

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 7, 2013

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 7, 2013, Discovery Laboratories, Inc. (the “Company”) issued a press release (the “Press Release”) highlighting the results of operations for the quarter ended March 31, 2013, 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, 2013 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.

As set forth in the Press Release, for the second quarter of 2013, the Company anticipates net cash outflows of approximately \$10.0 million, before taking into account financing activities. The Press Release also provides certain program updates relating to the Company’s SURFAXIN[®], AEROSURF[®] and AFECTAIR[®] programs.

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 7, 2013

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: Chief Executive Officer, President
and Chief Financial Officer

Date: May 7, 2013



Discovery Labs Reports First Quarter 2013 Financial Results

WARRINGTON, PA — May 7, 2013 — 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, 2013 and also provides certain program updates.

Selected operational updates:

- **SURFAXIN®:** On April 15, 2013, the Company reported that it had received from the U.S. Food and Drug Administration (FDA) a response to a previous Company submission regarding an improved and revalidated analytical chemistry method and updated SURFAXIN drug product specifications. The FDA requested information and provided recommendations intended to clarify certain aspects of the revalidated analytical chemistry method and updated product specifications. The Company believes it can respond to the FDA by early-June. FDA procedure allows for up to four months for the FDA to review such submissions. If its plan is successful and the FDA agrees with its response, the Company expects to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013.
- **AEROSURF®:** AEROSURF is a drug/device combination product that combines the Company's KL4 surfactant with its capillary aerosol generator (CAG) technology. The Company is developing AEROSURF with the goal of administering aerosolized KL4 surfactant to premature infants without having to use invasive endotracheal intubation. The Company believes that AEROSURF could enable the treatment of a significantly greater number of premature infants with respiratory distress syndrome (RDS). The Company, with the assistance of a third-party medical device expert, is advancing its efforts to optimize and manufacture its CAG for use in its planned phase 2 AEROSURF clinical program. The Company plans to use a lyophilized dosage form of its KL4 surfactant for AEROSURF and is also working to complete the technology transfer of its lyophilized manufacturing process to a contract manufacturing organization (CMO) with expertise in lyophilization. The Company plans to initiate its AEROSURF phase 2 clinical program in the fourth quarter of 2013.
- **AFECTAIR®:** The Company has begun the commercial introduction of its AFECTAIR aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal and pediatric intensive care units with a user experience program that is being conducted in select U.S. critical care centers representing approximately ten percent of target institutions. This initial phase is intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device. This phase is expected to continue through the second quarter of 2013, after which the Company plans to initiate the broader introduction of AFECTAIR.

Summary Financial Results for the First Quarter ended March 31, 2013

For the quarter ended March 31, 2013, the Company reported a net loss of \$12.6 million (\$0.29 per share) on 43.7 million weighted-average common shares outstanding, compared to a net loss of \$10.0 million (\$0.37 per share) on 27.2 million weighted-average common shares outstanding for the same period in 2012. 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 \$0.2 million in 2013 and non-cash expense of \$3.4 million for the same period in 2012.

The Company reported an operating loss of \$12.6 million for the quarter ended March 31, 2013 compared to an operating loss of \$6.6 million for the same period in 2012. The increase in operating loss from 2012 to 2013 is primarily due to (i) expenses of \$2.7 million in the first quarter of 2013 related to the Company's U.S. specialty respiratory critical care commercial and medical affairs organizations that are experienced in neonatal/pediatric respiratory critical care and are focused on gaining hospital formulary acceptance of SURFAXIN and adoption of AFECTAIR; (ii) \$1.6 million of expenses in the first quarter of 2013 to advance the AEROSURF development program, primarily the optimization of the CAG and the technology transfer of the lyophilized KL4 surfactant manufacturing process to a CMO; and, (iii) a \$1.3 million increase in raw material purchases for drug product manufacturing in support of the SURFAXIN and AEROSURF programs.

Operating cash outflows before financing activities for the quarter ended March 31, 2013 were \$10.4 million. As of March 31, 2013, the Company had cash and cash equivalents of \$26.4 million. For the second quarter of 2013, the Company anticipates operating cash outflows of approximately \$10.0 million, before taking into account financing activities.

In February 2013, the Company secured a \$30 million loan facility with Deerfield (Deerfield Facility). Upon execution of the agreement, Deerfield advanced \$10 million to the Company and agreed to advance an additional \$20 million, conditioned upon the first commercial sale of SURFAXIN occurring on or before December 31, 2013. Amounts outstanding under the Deerfield Facility accrue interest at a rate of 8.75%, payable quarterly in cash, and principal is due in three equal installments on the fourth, fifth and sixth anniversaries of the agreement, except that, if the Company achieves certain revenue or market capitalization milestones, the amounts due on the fourth and fifth anniversaries of the agreement will be deferred for one year. Thus, if the milestones are achieved on the fourth and fifth anniversaries of the agreement, the principal amount under the Deerfield Facility will not be due until the sixth anniversary of the agreement. There can be no assurance that the condition for the \$20 million disbursement will be met or that the milestones required to defer the first two installments of principal will be achieved. In conjunction with the \$10 million advance, Deerfield received warrants to purchase approximately 2.3 million shares of common stock at an exercise price of \$2.81. If the first SURFAXIN commercial sale occurs on or before December 31, 2013, upon disbursement of the \$20 million advance, Deerfield will receive additional warrants to purchase approximately 4.7 million shares of common stock at an exercise price of \$2.81. All of the warrants will expire on the sixth anniversary date of the Deerfield Facility.

Also in February 2013, the Company entered into an at-the-market equity sales agreement (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel). Under the ATM Program, at the Company's discretion and at such times and amounts as it deems appropriate, Stifel may sell up to \$25 million of the Company's common stock to support the Company's business plans. The Company will pay Stifel a commission of 3% on the gross proceeds of all sales. The Company is not obligated to effect any sales under the ATM Program. The Company has not used the ATM Program in 2013.

As of March 31, 2013, the Company had approximately \$7 million of accounts payable and accrued expenses and \$10 million of debt under the Deerfield Facility, which has been reported as long-term debt, net of \$3.9 million of discounts.

As of March 31, 2013, the Company reported a common stock warrant liability of \$6.1 million, predominantly related to five-year warrants issued in February 2011. The terms of these Warrants provide that no cash settlement by the Company shall be required; however, the Warrants are 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 Company had 43.8 and 43.7 million shares of common stock outstanding as of March 31, 2013 and December 31, 2012, respectively.

Readers are referred to, and encouraged to read in their entirety the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 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 focused on advancing 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. Discovery Labs is also developing its proprietary drug delivery technologies to enable efficient delivery of aerosolized KL4 surfactant and other inhaled therapies. Discovery Labs' strategy is initially focused on neonatology and improving the management of respiratory distress syndrome (RDS) in premature infants. Discovery Labs believes that its RDS product portfolio has the potential to become the new standard of care for RDS and, over time, significantly expand the current worldwide RDS market.

For more information, please visit the Company's 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 include: risks that Discovery Labs will be unable to secure significant additional capital as needed, and may be unable in a timely manner, if at all, to identify potential strategic partners to support product development and, if approved, commercialize products in markets outside the U.S., or access its Deerfield Facility or other debt or equity financings, which could result in substantial equity dilution; risks related to the delay in commercial availability of SURFAXIN, including (a) Discovery Labs' plan to maintain its commercial and medical affairs capabilities and continue its investments in the AEROSURF[®] program limits its ability to reduce cash outflows, (b) it may be unable to timely respond to the FDA's recent correspondence, or the FDA may not review the response within four months or may not agree with the response, which could further delay or prevent the commercial introduction of SURFAXIN, and (c) it may lose access to \$20 million under the Deerfield Facility if the delay extends beyond December 31, 2013; risks relating to efforts to commercialize SURFAXIN and AFECTAIR, including (1) whether Discovery Labs' commercial and medical affairs organizations will succeed in introducing the products, (2) whether the products will be approved by hospitals and will gain market acceptance and be preferred by healthcare providers over current products, (3) whether the products will generate revenues sufficient to fund Discovery Labs' research and development activities and support its operations, and (4) whether Discovery Labs will successfully develop a planned second vial size for SURFAXIN and follow-on AFECTAIR devices; risks related to development programs, including time-consuming and expensive pre-clinical studies and 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, contract manufacturers or suppliers in manufacturing drug products, drug substances, aerosol-conducting airway connectors, CAG devices and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the FDA or other regulatory authorities may not agree with Discovery Labs on matters raised during regulatory reviews, may require significant additional activities, or may not accept or may withhold or delay consideration of applications, or may not approve or may limit approval of Discovery Labs' products, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals; other risks, including those related to (1) continued compliance with The Nasdaq Capital Market listing requirements, (2) Discovery Labs' efforts to maintain and protect the patents and licenses related to its products, (3) whether it or its strategic partners will be able to attract and retain qualified personnel, (3) other companies' competing products, (3) legal proceedings, and (4) 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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Company

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

	Three Months Ended March 31, (unaudited)	
	2013	2012
Grant revenue	\$ 72	\$ –
Operating expenses: ⁽¹⁾		
Research and development	8,472	4,533
Selling, general and administrative	4,220	2,047
Total expenses	<u>12,692</u>	<u>6,580</u>
Operating loss	(12,620)	(6,580)
Change in fair value of common stock warrant liability	162	(3,434)
Other income / (expense), net	(177)	(2)
Net loss	<u>\$ (12,635)</u>	<u>\$ (10,016)</u>
Net loss per common share	<u>\$ (0.29)</u>	<u>\$ (0.37)</u>
Weighted avg. common shares outstanding	43,657	27,162

(1) Includes non-cash charges for depreciation and stock-based compensation the three months ended March 31, 2013 and 2012 of \$0.6 million (\$0.4 million in R&D and \$0.2 million in SG&A) and \$0.7 million (\$0.4 million in R&D and \$0.3 million in SG&A), respectively.

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

	March 31, 2013 (Unaudited)	December 31, 2012
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 26,370	\$ 26,892
Inventory	–	195
Prepaid expenses and other current assets	621	719
Total current assets	<u>26,991</u>	<u>27,806</u>
Property and equipment, net	1,660	1,737
Restricted cash and other assets	511	400
Total Assets	<u>\$ 29,162</u>	<u>\$ 29,943</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,825	\$ 1,166
Accrued expenses	4,974	4,159
Common stock warrant liability	6,143	6,305
Equipment loan and capitalized leases, current portion	70	69
Total Current Liabilities	<u>13,012</u>	<u>11,699</u>
Long-Term Liabilities:		
Long-term debt, net of discount of \$3.9 million in 2013 and \$0 in 2012, respectively	6,083	–
Equipment loan, non-current portion & other liabilities	610	591
Total Liabilities	<u>19,705</u>	<u>12,290</u>
Stockholders' Equity:		
Total Liabilities and Stockholders' Equity	<u>\$ 29,162</u>	<u>\$ 29,943</u>