

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 3, 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 May 3, 2012, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended March 31, 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 March 31, 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 May 3, 2012, the Company issued a press release highlighting the results of operations for the quarter ended March 31, 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 international strategic partners who could provide development and commercial expertise outside of the United States as well as financial resources, including large multinational pharmaceutical companies with significant capabilities to develop and commercialize hospital-based products in major markets outside the United States, and specialty pharmaceutical companies with hospital-based products and a significant commercial presence throughout Europe and select other geographic regions. However, there can be no assurance that any such arrangement will be concluded within that time frame, if at all.

For the second quarter of 2012, the Company anticipates net cash outflows of approximately \$8.5 million to \$9 million, which includes a milestone payment of \$0.5 million to Johnson & Johnson (J&J) related to the U.S. regulatory approval of SURFAXIN.

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 May 3, 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: May 3, 2012



Discovery Labs Reports First Quarter 2012 Financial Results

WARRINGTON, PA — May 3, 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 first quarter ended March 31, 2012. The Company will host a conference call this morning at 10:00 AM ET. Conference call details are below.

Key financial information includes:

- For the first quarter of 2012, the Company reported an operating loss of \$6.6 million compared with an operating loss of \$6.1 million for the comparable period in 2011. Operating cash outflows before financing activities were \$5.7 million for the first quarter of 2012.
- As of March 31, 2012, the Company had cash and cash equivalents of \$54.8 million. In the first quarter 2012, the Company received net proceeds of approximately \$50.3 million from offerings of common stock and the exercise of warrants to purchase shares of common stock. Currently, there are warrants outstanding to purchase 2.8 million shares of common stock at an exercise price of \$2.94 which expire on May 22, 2012. If the price of the Company's common stock should be above \$2.94 and if holders determine in their discretion to exercise these warrants, the Company could potentially realize up to an additional \$8.1 million in proceeds.
- With receipt in the first quarter of 2012 of both U.S. regulatory approval of SURFAXIN® (lucinactant) and U.S. marketing clearance for the initial AFECTAIR® device, the Company is implementing its plans to build U.S. commercial and medical affairs capabilities, and to advance its SURFAXIN LS™ and AEROSURF® pipeline programs. The Company anticipates operating cash outflows before financing activities of \$8.5 - \$9.0 million for the second quarter of 2012, which includes a milestone payment of \$0.5 million to Johnson & Johnson (J&J) related to the U.S. regulatory approval of SURFAXIN.

“During this past quarter, we significantly strengthened our company. With two products gaining FDA marketing authorization and an improved financial position, we are prepared to execute our business plan,” said W. Thomas Amick, Chairman of the Board and Chief Executive Officer, Discovery Labs. “We are making good progress on our top priorities: implementing the U.S. commercial launch of SURFAXIN and AFECTAIR, targeted for Q4 2012; developing our high-value pipeline programs, SURFAXIN LS and AEROSURF, and securing potential international strategic partners for these pipeline programs. We believe that our KL4 surfactant and aerosol drug delivery technologies have the potential to significantly advance respiratory critical care, beginning with respiratory distress syndrome.”

Summary Financial Results for the First Quarter Ended March 31, 2012

The net loss for the first quarter of 2012 was \$10.0 million (\$0.37 per share) on 27.2 million weighted-average common shares outstanding, compared to a net loss of \$3.8 million (\$0.21 per share) on 18.1 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 \$3.4 million for the first quarter of 2012 and non-cash income of \$2.2 million for the comparable period in 2011.

The Company reported an operating loss of \$6.6 million for the first quarter of 2012 compared to \$6.1 million for the comparable period in 2011. Included in the operating loss were (i) in the first quarter of 2012, a charge related to a milestone payment of \$0.5 million that became payable to J&J as a result of the approval of SURFAXIN by the U.S. Food and Drug Administration (FDA); (ii) non-cash items related to depreciation and stock-based compensation of \$0.7 million and \$0.5 million for 2012 and 2011, respectively; and (iii) in the first quarter of 2011, grant revenue of \$0.4 million related to funds received and expended under a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL4 surfactant for respiratory distress syndrome. Excluding these one-time, non-recurring items and non-cash items related to depreciation and stock-based compensation, the operating loss was \$5.4 million and \$5.9 million for 2012 and 2011, respectively.

Operating cash outflows for the first quarter of 2012 were \$5.7 million and net cash inflows for the first quarter, after taking into consideration financing activities, were \$44.6 million.

As of March 31, 2012, the Company had cash and cash equivalents of \$54.8 million. During the first quarter of 2012, the Company raised \$50.3 million consisting of (i) \$42.1 million in net proceeds from a March 2012 public offering of 16.1 million shares of common stock at a price of \$2.80 per share; (ii) \$6.7 million in proceeds from the exercise of warrants to purchase 2.3 million shares of common stock; and, (iii) \$1.5 million net proceeds from the an offering of 350,374 shares of common stock that was concluded in March 2012 under its "at-the-market" (ATM) Program.

The Company had 43.4 million and 24.6 million shares of common stock outstanding as of March 31, 2012 and December 31, 2011, respectively.

Additionally, the Company currently has: (i) outstanding warrants to purchase 2.8 million shares of common stock at an exercise price of \$2.94 that expire on May 22, 2012, which if exercised by the holders could result in up to an additional \$8.1 million in proceeds; (ii) its ATM Program, which may allow the Company, at its discretion, to raise up to \$13.4 million additional capital to support its business plans; and (iii) 1.1 million shares available under its 2010 Committed Equity Financing Facility (CEFF) that, subject to certain conditions, including price and volume limitations, may allow the Company to raise additional capital to support its business plans. In connection with the March 2012 public offering, the Company and its executive officers agreed, subject to certain exceptions, not to sell or otherwise dispose of shares of the Company's common stock for a period of 90 days, ending on June 14, 2012.

As of March 31, 2012, the Company reported a common stock warrant liability of \$10.3 million, of which \$9.3 million is related to five-year warrants issued in February 2011. These warrants contain anti-dilution provisions that adjust the exercise price of the warrants in certain circumstances and, therefore, have been classified as derivative liabilities in accordance with generally accepted accounting principles. The remaining balance of \$1.0 million is related to warrants issued in May 2009 and February 2010. Although these warrants state that the warrants may be exercised on a cashless basis if a registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrants, these 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 shall be required to settle the warrants in cash. In classifying these warrants as liabilities, the accounting literature does not permit us to take into account the remoteness of any potential cash settlement.

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, 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 Information

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 (877) 215-0093 for domestic callers and (706) 679-3237 for international callers. The conference call passcode is 76592677. This conference call will also be available through a live broadcast, listen only, via the web at http://us.meeting-stream.com/discoverylaboratories_050312 and www.discoverylabs.com.

A replay of the conference call will be available for thirty days. 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 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.

About SURFAXIN

SURFAXIN (lucinactant intratracheal suspension) is indicated for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. A single randomized, active-controlled, multi-dose study involving 1,294 premature infants demonstrated the safety and efficacy of SURFAXIN. Within 30 minutes of birth, infants in the study received SURFAXIN, Exosurf (colfosceril palmitate) or Survanta® (beractant). Surfaxin and Exosurf served as the primary comparison for this study; Survanta served as another comparison. Surfaxin demonstrated significant improvement in both RDS at 24 hours after birth and RDS-related mortality through two weeks, when compared with Exosurf.

SURFAXIN is intended for intratracheal use only. The administration of exogenous surfactants, including SURFAXIN, can rapidly affect oxygenation and lung compliance. SURFAXIN should be administered only by clinicians trained and experienced with intubation, ventilator management, and general care of premature infants in a highly supervised clinical setting. Infants receiving SURFAXIN should receive frequent clinical assessments so that oxygen and ventilatory support can be modified to respond to changes in respiratory status. Most common adverse reactions associated with the use of SURFAXIN are endotracheal tube reflux, pallor, endotracheal tube obstruction, and need for dose interruption. During SURFAXIN administration, if bradycardia, oxygen desaturation, endotracheal tube reflux, or airway obstruction occurs, administration should be interrupted the infant's clinical condition assessed and stabilized. SURFAXIN is not indicated for use in acute respiratory distress syndrome (ARDS). For more information about SURFAXIN, please visit www.surfaxin.com. Information contained in, or accessible through, this website does not constitute a part of, and is not incorporated into, this Annual Report on Form 10-K.

About AFECTAIR

AFECTAIR was developed initially as part of the AEROSURF[®] development program and is being developed as a series of proprietary disposable ventilator circuit/patient interface connectors that simplify the delivery of aerosolized medications to critical-care patients requiring ventilatory support. According to national health statistics and market assessment data, it is estimated that each year more than 1.3 million patients in the United States and European Union receive aerosolized medications while requiring ventilator support. Discovery Labs is implementing a business plan that potentially will allow for the commercial introduction of AFECTAIR in the United States and the European Union in late 2012.

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 gain market acceptance and meet the requirements to be included in the hospitals' purchasing list of approved products, including SURFAXIN drug product, the WARMING CRADLE[®], which Discovery Labs plans to provide to hospitals to facilitate the administration of SURFAXIN, and AFECTAIR devices, (ii) whether the perceived advantages of Discovery Labs' products over the currently available products will be recognized by healthcare professionals, including neonatologists, (iii) whether Discovery Labs will be successful in establishing an effective sales force and medical affairs capability; (iv) whether Discovery Labs will be successful in completing development of, and introducing, its planned follow-on products, including a second vial size for SURFAXIN and the second AFECTAIR device; 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; the risks that (a) Discovery Labs may be unable (i) to identify potential strategic partners or collaborators to support development of its products and, if approved, commercialize its products, particularly in markets outside the U.S., in a timely manner, if at all, (ii) to access its ATM Program or committed equity financing facility (CEFF), or (iii) to raise additional capital; or (b) 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; 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; risks relating to Discovery Labs' ability to develop and manufacture drug products, additional AFECTAIR[®] ventilator circuit / patient interface connectors and capillary aerosol generator (CAG) devices for clinical studies, and, if approved, for commercialization of drug and combination drug-device products and, if cleared for marketing, medical 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 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; 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:

Media Relations: Michael Parks, Pitch360 - 484.356.7105 or Michael@pitch360inc.com

Investor Relations: John G. Cooper, President and Chief Financial Officer 215.488.9490

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

	Three Months Ended March 31, (unaudited)	
	2012	2011
Grant revenue	\$ -	\$ 381
Operating expenses: ⁽¹⁾		
Research and development	4,533	4,620
General and administrative	2,047	1,820
Total expenses	6,580	6,440
Operating loss	(6,580)	(6,059)
Change in fair value of common stock warrant liability	(3,434)	2,228
Other income / (expense), net	(2)	(6)
Net loss	\$ (10,016)	\$ (3,837)
Net loss per common share	\$ (0.37)	\$ (0.21)
Weighted avg. common shares outstanding	27,162	18,114

(1) Includes non-cash charges for depreciation and stock-based compensation the three months ended March 31, 2012 and 2011 of \$0.7 million (\$0.4 million in R&D and \$0.3 million in G&A) and \$0.5 million (\$0.3 million in R&D and \$0.2 million in G&A), respectively.

Discovery Laboratories, Inc
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2012 (Unaudited)	December 31, 2011
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 54,802	\$ 10,189
Prepaid expenses and other current assets	393	442
Total current assets	55,195	10,631
Property and equipment, net	2,143	2,293
Restricted Cash	400	400
Total Assets	\$ 57,738	\$ 13,324
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,339	\$ 1,111
Accrued expenses	2,887	2,972
Common stock warrant liability	10,304	6,996
Equipment loan and capitalized leases, current portion	67	68
Total Current Liabilities	14,597	11,147
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	908	913
Total Liabilities	15,505	12,060
Stockholders' Equity	42,233	1,264
Total Liabilities and Stockholders' Equity	\$ 57,738	\$ 13,324