

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 10, 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 November 10, 2011, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended September 30, 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 September 30, 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 November 10, 2011, the Company issued a press release highlighting the results of operations for the quarter ended September 30, 2011, and providing an update on its lead pipeline programs. The Company noted that, although it does not currently plan to conduct a significant capital-raising transaction prior to March 6, 2011, the target action date set by the Food and Drug Administration (FDA) under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for Surfaxin® for the prevention of respiratory distress syndrome (RDS) in premature infants, the Company is assessing various forms of financing facilities that would allow it to partially offset cash outflows and raise capital in its discretion from time to time. There can be no assurance, however, that the Company will not undertake a financing or that it will enter into a financing facility to allow it to partially offset cash outflows.

For the fourth quarter of 2011, the Company anticipates net cash outflows of approximately \$5.4 million, including proceeds realized in connection with draw downs under the Company’s 2010 CEFF, but before taking into account any other potential financing activities.

Subject to the note relating to the press release contained in Item 2.02 of 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 10, 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/ W. Thomas Amick
Name: W. Thomas Amick
Title: Chairman of the Board and Chief Executive Officer

Date: November 10, 2011



**Discovery Labs Reports Third Quarter Financial Results and
Progress on Lead Programs**

WARRINGTON, PA — November 10, 2011 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to improving the standard of respiratory critical care, today reports financial results for the third quarter ended September 30, 2011, as well as the status of the SURFAXIN® and AFECTAIR™ programs. The Company will host a conference call this morning at 10:00 AM ET. Conference call details are below.

Selected third quarter highlights include:

- **SURFAXIN®** – The U.S. Food and Drug Administration (“FDA”) accepted the Company’s Complete Response for SURFAXIN and has established March 6, 2012 as the target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant U.S. marketing approval of SURFAXIN for the prevention of respiratory distress syndrome (RDS) in premature infants. If approved, SURFAXIN would represent the first synthetic, peptide-containing surfactant for use in neonatal medicine and provide a potential alternative to the currently approved, animal-derived surfactants that today are the standard of care to manage RDS in premature infants.
- **AFECTAIR™** – The Company introduced AFECTAIR as a new product candidate in the third quarter of 2011. AFECTAIR is intended to simplify the delivery of inhaled therapies for critical care patients requiring ventilatory support and was originally developed for the Aerosurf program. According to national health statistics and recent market assessment data, it is estimated that more than 1.3 million patients annually in the United States and European Union receive aerosolized medications while requiring ventilatory support. The Company is implementing a regulatory plan that will potentially allow for market introduction of the first AFECTAIR product in the United States in the first half of 2012 and in the European Union later in 2012. The Company believes that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients.

“We believe we have made significant progress this past quarter. We have filed a Complete Response and have a PDUFA date for SURFAXIN, and we have introduced a new product candidate, AFECTAIR. We believe that both of these products could be introduced commercially in 2012,” said W. Thomas Amick, Chairman of the Board and Chief Executive Officer, Discovery Labs. “We also believe that these results have strengthened our company and potentially position us to realize our goal of improving the standard of respiratory critical care.”

Summary Operating Results and Financial Position for the Quarter ended September 30, 2011

For the quarter ended September 30, 2011, the Company reported a net loss of \$4.8 million (\$0.20 per share) on 24.1 million weighted-average common shares outstanding, compared to a net loss of \$6.6 million (\$0.51 per share) on 12.9 million weighted-average common shares outstanding for the comparable period in 2010. Included in the net loss is the change in fair value of certain common stock warrants that are classified as derivative liabilities, resulting in non-cash income of \$1.4 million for the quarter ended September 30, 2011 and non-cash expense of \$0.4 million for the quarter ended September 30, 2010.

The Company reported an operating loss of \$6.2 million for each of the quarters ended September 30, 2011 and 2010. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss was \$5.7 million for the quarter ended September 30, 2011, compared to \$5.6 million for the quarter ended September 30, 2010. The operating loss for the third quarter of 2011 includes costs related to the completion of the comprehensive preclinical program to support the Surfaxin Complete Response, which was filed in September, and a one-time charge of \$0.4 million related to severance obligations to a former executive.

Net cash outflows for the third quarter of 2011 were \$6.1 million. During the fourth quarter of 2011, the Company anticipates net cash outflows of approximately \$5.4 million.

As of September 30, 2011, the Company had cash and cash equivalents of \$15.4 million. Additionally, the Company currently has its 2010 Committed Equity Financing Facility (CEFF) 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. During the fourth quarter to date, the Company has completed financings under the CEFF for net proceeds of approximately \$343,000 through the issuance of 200,811 shares of common stock. Under the CEFF, there are currently 1.1 million shares available for potential future issuance that may allow the Company to raise an additional \$1.7 million of capital at current market prices. Additionally, in connection with a public offering conducted in February 2011, the Company issued fifteen-month warrants (expiring May 2012) to purchase 5.0 million shares of common stock at an exercise price of \$2.94. If the market price of the Company's common stock should exceed \$2.94 at any time prior to May 2012, and all fifteen-month warrants are exercised, the Company may realize up to an additional \$14.7 million in proceeds.

As of September 30, 2011, the Company reported a common stock warrant liability of \$8.6 million, of which \$7.4 million is related to five-year warrants issued in February 2011. These warrants state that there is no circumstance in which the Company shall be required to effect a net cash settlement; however, they have been classified as derivative liabilities in accordance with generally accepted accounting principles because they contain anti-dilution provisions that adjust the exercise price of the warrants in certain circumstances. The remaining balance of \$1.2 million is related to warrants issued in May 2009 and February 2010. These warrants state that, in the event a related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. However, since these warrants do not expressly state that there is no circumstance in which the Company shall be required to settle the warrants in cash, the warrants have been classified as derivative liabilities in accordance with generally accepted accounting principles, regardless of the remote likelihood that an event would result in cash settlement.

The Company currently has 24.5 million shares of common stock outstanding and had 24.3 million and 24.2 million, shares of common stock outstanding as of September 30, 2011 and June 30, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Conference Call and Webcast Details

Discovery Labs will hold a conference call and webcast today at 10:00 AM EST to discuss the foregoing.

A live webcast of the conference call, including a slide presentation, is available at https://us.reg.meeting-stream.com/discoverylaboratories_111011 and www.discoverylabs.com. An archive of the webcast will be available on Discovery Labs Investor Relations web site for approximately 45 days.

For both "listen-only" participants and those who wish to take part in the question and answer portion of the call, the dial-in numbers are (877) 215-0093 (U.S.) or (706) 679-3237 (international). The passcode for the call is 22715326.

An audio replay of the conference call will be available two hours after the call's completion. The dial-in numbers for the replay are (855) 859-2056 or (404) 537-3406. The passcode for the replay is 22715326.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to create life-saving products for critical care patients with respiratory disease and improve the standard of care for pulmonary medicine. 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, lyophilized and aerosolized formulations. Discovery Labs is also developing its proprietary drug delivery technologies to enable efficient, targeted upper-respiratory or alveolar delivery of aerosolized KL4 surfactant and other inhaled therapies. Discovery Labs believes that its proprietary technologies make it possible, for the first time, to develop a significant pipeline of 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 (including in connection with the review by regulatory authorities of SURFAXIN and AFECTAIR), (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 (including in connection with the FDA's review of Discovery Labs' Complete Response for SURFAXIN), 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 facility (CEFF), or that the minimum share price at which Discovery Labs may access the CEFF from time to time will prevent Discovery Labs from accessing the full dollar amount potentially available under the CEFF; 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:

Investor Relations:

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215-488-9490

Media Relations:

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484-356-7105

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

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30 (unaudited)	
	2011	2010	2011	2010
Revenue from collaborative arrangement and grants	\$ -	\$ -	\$ 582	\$ -
Operating expenses: ⁽¹⁾				
Research and development	3,981	4,727	13,216	13,223
General and administrative	2,189	1,476	5,975	6,273
Total expenses	<u>6,170</u>	<u>6,203</u>	<u>19,191</u>	<u>19,496</u>
Operating loss	(6,170)	(6,203)	(18,609)	(19,496)
Change in fair value of common stock warrant liability ⁽¹⁾	1,422	(365)	1,957	6,384
Other income / (expense), net	(3)	(16)	(12)	(323)
Net loss	<u>\$ (4,751)</u>	<u>\$ (6,584)</u>	<u>\$ (16,664)</u>	<u>\$ (13,435)</u>
Net loss per common share	<u>\$ (0.20)</u>	<u>\$ (0.51)</u>	<u>\$ (0.75)</u>	<u>\$ (1.23)</u>
Weighted avg. common shares outstanding	24,106	12,945	22,104	10,954

(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 and nine months ended September 30, 2011, the charges for depreciation and stock-based compensation were \$0.5 million (\$0.4 million in R&D and \$0.1 million in G&A) and \$1.5 million (\$1.1 million in R&D and \$0.4 million in G&A), respectively. For the three and nine months ended September 30, 2010, the 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 \$2.1 million (\$1.3 million in R&D and \$0.8 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2011 (Unaudited)	December 31, 2010
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 15,411	\$ 10,211
Prepaid expenses and other current assets	327	285
Total current assets	<u>15,738</u>	<u>10,496</u>
Property and equipment, net	2,585	3,467
Other assets	400	574
Total Assets	<u>\$ 18,723</u>	<u>\$ 14,537</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,386	\$ 1,685
Accrued expenses	3,003	3,286
Common stock warrant liability	8,599	2,469
Equipment loan and capitalized leases, current portion	74	136
Total Current Liabilities	<u>13,062</u>	<u>7,576</u>
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	933	935
Total Liabilities	<u>13,995</u>	<u>8,511</u>
Stockholders' Equity	4,728	6,026
Total Liabilities and Stockholders' Equity	<u>\$ 18,723</u>	<u>\$ 14,537</u>