant liability of \$8.3 million, as compared to \$2.5 million as of December 31, 2010. The increase in common stock warrant liability is due primarily to the issuance in February 2011 of the five-year warrants discussed above. These warrants may be exercised for cash only, except in certain limited circumstances, and expressly state that there is no circumstance in which the Company shall be required to settle the warrants in cash. These warrants contain anti-dilution provisions that reset the exercise price upon the future issuance of lower-priced securities (with certain exceptions). Due to the nature of the anti-dilution provisions, to comply with applicable accounting guidelines (Accounting Standards Codification Topic 815), these warrants were classified as derivative liabilities and reported as of March 31, 2011 at an estimated fair value of \$7.3 million using a trinomial valuation model.

The Company had 24.1 million and 13.8 million common shares outstanding as of March 31, 2011 and December 31, 2010, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 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.

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. The capillary aerosol generator and the proprietary patient interface are investigational devices 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 Wednesday May 11, 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_051111 and www.discoverylabs.com. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 63905586.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty 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. Discovery Labs is also developing its proprietary capillary aerosolization technology and novel patient interfaces, to enable efficient, targeted upper respiratory or alveolar delivery of aerosolized KL₄ surfactant. Discovery Labs believes that its proprietary technology 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 aerosol generators and patient interface 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 aerosol generators and patient interface 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 March 31, (unaudited)	
	2011	2010
Revenue from collaborative arrangement and grants	\$ 381	\$ -
Operating expenses: ⁽¹⁾		
Research and development	4,620	4,133
General and administrative	1,820	2,932
Total expenses	<u>6,440</u>	<u>7,065</u>
Operating loss	(6,059)	(7,065)
Change in fair value of common stock warrant liability ⁽¹⁾	2,228	1,230
Other expense, net	<u>(6)</u>	<u>(223)</u>
Net loss	<u>\$ (3,837)</u>	<u>\$ (6,058)</u>
Net loss per common share	\$ (0.21)	\$ (0.66)
Weighted avg. common shares outstanding	18,114	9,180

⁽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. For the three months ended March 31, 2011 and 2010, charges for depreciation and stock-based compensation were \$0.6 million (\$0.4 million in R&D and \$0.2 million in G&A) and \$0.8 million (\$0.5 million in R&D and \$0.3 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2011	December 31, 2010
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 27,663	\$ 10,211
Prepaid expenses and other current assets	289	285
Total Current Assets	<u>27,952</u>	<u>10,496</u>
Property and equipment, net	3,159	3,467
Other assets	569	574
Total Assets	<u>\$ 31,680</u>	<u>\$ 14,537</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,873	\$ 1,685
Accrued expenses	3,500	3,286
Common stock warrant liability	8,328	2,469
Equipment loan and capitalized leases, current portion	122	136
Total Current Liabilities	<u>13,823</u>	<u>7,576</u>
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	991	935
Total Liabilities	<u>14,814</u>	<u>8,511</u>
Stockholders' Equity	<u>16,866</u>	<u>6,026</u>
Total Liabilities and Stockholders' Equity	<u>\$ 31,680</u>	<u>\$ 14,537</u>