
**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**

March 13, 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 March 13, 2014, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the year and quarter ended December 31, 2013, 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 year and quarter ended December 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.

On March 13, 2014, the Company issued a press release highlighting the results of operations for the year and quarter ended December 31, 2013 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. In addition, the Company indicated that its previous short-term revenue guidance for 2014 no longer applies. SURFAXIN® drug product has been available commercially for only a brief period and interest in SURFAXIN among neonatologists is high; however, experience to date indicates that the cycle time required to have SURFAXIN reviewed by hospital committees, accepted on hospital formulary, purchased by the hospital pharmacy, and ultimately used in the neonatal intensive care unit (“NICU”) is considerably longer than the Company assumed in its previous guidance for 2014. The Company believes that, to effectively forecast revenue in the short term, it will require more actual experience with the SURFAXIN product cycle time. Until that time, the Company will not be in a position to provide informative short-term revenue guidance.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated March 13, 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, Chief Executive Officer and
Chief Financial Officer

Date: March 13, 2014



Discovery Labs Reports Fourth Quarter 2013 Financial Results

Conference Call Today, March 13, 2014 at 10:00 a.m. ET

WARRINGTON, PA — March 13, 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 fourth quarter ended December 31, 2013, as well as recent business updates. The Company will host a conference call today, March 13, 2014 at 10:00 AM ET. Conference call details are below.

Key highlights include:

- **Financial Update:** For the fourth quarter of 2013, the Company reported an operating loss of \$10.3 million and net cash outflows before financings of \$10.4 million. As of December 31, 2013, the Company had cash and cash equivalents of \$86.3 million. During the quarter, the Company received an advance of \$20 million under its secured loan with Deerfield Management Co., L.P. (Deerfield). As of December 31, 2013, the amount due Deerfield was \$30 million, payable in three equal annual installments beginning in 2017, subject to deferral of the first two payments if certain financial milestones are achieved.
- **SURFAXIN®:** In November, 2013, the Company initiated the U.S. commercial launch of SURFAXIN (lucinactant) Intratracheal Suspension for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first FDA-approved synthetic, peptide-containing surfactant and the only alternative to animal-derived surfactants available in the U.S.
- **AEROSURF®:** The Company currently is conducting its AEROSURF phase 2 clinical program beginning with a phase 2a clinical study. The phase 2a study is an open label, single-dose study with the primary goal of evaluating 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. Results from the phase 2a study are expected in the third quarter of 2014.

“The fourth quarter of 2013 marked the beginning of a potential transformation in the management of RDS in premature infants,” commented John G. Cooper, President and Chief Executive Officer at Discovery Labs. “We initiated the AEROSURF phase 2 clinical program, the first-ever with an aerosolized surfactant intended to support registration in the U.S. and potentially in other markets. AEROSURF has the potential to enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy without the need for invasive endotracheal intubation. In addition, we introduced SURFAXIN in the U.S., representing the first step in achieving our vision of advancing a new standard of care for premature infants with RDS.”

Summary Financial Results for the Fourth Quarter ended December 31, 2013

The Company reported a net loss of \$11.7 million (\$0.16 per share) on 73.1 million weighted-average common shares outstanding for the quarter ended December 31, 2013, compared to a net loss of \$6.8 million (\$0.16 per share) on 43.5 million weighted-average common shares outstanding for the comparable 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 expense of \$0.9 million and non-cash income of \$5.6 million for the quarters ended December 31, 2013 and 2012, respectively.

For the quarter ended December 31, 2013, the Company reported an operating loss of \$10.3 million compared to \$12.4 million for the comparable period in 2012. During the fourth quarter of 2013, the Company shipped approximately \$140,000 of SURFAXIN to its specialty distributor. 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. For the fourth quarter of 2013, all SURFAXIN sales have been deferred in accordance with the Company's revenue recognition policy. The operating loss in the fourth quarter of 2013 includes (i) investments to support the initiation of the AEROSURF Phase 2a clinical trial; and, (ii) costs associated with the initiation of the launch of SURFAXIN.

Other income / expense for the quarter end December 31, 2013 was \$0.6 million expense and represents interest related to the Deerfield loan. Of the \$0.6 million, \$0.4 million is cash interest expense and \$0.2 million is non-cash amortization of the debt discount.

Net cash outflows before financing activities for the quarter ended December 31, 2013 were \$10.4 million.

As of December 31, 2013, the Company had cash and cash equivalents of \$86.3 million. In November 2013, the Company completed a public offering of 28.75 million shares of common stock at a price of \$2.00 per share, resulting in net proceeds to the Company (after underwriting discount and expenses) of approximately \$54 million.

Additionally, with the commercial introduction of SURFAXIN, the Company became eligible under its \$30 million secured loan with Deerfield to receive the final \$20 million advance, which was received in December 2013. In connection with the \$20 million advance, Deerfield received a cash transaction fee equal to 1.5% of the advance and warrants to purchase approximately 4.7 million shares of common stock at an exercise price of \$2.81 per share. As of December 31, 2013, the Company had \$30 million of long-term debt due to Deerfield with principal payable in three equal annual installments beginning in February 2017, subject to deferral of the amounts due in 2017 and 2018 if certain financial milestones are achieved.

In October 2013, the Company initiated an offering under its at-the-market (ATM) program with Stifel, Nicolaus & Company, Incorporated and issued 713,920 shares of common stock at an average price per share of \$2.75, resulting in net proceeds (after a 3% commission) of approximately \$1.8 million. Following this offering, approximately \$23.0 million remains available under the Company's ATM program.

For the first quarter of 2014, the Company anticipates operating cash outflows before financing activities of approximately \$11 million.

As of December 31, 2013, the Company reported a common stock warrant liability of \$5.4 million, predominantly related to five-year warrants issued in February 2011. These warrants are not subject to cash settlement; however, they 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 84.6 million and 43.7 million shares of common stock outstanding as of December 31, 2013 and 2012, respectively.

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 Annual Report on Form 10-K for the year ended December 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.

Conference Call and Audio 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 and participate in the question-and-answer session, the number for domestic callers is (877) 870-4263 and for international callers (412) 317-0790. The conference call passcode is 10041838. The conference call replay number is (877) 344-7529 or (412) 317-0088 using the same conference call password listed above.

The live audio webcast of the conference call will be available at <http://bit.ly/1ctWW8L> and on the Discovery Labs website at www.discoverylabs.com. It is recommended that participants log onto the audio webcast at least 15 minutes prior to the call. A replay of the audio webcast will be available after the call at the Company's website.

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.

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 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, 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 in particular the AEROSURF development program, including time-consuming and expensive pre-clinical studies and clinical trials, which 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:

Company

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Investor Relations

Michael Rice, LifeSci Advisors: 646.597.6979 or mrice@lifesciadvisors.com

Condensed Consolidated Statement of Operations

(in thousands, except per share data)

	Three Months Ended December 31, (unaudited)		Twelve Months Ended December 31 (unaudited)	
	2013	2012	2013	2012
Grant revenue	\$ 74	\$ 195	\$ 388	\$ 195
Operating expenses: ⁽¹⁾				
Cost of product sales	517	–	517	–
Research and development	5,752	6,088	27,661	21,570
Selling, general and administrative	4,070	6,532	16,718	16,444
Total expenses	<u>10,339</u>	<u>12,620</u>	<u>44,896</u>	<u>38,014</u>
Operating loss	(10,265)	(12,425)	(44,508)	(37,819)
Change in fair value of common stock warrant liability ⁽¹⁾	(867)	5,618	761	555
Other income / (expense), net	<u>(597)</u>	<u>(8)</u>	<u>(1,468)</u>	<u>(51)</u>
Net loss	<u>\$ (11,729)</u>	<u>\$ (6,815)</u>	<u>\$ (45,215)</u>	<u>\$ (37,315)</u>
Net loss per common share	\$ (0.16)	\$ (0.16)	\$ (0.82)	\$ (0.95)
Weighted avg. common shares outstanding	73,129	43,521	55,258	39,396

(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 twelve months ended December 31, 2013, the charges for depreciation and stock-based compensation were \$0.8 million (\$0.4 million in R&D and \$0.4 in S,G&A) and \$2.9 million (\$1.4 million in R&D and \$1.5 million in S,G&A), respectively. For the three and twelve months ended December 31, 2012, the charges for depreciation and stock-based compensation were \$1.1 million (\$0.1 million in R&D and \$1.0 million in S,G&A) and \$2.4 million (\$0.5 million in R&D and \$1.9 million in S,G&A), respectively. Included in non-cash charges for the three and twelve months ended December 31, 2012 are one-time charges of \$0.8 million associated with stock based compensation modification charges related to the severance agreement with its former CEO.

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2013	December 31, 2012
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 86,283	\$ 26,892
Accounts receivable	67	–
Inventory, net	112	195
Prepaid expenses and other current assets	777	719
Total current assets	87,239	27,806
Property and equipment, net	1,656	1,737
Restricted cash	325	400
Other assets	97	–
Total Assets	\$ 89,317	\$ 29,943
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,433	\$ 1,166
Accrued expenses	4,785	4,159
Deferred revenue	139	–
Common stock warrant liability	5,425	6,305
Equipment loan and capitalized leases, current portion	73	69
Total Current Liabilities	11,855	11,699
Long-term debt, net of discount of \$11,646 at December 31, 2013 and \$0 at December 31, 2012	18,354	–
Equipment loans, non-current portion	69	148
Other liabilities	538	443
Stockholders' Equity	58,501	17,653
Total Liabilities and Stockholders' Equity	\$ 89,317	\$ 29,943