
UNITED STATES
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 17, 2015

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 16, 2015, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended December 31, 2014, and providing key financial and business updates. 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 December 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 March 16, 2015, the Company issued a press release highlighting the results of operations for the quarter ended December 31, 2014, and providing an update on its development programs. For the fourth 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 updates relating to the commercialization of 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 March 16, 2015

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.



Discovery Labs Reports Fourth Quarter 2014 Financial Results and Provides Update on SURFAXIN® (lucinactant) Intratracheal Suspension and AEROSURF® Program

WARRINGTON, PA — **March 16, 2015** — 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, 2014, as well as recent business updates. The Company will host a conference call on Tuesday March 17, 2015 at 8:30 AM ET. Conference call details are below.

Key Financial and Business Updates

The Company reported a net loss of \$10.6 million (\$0.12 per basic share) on 85.4 million weighted-average common shares outstanding for the quarter ended December 31, 2014, compared to a net loss of \$11.7 million (\$0.16 per basic share) on 73.1 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 \$1.8 million and non-cash expense of \$0.9 million for the quarters ended December 31, 2014 and 2013, respectively. For the quarter ended December 31, 2014, the Company reported an operating loss of \$11.2 million compared to \$10.3 million for the comparable period in 2013.

Net cash outflows for the quarter ended December 31, 2014 were \$10.2 million. As of December 31, 2014, the Company had cash and cash equivalents of \$44.7 million.

The Company is planning to restructure its business to focus on the development of aerosolized KL4 surfactant for respiratory diseases beginning with AEROSURF® for respiratory distress syndrome (RDS) in premature infants. With respect to SURFAXIN® (lucinactant) intratracheal suspension, the Company has made significant cash investments to support manufacturing, quality systems, supply chain and distribution, marketing, medical and commercial activities. In 2014, cash outflows in support of such operating activities for SURFAXIN were approximately \$19.0 million. The Company now believes that more of its capital and resources than previously anticipated would have to be allocated to SURFAXIN to achieve broad market acceptance within an acceptable period. Therefore, the Company is actively pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN. The preferred alternative would be a potential strategic alliance or collaboration arrangement, but if an alliance or collaboration arrangement cannot be implemented promptly, the Company would plan to cease the commercialization of SURFAXIN.

Enrollment in the ongoing AEROSURF phase 2a open label trial in 29 to 34 week GA infants (n=48) with respiratory distress syndrome (RDS) is proceeding in the third and final dose group. Enrollment in this phase 2a study is expected to be completed by the end of the first quarter of 2015 or early second quarter of 2015 with results communicated shortly thereafter. The goal of this study is to assess: (1) the safety and tolerability of AEROSURF, (2) physiological evidence of delivery of aerosolized KL4 surfactant in the lung, and (3) performance of the Company's proprietary aerosolization technology. Based on results to date in safety and tolerability, evidence suggesting delivery of surfactant to the lung, and performance of the aerosolization technology, the Company has initiated work to prepare to advance to the next phase of clinical evaluation to include 26 to 28 week GA infants, and has initiated startup activities, site selection and investments in devices and infrastructure to prepare for the planned phase 2b study in 26 to 32 week GA infants. The phase 2b study is expected to be a multicenter trial conducted in select medical centers both within and outside the U.S. The primary objective of this trial will be to determine the optimal dose(s) and define the expected efficacy margin. The Company expects the phase 2b study to conclude in 2Q 2016.

“Although we continue to believe that SURFAXIN has the potential to become the market-leading surfactant, we believe our existing capital is best used for the development of AEROSURF, which has the potential to revolutionize the management of RDS and generate the greatest value for our stakeholders,” commented John G. Cooper, Discovery Labs’ President and Chief Executive Officer. “If successful with AEROSURF, we believe that we may be able to develop a pipeline of other aerosolized KL₄ surfactant products, potentially to address other respiratory diseases where there are currently significant unmet medical needs.”

Select Additional Financial Results for the Fourth Quarter ended December 31, 2014

During the fourth quarter of 2014, the Company recognized \$1.0 million in grant revenue - \$0.7 million of a \$1.0 million award under a Small Business Innovation Research (SBIR) Grant from the National Institutes of Health (NIH) for up to \$3.0 million to support the development of the Company’s aerosolized KL₄ surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury, and \$0.3 million under a \$1.9 million Fast Track SBIR Grant from the NIH to support for the ongoing AEROSURF phase 2a clinical trial. Additionally, for the fourth quarter of 2014, the Company recognized \$136,000 in revenue for sales of SURFAXIN, compared to \$106,000 in recognized revenue in the third quarter of 2014.

Operating expenses for the fourth quarter ended December 31, 2014 were \$12.4 million. Approximately \$4.5 million of this amount were expenditures to support manufacturing, quality, medical affairs and commercialization activities to support SURFAXIN. Included in research and development costs were: (1) activities to conduct our AEROSURF phase 2a clinical program and manufacture of capillary aerosol generator (CAG) devices and related components for preparation for the AEROSURF phase 2b clinical program; (2) investments associated with the Battelle collaboration to prepare our CAG and related aerosol technologies for AEROSURF phase 3 studies and, if successful, commercialization; (3) investments in clinical, medical, and aerosolization device expertise to manage the AEROSURF clinical program and pipeline development; and (4) activities to support the NIH-funded study using aerosolized KL₄ surfactant in radiation-induced lung injury.

Other expense for the quarter ended December 31, 2014 was \$1.2 million which represents interest expense related to long-term debt. Of the \$1.2 million, \$0.7 million is cash interest expense and \$0.5 million is non-cash amortization of the debt discount.

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

As of December 31, 2014, the Company reported common stock warrant liability of \$1.3 million, related to five-year warrants issued in February 2011. These warrants are not subject to cash settlement, but 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 85.6 million and 84.6 million shares of common stock outstanding as of December 31, 2014 and December 31, 2013, 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 quarter and year ended December 31, 2014 filed with the Securities and Exchange Commission on March 16, 2015, which include discussions about 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 8:30 a.m. Eastern Time on Tuesday March 17, 2015. During the conference call, Discovery Labs' management will discuss the 2014 fourth 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 archive will be available after the call at the same address until Tuesday March 31, 2015.

To participate in the live conference call, please dial (888) 346-0767 (domestic) or (412) 902-4251 (international). After placing the call, please ask to be joined into the Discovery Labs conference call. The conference call replay number is (877) 344-7529 (domestic) or (412) 317-0088 (international); please use 10061701 as the replay passcode.

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 currently are not treated. Discovery Labs is conducting a phase 2a clinical trial to evaluate the safety and tolerability of aerosolized KL4 surfactant drug product administered in escalating inhaled doses in premature infants 29 to 34 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. SURFAXIN® (lucinactant) Intratracheal Suspension, Discovery Labs' first synthetic KL4 surfactant, is the only available non-animal derived surfactant approved by the U.S. Food and Drug Administration (FDA). Full prescribing information can be found at <http://www.surfaxin.com>.

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: the risk that Discovery Labs may be unable in the near term to secure on acceptable terms, or at all, a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., which would require Discovery Labs to negotiate a lease extension for its manufacturing facility in Totowa, NJ (Totowa Facility) and may require it to seek consent under a secured loan (Deerfield Loan) from affiliates of Deerfield Management Company, L.P. In such event, Discovery Labs would be exposed to risks associated with ceasing its commercialization activities for SURFAXIN and termination of manufacturing activities at the Totowa Facility; 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 Discovery Labs' development programs, including in particular the AEROSURF development program, with time-consuming and expensive pre-clinical studies and clinical trials, which may be subject to potentially significant delays or regulatory holds, or fail; 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, 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:

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

	Three Months Ended December 31, (unaudited)		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Revenues:				
Product sales	\$ 136	\$ –	\$ 312	\$ –
Grant revenue	1,048	74	2,523	388
Total Revenue	1,184	74	2,835	388
Operating expenses: (1)				
Cost of product sales	902	517	2,671	517
Research and development	7,771	5,752	26,690	27,661
Selling, general and administrative	3,737	4,070	16,732	16,718
Total expenses	12,410	10,339	46,093	44,896
Operating loss	(11,226)	(10,265)	(43,258)	(44,508)
Change in fair value of common stock warrant liability (1)	1,792	(867)	3,791	761
Other income/(expense), net	(1,201)	(597)	(4,591)	(1,468)
Net loss	\$ (10,635)	\$ (11,729)	\$ (44,058)	\$ (45,215)
Net loss per common share:				
Basic	\$ (0.12)	\$ (0.16)	\$ (0.52)	\$ (0.82)
Diluted	\$ (0.15)	\$ (0.16)	\$ (0.56)	\$ (0.82)
Weighted avg. common shares outstanding:				
Basic	85,358	73,129	85,095	55,258
Diluted	85,560	73,129	86,025	55,258

(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 both of the three months ended December 31, 2014 and 2013, the charges for depreciation and stock-based compensation were \$0.8 million (\$0.4 million in R&D and \$0.4 million in S,G&A). For the twelve months ended December 31, 2014 and 2013, the charges for depreciation and stock-based compensation were \$3.7 million (\$1.8 million in R&D and \$1.9 million in S,G&A) and \$2.9 million (\$1.4 million in R&D and \$1.5 million in S,G&A), respectively.

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

	December 31, 2014	December 31, 2013
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 44,711	\$ 86,283
Accounts receivable	–	67
Inventory	27	112
Prepaid expenses and other current assets	821	777
Total current assets	45,559	87,239
Property and equipment, net	1,637	1,656
Restricted cash	225	325
Other assets	78	97
Total Assets	\$ 47,499	\$ 89,317
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable and accrued liabilities	\$ 6,466	\$ 6,218
Deferred revenue	43	139
Common stock warrant liability	1,258	5,425
Equipment loans, current portion	62	73
Total Current Liabilities	7,829	11,855
Long-Term Liabilities:		
Long-term debt, net of discount of \$9,698 and \$11,646 at December 31, 2014 and 2013, respectively	20,302	18,354
Equipment loan, non-current portion	–	69
Other liabilities	169	538
Total Liabilities	28,300	30,816
Stockholders' Equity:		
Total Liabilities and Stockholders' Equity	\$ 47,499	\$ 89,317

