
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 8, 2014

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 8, 2014, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended March 31, 2014, and providing a business update. 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, 2014 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 8, 2014, the Company issued a press release highlighting the results of operations for the quarter ended March 31, 2014 and providing an update on its development programs. For the first quarter of 2014, the Company anticipates operating cash outflows of approximately \$11 million, before taking into account any financing activities. The press release also provides certain program updates relating to SURFAXIN®(lucinactant) and the Company’s AEROSURF® phase 2 clinical program.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated May 8, 2014

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 , cash flows, future revenues, the timing of planned clinical trials 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. Any forward-looking statement made by us in this Current Report on Form 8-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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: President and Chief Executive Officer

Date: May 8, 2014



Discovery Labs Reports First Quarter 2014 Financial Results

WARRINGTON, PA — May 8, 2014 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today announced financial results for the first quarter ended March 31, 2014, as well as recent business updates. The Company will host a conference call today, May 8, 2014 at 9:00 AM ET.

Key highlights include:

- Reported an operating loss of \$10.8 million and net cash outflows before financing activities of \$10.8 million for the first quarter of 2014;
- Ended the first quarter of 2014 with cash and cash equivalents of \$75.9 million;
- Received Notices of Allowance for two patents, each covering composition of matter and methods of manufacturing for lyophilized KL4 surfactant, central to AEROSURF® program;
- Remained on track to announce in the third quarter of 2014 the results from the AEROSURF® phase 2a clinical study assessing the safety and tolerability of aerosolized KL4 surfactant in premature infants 29 to 32 weeks gestational age receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS); and
- Advanced the launch of SURFAXIN® (lucinactant), focusing on achieving formulary acceptance at key hospitals representing centers of excellence that convey regional and national influence.

“The first quarter of 2014 was important as we began to position our products and programs to transform the management of neonates with respiratory distress syndrome, or RDS,” commented John G. Cooper, President and Chief Executive Officer at Discovery Labs. “We completed our first full quarter of the SURFAXIN launch, and consistent with our measured approach, we are communicating to hospitals the attributes of a scientifically engineered, synthetic KL4 surfactant product – the only approved alternative to the animal-derived surfactants that have been used for the past decade to manage RDS. We also expect to announce the first clinical data in the third quarter of 2014 from our ongoing phase 2a clinical trial for AEROSURF, a product opportunity that could generate a significant paradigm shift in the management of infants at risk for RDS. As we introduce our RDS portfolio based on our synthetic KL4 technology, we are developing important relationships in key centers of influence across the U.S. as part of our efforts to improve the standard of care for infants born at risk of this condition.”

Summary Financial Results for the First Quarter Ended March 31, 2014

The Company reported a net loss of \$11.5 million (\$0.14 per share) on 84.7 million weighted-average common shares outstanding for the quarter ended March 31, 2014, compared to a net loss of \$12.6 million (\$0.29 per share) on 43.7 million weighted-average common shares outstanding for the comparable period in 2013. 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 \$0.4 million and \$0.2 million for the quarters ended March 31, 2014 and 2013, respectively.

For the quarter ended March 31, 2014, the Company reported an operating loss of \$10.8 million compared to \$12.6 million for the comparable period in 2013. For the first quarter of 2014, the Company recognized \$28,000 in revenue for sales of SURFAXIN. The Company currently uses the sell-through method for revenue recognition, which means revenue is deferred until its specialty distributor ships product to a hospital and all revenue recognition criteria are met. The decrease in the operating loss compared to the first quarter of 2013 is due to investments in 2013 associated with the capillary aerosol generator (CAG) and the technology transfer of the Company’s lyophilized KL4 surfactant manufacturing process to a contract manufacturing organization (CMO) to support the AEROSURF phase 2 program.

Other income / expense for the quarter ended March 31, 2014 was \$1.1 million and represents interest expense related to long-term debt. Of the \$1.1 million, \$0.6 million is cash interest expense and \$0.5 million is non-cash amortization of the debt discount.

Net cash outflows before financing activities for the quarter ended March 31, 2014 were \$10.8 million. As of March 31, 2014, the Company had cash and cash equivalents of \$75.9 million. For the second quarter of 2014, the Company anticipates operating cash outflows before financing activities of approximately \$11 million.

As of March 31, 2014, the Company had \$30 million of long-term debt with principal payable in three equal annual installments beginning in 2017 subject to a one year deferral of the amounts due in each of 2017 and 2018 if certain financial milestones are achieved.

As of March 31, 2014, the Company reported a common stock warrant liability of \$4.7 million, predominantly 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 Company had 85.1 million and 84.6 million shares of common stock outstanding as of March 31, 2014 and December 31, 2013, respectively.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 to be filed with the Securities and Exchange Commission on or before May 12, 2014, 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 Audio Webcast Details

The Company will host a live teleconference and webcast at 9:00 a.m. Eastern Time today. During the conference call, Discovery Labs' management will discuss the 2014 first quarter financial results along with other business updates.

The press release and the live webcast of the conference call will be available via Discovery Labs' corporate website at www.discoverylabs.com. The webcast will be made available on the events page. An audio archive will be available after the call at the same address until Thursday June 5, 2014

To participate in the live conference call, please dial (877) 870-4263 (domestic) and (412) 317-0790 (international). After placing the call, please use 10045704 as the passcode. The conference call replay number is (877) 344-7529 (domestic) or (412) 317-0088 (international) using the same conference call password listed above.

About SURFAXIN®

The U.S. Food and Drug Administration (FDA) approved SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants who are at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal derived surfactants.

IMPORTANT SAFETY INFORMATION

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 and 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.

About AEROSURF®

AEROSURF is a novel investigational drug-device combination product being developed to deliver Discovery Labs' KL4 surfactant in aerosolized form to premature infants with respiratory distress syndrome (RDS). AEROSURF could potentially allow for the administration of KL4 surfactant to premature infants without invasive endotracheal intubation, and may enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated. Discovery Labs has initiated a phase 2a clinical study to evaluate the safety and tolerability of aerosolized KL4 surfactant drug product administered in escalating inhaled doses in premature infants 29 to 32 weeks gestational age who are receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company focused on advancing a new standard in respiratory critical care. Discovery Labs' technology platform includes its novel proprietary KL4 surfactant, a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant, and its proprietary drug delivery technologies being developed to enable efficient delivery of aerosolized KL4 surfactant. 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, including AEROSURF, if approved, has the potential to become the new standard of care for RDS and, over time, enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated.

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 to access debt or equity financings, which could result in substantial equity dilution; risks related to development programs, including the AEROSURF development program, which may involve time-consuming and expensive pre-clinical studies and clinical trials that may be subject to potentially significant delays or regulatory holds, or fail; risks relating to efforts to commercialize SURFAXIN, 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; 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; and 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.

Contact Information:

John Tattory, Chief Financial Officer: 215.488.9418 or jtattory@discoverylabs.com

Will Roberts, Vice President, Corporate Communication and Investor Relations: 215.488.9489 or wroberts@discoverylabs.com

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

	Three Months Ended March 31, (unaudited)	
	2014	2013
Revenues:		
Product sales	\$ 28	\$ –
Grant revenue	3	72
	<u>31</u>	<u>72</u>
Operating expenses: ⁽¹⁾		
Cost of product sales	781	–
Research and development	5,590	8,472
Selling, general and administrative	4,423	4,220
Total expenses	<u>10,794</u>	<u>12,692</u>
Operating loss	(10,763)	(12,620)
Change in fair value of common stock warrant liability ⁽¹⁾	378	162
Other income / (expense), net	(1,091)	(177)
Net loss	<u>\$ (11,476)</u>	<u>\$ (12,635)</u>
Net loss per common share	<u>\$ (0.14)</u>	<u>\$ (0.29)</u>
Weighted avg. common shares outstanding	84,728	43,657

- (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 months ended March 31, 2014 and 2013, the charges for depreciation and stock-based compensation were \$0.9 million (\$0.4 million in R&D and \$0.5 million in S,G&A) and \$0.6 million (\$0.4 million in R&D and \$0.2 million in S,G&A), respectively.

Discovery Laboratories, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except per share data)

	March 31, 2014	December 31, 2013
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 75,942	\$ 86,283
Accounts receivable	–	67
Inventory	173	112
Prepaid expenses and other current assets	702	777
Total current assets	<u>76,817</u>	<u>87,239</u>
Property and equipment, net	2,007	1,656
Restricted cash	325	325
Other assets	349	97
Total Assets	<u>\$ 79,498</u>	<u>\$ 89,317</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payable and accrued expenses	\$ 6,304	\$ 6,218
Deferred revenue	85	139
Common stock warrant liability	4,672	5,425
Equipment loan and capitalized leases, current portion	74	73
Total Current Liabilities	<u>11,135</u>	<u>11,855</u>
Long-term debt, net of discount of \$11,207 at March 31, 2014 and \$11,646 at December 31, 2013	18,793	18,354
Equipment loans, non-current portion	49	69
Other liabilities	714	538
Stockholders' Equity	<u>48,807</u>	<u>58,501</u>
Total Liabilities and Stockholders' Equity	<u>\$ 79,498</u>	<u>\$ 89,317</u>