

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, 2012

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 8, 2012, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended September 30, 2012, 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, 2012 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.

For the fourth quarter of 2012, the Company anticipates operating cash outflows of \$9.5 million, before taking into account financing activities.

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 8, 2012

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 8, 2012



Discovery Labs Reports Third Quarter 2012 Financial Results

WARRINGTON, PA — November 8, 2012 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today reported financial results for the third quarter ended September 30, 2012.

- For the third quarter of 2012, the Company reported an operating loss of \$10.0 million with net cash outflows of \$9.9 million. As of September 30, 2012, the Company had cash and cash equivalents of \$36.1 million.
- The Company has deployed its newly-hired field force to focus on the near-term objective of securing hospital formulary acceptance for SURFAXIN® and adoption of AFECTAIR®.
- The Company anticipates product availability for SURFAXIN early in the second quarter of 2013 and its initial AFECTAIR device for infants in December 2012.
- The Company remains focused on the development of AEROSURF® and is on track for the potential initiation of a phase 2 clinical trial in the second half of 2013. To prepare for this effort, the Company plans to complete development and validation of its commercial scale manufacturing process for its lyophilized KL4 surfactant and a 'clinic ready' capillary aerosol generator (CAG) device by mid-2013.

For the quarter ended September 30, 2012, the Company reported a net loss of \$13.3 million (\$0.31 per share) on 43.4 million weighted-average common shares outstanding, compared to a net loss of \$4.8 million (\$0.20 per share) on 24.1 million weighted-average common shares outstanding for the comparable period in 2011. 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 expense of \$3.3 million for quarter ended September 30, 2012 and non-cash income of \$1.4 million for the quarter ended September 30, 2011.

The Company reported an operating loss of \$10.0 million for the quarter ended September 30, 2012 compared to an operating loss of \$6.2 million for the comparable period in 2011. The increase in the operating loss is primarily due to investments in the Company's specialty commercial and medical affairs organizations, including a field sales force, national accounts team and medical science liaison team. These teams are focused primarily on gaining hospital formulary acceptance for SURFAXIN and adoption of AFECTAIR.

Net cash outflows for the quarter ended September 30, 2012 were \$9.9 million. For the fourth quarter of 2012, the Company anticipates operating cash outflows of \$9.5 million, before taking into account financing activities.

As of September 30, 2012, the Company had cash and cash equivalents of \$36.1 million. The Company had 43.5 million and 24.6 million shares of common stock outstanding as of September 30, 2012 and December 31, 2011, respectively.

As of September 30, 2012, the Company reported a common stock warrant liability of \$11.9 million, of which \$11.4 million is related to five-year warrants issued in February 2011. These warrants 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 \$0.5 million is related to registered 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 warrants, the holder may exercise the warrants on a cashless basis. However, regardless of the remote likelihood that an event would result in cash settlement, the warrants have been classified as derivative liabilities in accordance with generally accepted accounting principles because they do not expressly state that there is no circumstance in which the Company will be required to settle the warrants in cash.

Readers are referred to, and encouraged to read in their entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 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.

ABOUT DISCOVERY LABS

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to advance a new standard in respiratory critical care. 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 dosage forms. Discovery Labs is also developing its proprietary drug delivery technologies to enable efficient 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, including projections of future cash balances and anticipated cash outflows, to differ materially from the statements made. Examples of such risks and uncertainties are: risks relating to Discovery Labs' efforts to successfully commercialize SURFAXIN and AFECTAIR, including: (i) whether Discovery Labs' products will meet the requirements to be included in the hospitals' purchasing lists of approved drug products, medical devices and equipment, (ii) whether Discovery Labs' products will gain market acceptance and healthcare professionals will recognize the perceived advantages over the currently available products, (iii) whether Discovery Labs will succeed in introducing its products using its own commercial and medical affairs organizations; (iv) whether Discovery Labs will be successful in completing development of, and introducing, its planned second vial size for SURFAXIN and follow-on AFECTAIR devices; and (v) even if Discovery Labs is successful in commercializing its products, whether its products will be profitable and whether the revenues generated will be sufficient to fund Discovery Labs' research and development activities and support its operations; risks that Discovery Labs may be unable in a timely manner, if at all, (i) to identify potential strategic partners or collaborators to support development of its products and, if approved, commercialize its products in markets outside the U.S., (ii) to access its committed equity financing facility (CEFF), or (iii) to raise additional capital to fund its activities, or that additional financings could result in substantial equity dilution; risks related to Discovery Labs' research and development activities, including time-consuming and expensive pre-clinical studies, clinical trials, which may be subject to potentially significant delays or regulatory holds, or fail, and the need for sophisticated and extensive analytical methodologies; risks related to 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 ventilator circuit/patient interface connectors and CAG devices on a timely basis and in an amount sufficient to support Discovery Labs' development efforts and, if approved, commercialization; risks relating to the rigorous regulatory requirements required for approval of any drug, drug-device combination or medical device products that Discovery Labs may develop, including that: (a) the U.S. Food and Drug Administration (FDA) or other regulatory authorities may not agree with Discovery Labs on matters raised during regulatory reviews or may require Discovery Labs 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; 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; 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.

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Investor Relations

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

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30 (unaudited)	
	2012	2011	2012	2011
Revenue from collaborative arrangement and grants	\$ -	\$ -	\$ -	\$ 582
Operating expenses: ⁽¹⁾				
Research and development	5,743	3,981	15,482	13,216
Selling, general and administrative	4,255	2,189	9,912	5,975
Total expenses	<u>9,998</u>	<u>6,170</u>	<u>25,394</u>	<u>19,191</u>
Operating loss	(9,998)	(6,170)	(25,394)	(18,609)
Change in fair value of common stock warrant liability ⁽¹⁾	(3,309)	1,422	(5,063)	1,957
Other income / (expense), net	(39)	(3)	(43)	(12)
Net loss	<u>\$ (13,346)</u>	<u>\$ (4,751)</u>	<u>\$ (30,500)</u>	<u>\$ (16,664)</u>
Net loss per common share	\$ (0.31)	\$ (0.20)	\$ (0.80)	\$ (0.75)
Weighted avg. common shares outstanding	43,444	24,106	38,061	22,104

(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, 2012, the charges for depreciation and stock-based compensation were \$0.8 million (\$0.4 million in R&D and \$0.4 million in S,G&A) and \$2.1 million (\$1.2 million in R&D and \$0.9 million in S,G&A), respectively. 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 S,G&A) and \$1.5 million (\$1.1 million in R&D and \$0.4 million in S,G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2012 (Unaudited)	December 31, 2011
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 36,064	\$ 10,189
Prepaid expenses and other current assets	1,293	442
Total current assets	<u>37,357</u>	<u>10,631</u>
Property and equipment, net	1,995	2,293
Other assets	400	400
Total Assets	<u>\$ 39,752</u>	<u>\$ 13,324</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 208	\$ 1,111
Accrued expenses	3,665	2,972
Common stock warrant liability	11,923	6,996
Equipment loan and capitalized leases, current portion	68	68
Total Current Liabilities	<u>15,864</u>	<u>11,147</u>
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	837	913
Total Liabilities	<u>16,701</u>	<u>12,060</u>
Stockholders' Equity	23,051	1,264
Total Liabilities and Stockholders' Equity	<u>\$ 39,752</u>	<u>\$ 13,324</u>