

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**

August 2, 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 August 2, 2012, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended June 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 June 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.

On August 2, 2012, the Company issued a press release highlighting the results of operations for the quarter ended June 30, 2012. The Company noted that it continues to expect to launch its drug product candidate, SURFAXIN[®], and the initial AFFECTAIR[®] device in the United States in the fourth quarter of 2012. In connection with developing and potentially commercializing its pipeline products, SURFAXIN LS[™] and AEROSURF[®], the Company is engaged in discussions with potential international strategic partners who could provide development and commercial expertise outside of the United States as well as financial resources. However, there can be no assurance that any such arrangement will be concluded.

For the third quarter of 2012, the Company anticipates net cash outflows of approximately \$10.0 million to \$10.5 million. The anticipated increase is primarily due to increased personnel and other costs related to building specialty commercial and medical affairs organizations.

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 August 2, 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: August 2, 2012



Discovery Labs Reports Second Quarter 2012 Financial Results

WARRINGTON, PA — August 2, 2012 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today reports financial results for the second quarter ended June 30, 2012 and provides a business update. The Company will host a conference call this morning at 10:00 AM ET. Conference call details are below.

Key operating updates and financial information include:

- The Company has made significant progress in building its own specialty commercial and medical affairs organizations to specialize in neonatal respiratory critical care. These organizations will implement the commercialization of the Company's products and provide medical and scientific information to the neonatal medical community regarding the Company's proprietary KL4 surfactant and aerosol drug delivery technologies.
- The Company remains on track to launch SURFAXIN® in the U.S. in the fourth quarter of 2012. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage respiratory distress syndrome (RDS) in premature infants. The Company also remains on track to launch the neonatal size AFECTAIR® device in the fourth quarter of 2012.
- To advance the AEROSURF® program, the Company entered into a Research and Development Services Agreement ("Agreement") with Battelle Memorial Institute ("Battelle"), the world's largest nonprofit research and development organization with expertise in developing and integrating aerosol devices using innovative and advanced technologies. Battelle will provide technical support and expertise to optimize the design of, and assist in the development of, a clinic-ready capillary aerosol generator (CAG) device for use in the Company's Phase 2 AEROSURF clinical trials, which the Company is planning to initiate in late 2013. If approved, AEROSURF will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. The Company believes that AEROSURF potentially may enable the treatment of a significantly greater number of premature infants with or at risk for RDS who could benefit from surfactant therapy but who are currently not treated.
- For the second quarter of 2012, the Company reported an operating loss of \$8.8 million compared with an operating loss of \$6.4 million for the comparable period in 2011. As of June 30, 2012, the Company had cash and cash equivalents of \$46.0 million.

"We believe that our KL4 surfactant and aerosol drug delivery technologies have the potential to significantly advance respiratory critical care," said W. Thomas Amick, Chairman of the Board and Chief Executive Officer of the Company. "During this past quarter, we focused on attracting top notch talent for our specialty commercial and medical affairs organizations. These teams will launch both SURFAXIN and the neonatal AFECTAIR device in the United States and communicate with the medical community about our commitment to advancing a new standard in respiratory critical care. We are also actively involved in discussions with potential international strategic partners who are interested in developing and commercializing our KL4 surfactant and aerosol technologies to advance the standard of care for infants with RDS in various markets outside the United States."

Summary Financial Results for the Second Quarter ended June 30, 2012

For the quarter ended June 30, 2012, the Company reported a net loss of \$7.1 million (\$0.16 per share) on 43.4 million weighted-average common shares outstanding, compared to a net loss of \$8.1 million (\$0.34 per share) on 24.0 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 income of \$1.7 million for quarter ended June 30, 2012 and non-cash expense of \$1.7 million for the quarter ended June 30, 2011.

The Company reported an operating loss of \$8.8 million for the quarter ended June 30, 2012 compared to an operating loss of \$6.4 million for the quarter ended June 30, 2011. The increase is primarily due to increased personnel and other costs related to building the Company's specialty commercial and medical affairs organizations. Included in the operating loss were non-cash items related to depreciation and stock-based compensation of \$0.7 million and \$0.5 million for the quarters ended June 30, 2012 and 2011, respectively.

Net cash outflows before financing activities for the quarter ended June 30, 2012 were \$8.8 million and included a milestone payment of \$0.5 million that became payable to Johnson & Johnson following U.S. regulatory approval of SURFAXIN. For the third quarter 2012, the Company anticipates operating cash outflows of \$10.0 - \$10.5 million, before taking into account financing activities. The anticipated increase is primarily due to increased personnel and other costs related to building the Company's specialty commercial and medical affairs organizations.

As of June 30, 2012, the Company had cash and cash equivalents of \$46.0 million. The Company had 43.4 million and 24.6 million shares of common stock outstanding as of June 30, 2012 and December 31, 2011, respectively.

As of June 30, 2012, the Company reported a common stock warrant liability of \$8.6 million, of which \$8.3 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 \$0.3 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, 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 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 June 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.

Conference Call and Webcast Details

Discovery Labs will hold a conference call and audio webcast today at 10:00 AM ET to discuss the foregoing. To access the conference call, please dial (866) 332-5218 for domestic callers and (706) 679-3237 for international callers. The conference call passcode is 13676514. This conference call will also be available through a live broadcast, listen only, via the web at https://us.reg.meeting-stream.com/discoverylaboratories_080212 and www.discoverylabs.com.

A replay of the conference call will be available until August 10, 2012. The replay number is (855) 859-2056 or (404) 537-3406 using the same conference call passcode listed above. A replay will also be available at www.discoverylabs.com.

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, including projections of future cash balances, 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 be successful in establishing 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 the follow-on AFECTAIR devices; and (v) the risk that, even if Discovery Labs is successful in commercializing its products, its products will not be profitable or the revenues generated will not be sufficient to fund Discovery Labs' research and development activities and support its operations; risks that (a) 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 relating to Discovery Labs' research and development activities, including for follow-on AFECTAIR® ventilator circuit/patient interface connectors, new drug products and capillary aerosol generator (CAG) devices, 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 or 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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Condensed Consolidated Statement of Operations
(in thousands, except per share data)

	Three Months Ended June 30, (unaudited)		Six Months Ended June 30 (unaudited)	
	2012	2011	2012	2011
Revenue from collaborative arrangement and grants	\$ —	\$ 201	\$ —	\$ 582
Operating expenses: ⁽¹⁾				
Research and development	5,206	4,615	9,739	9,235
Selling, general and administrative	3,610	1,966	5,657	3,786
Total expenses	<u>8,816</u>	<u>6,581</u>	<u>15,396</u>	<u>13,021</u>
Operating loss	<u>(8,816)</u>	<u>(6,380)</u>	<u>(15,396)</u>	<u>(12,439)</u>
Change in fair value of common stock warrant liability ⁽¹⁾	1,680	(1,693)	(1,754)	535
Other income / (expense), net	(2)	(3)	(4)	(9)
Net loss	<u>\$ (7,138)</u>	<u>\$ (8,076)</u>	<u>\$ (17,154)</u>	<u>\$ (11,913)</u>
Net loss per common share	<u>\$ (0.16)</u>	<u>\$ (0.34)</u>	<u>\$ (0.49)</u>	<u>\$ (0.56)</u>
Weighted avg. common shares outstanding	43,369	24,027	35,325	21,086

(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 six months ended June 30, 2012, the charges for depreciation and stock-based compensation were \$0.7 million (\$0.4 million in R&D and \$0.3 million in S,G&A) and \$1.4 million (\$0.8 million in R&D and \$0.6 million in S,G&A), respectively. For the three and six months ended June 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 \$1.0 million (\$0.7 million in R&D and \$0.3 million in S,G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2012 (Unaudited)	December 31, 2011
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 46,008	\$ 10,189
Prepaid expenses and other current assets	538	442
Total current assets	<u>46,546</u>	<u>10,631</u>
Property and equipment, net	2,235	2,293
Other assets	400	400
Total Assets	<u>\$ 49,181</u>	<u>\$ 13,324</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,335	\$ 1,111
Accrued expenses	2,592	2,972
Common stock warrant liability	8,614	6,996
Equipment loan and capitalized leases, current portion	67	68
Total Current Liabilities	<u>12,608</u>	<u>11,147</u>
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	872	913
Total Liabilities	<u>13,480</u>	<u>12,060</u>
Stockholders' Equity	35,701	1,264
Total Liabilities and Stockholders' Equity	<u>\$ 49,181</u>	<u>\$ 13,324</u>