
**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**

November 6, 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 November 6, 2014, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended September 30, 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 September 30, 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 November 6, 2014, the Company issued a press release highlighting the results of operations for the quarter ended September 30, 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 program updates relating to SURFAXIN®(lucinactant) and the Company’s AEROSURF® phase 2 clinical program.

AEROSURF clinical program update:

The Company is conducting a phase 2a clinical trial, which 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 42 premature infants 29 to 34 weeks gestational age (GA) who are receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone. In addition, the Company hopes to demonstrate that drug is being effectively delivered into the lungs. If safety and tolerability are demonstrated in the phase 2a clinical trial, the Company will be able to proceed with a phase 2b clinical trial. The design of the phase 2b clinical trial will be informed by the results of the phase 2a clinical trial. The primary objective of the phase 2b trial will be to determine the optimal dose and estimate the expected efficacy margin for the planned phase 3 clinical trial focused on safety and efficacy.

The Company is conducting the phase 2a clinical trial at four sites and is currently in the second half of the planned enrollment. The rates of enrollment have been slower than expected. The Company has implemented preparatory activities for the planned phase 2b clinical trial and, through this process, has identified four new clinical sites that will begin enrolling patients in the phase 2a clinical trial beginning in November 2014. The Company expects that these eight sites, based on their experience and knowledge of AEROSURF from the phase 2a program, will be positioned to be transitioned to the next phase of the clinical program.

The AEROSURF phase 2a clinical trial is an open-label study, which has allowed the Company visibility into selected outcomes of premature infants participating in the trial. These observations are not predictors of the trial results and may not continue to be accurate for the duration of the trial. The Company’s novel capillary aerosol generator (CAG) has performed well in the clinic thus far. Clinically, the infants appear to be tolerating the aerosol well and the clinicians using the CAG report a positive experience and remain enthusiastic about the study. Additionally, they have observed that some infants after treatment with AEROSURF are showing evidence that suggests aerosolized KL4 surfactant is getting into the lung. In both treatment groups we have observed known complications of prematurity expected in this patient population. We have seen numerically more pneumothoraces in the AEROSURF treated group, at a rate within the range reported for this population in the medical literature. Otherwise, the adverse event profile of the AEROSURF-treated group is comparable to the control group. These data have been reviewed with our medical advisors, expert consultants and Safety Review Committee members, and they will continue to do so as the trial proceeds.

Based upon the Company's most recent assessment of the clinical trial plan, the Company now anticipates completion of the phase 2a clinical trial in the first quarter of 2015, and completion of the phase 2b clinical trial in the first half of 2016.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated November 6, 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: November 6, 2014



Discovery Labs Reports Third Quarter 2014 Financial Results

WARRINGTON, PA — November 6, 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 third quarter ended September 30, 2014, as well as recent business updates. The Company will host a conference call today, November 6, 2014 at 9:00 AM ET to discuss the 2014 third quarter financial results and other business updates.

Financial update

- Reported an operating loss of \$10.3 million and net cash outflows before financing activities of \$10.6 million for the third quarter of 2014;
- Ended the third quarter of 2014 with cash and cash equivalents of \$54.9 million; and
- Awarded \$1.0 million of a Phase II Small Business Innovation Research (SBIR) Grant valued at up to \$3.0 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the development of aerosolized KL₄ surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury.

SURFAXIN® (lucinactant) Intratracheal Suspension: SURFAXIN is the liquid instillate dosage form of the Company's novel KL₄ surfactant and is the first FDA-approved synthetic, peptide-containing alternative to animal-derived surfactants. Currently, the Company is focused on securing formulary acceptance with hospitals that it considers to be influential centers of influence with strong reputations in the neonatal community, as well as affiliated and regional hospitals. The Company achieved formulary acceptance or restricted use allowance in 17 neonatal critical care facilities as of the end of the third quarter, compared to 13 as of the end of the second quarter.

AEROSURF®: AEROSURF, the Company's novel investigational drug-device combination product being developed to deliver aerosolized KL₄ surfactant to premature infants with respiratory distress syndrome (RDS), addresses a significant unmet medical need. The phase 2 clinical program consists of an ongoing phase 2a trial designed to assess safety and tolerability of aerosolized KL₄ surfactant delivered through continuous positive airway pressure (nCPAP), and a planned phase 2b trial intended to determine the optimal dose and define the expected efficacy margin for a phase 3 clinical program. Based upon the Company's most recent assessment of the clinical trial plan, the Company now anticipates phase 2a data in the first quarter of 2015.

Strategic Collaboration: In October, the Company entered into a strategic collaboration with Battelle Memorial Institute (Battelle) intended to advance the design of its capillary aerosol generator (CAG) and related components (the AEROSURF System) for use in the planned phase 3 clinical program and, if approved, potential commercial activities. The collaboration combines Battelle's world-class capabilities in aerosol drug delivery device development with Discovery Labs' expertise in synthetic surfactant technology and neonatal RDS. Battelle and the Company generally will share equally in the agreed costs of the device development for the AEROSURF System; Battelle received 1.5 million warrants to purchase the Company's common stock at an exercise price of \$5.00, exercisable upon the achievement of certain milestones and, if the project is successful, will be entitled to future royalties on AEROSURF sales and license sales revenues.

“For decades, there have been no alternatives to animal derived surfactants and limited therapeutic advancements in the management of premature infants born at risk of RDS,” commented John G. Cooper, President and Chief Executive Officer at Discovery Labs. “We believe that our proprietary synthetic KL4 surfactant represents the future of surfactant therapy, beginning with SURFAXIN, which enables us to begin building relationships with key hospitals in the U.S. Our AEROSURF development program represents our commitment to further innovation for the NICU, and has the potential to transform the way neonatologists manage these fragile infants.”

Summary Financial Results for the Third Quarter Ended September 30, 2014

The Company reported a net loss of \$11.3 million (\$0.13 per basic share) on 85.2 million weighted-average common shares outstanding for the quarter ended September 30, 2014, compared to a net loss of \$12.2 million (\$0.22 per basic share) on 54.8 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 \$0.2 million and non-cash expense of \$1.1 million for the quarters ended September 30, 2014 and 2013, respectively.

For the quarter ended September 30, 2014, the Company reported an operating loss of \$10.3 million compared to \$10.8 million for the comparable period in 2013.

During the third quarter of 2014, sales of SURFAXIN to the Company’s specialty distributor were approximately \$219,000, compared to \$114,000 in the second quarter of 2014. Demand sales into hospitals grew approximately 60 percent during the third quarter to \$116,000, compared to \$72,000 in the second quarter of 2014. In accordance with the Company’s revenue recognition policy, for the third quarter of 2014, the Company recognized \$106,000 in revenue for sales of SURFAXIN, compared to \$42,000 in recognized revenue in the second quarter of 2014. The Company also recognized \$0.4 million in grant revenue under a \$1.9 million Fast Track SBIR Grant from the NIH to provide support for the ongoing phase 2a clinical trial for AEROSURF. The remaining \$0.4 million available under the grant is expected to be received by the end of 2014.

Operating expenses for the third quarter ended September 30, 2014 and 2013 were \$10.9 million. Key investments in the third quarter of 2014 were to support ongoing conduct of the AEROSURF phase 2a clinical study and the initial manufacturing of clinic-ready CAG devices for the planned AEROSURF phase 2b clinical study. Key investments in the third quarter of 2013 were related to activities in preparation for the AEROSURF phase 2a clinical study including development of our clinic-ready CAG and developing our lyophilized KL4 surfactant manufacturing process at our contract manufacturer.

Other expense for the quarter ended September 30, 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.

Net cash outflows before financing activities for the quarter ended September 30, 2014 were \$10.6 million.

As of September 30, 2014, the Company had cash and cash equivalents of \$54.9 million. For the fourth quarter of 2014, the Company anticipates operating cash outflows before financing activities of approximately \$11 million.

As of September 30, 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 September 30, 2014, the Company reported a common stock warrant liability of \$3.0 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 85.3 million and 84.6 million shares of common stock outstanding as of September 30, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 to be filed with the Securities and Exchange Commission on or before November 10, 2014, which includes further detail on the above-referenced transactions, including an update on the Company's AEROSURF clinical program, 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 third 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 Thursday November 20, 2014.

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 10054486 as the replay passcode.

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 KL4 surfactant-based product, is the only available synthetic alternative to animal derived surfactants 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: risks that Discovery Labs will be unable to secure significant additional capital as needed, or to access debt or equity financings, which could result in substantial equity dilution, 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.; risks related to the AEROSURF and other development programs, 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 SURFAXIN, (2) whether SURFAXIN will be approved by hospitals and will gain market acceptance and be preferred by healthcare providers over current products, and (3) whether SURFAXIN will generate revenues sufficient to fund Discovery Labs' research and development activities, pay its debt, and support its operations, and (4) whether Discovery Labs will be successful in implementing its long-term manufacturing strategy to assure continuity of SURFAXIN commercial drug product supply, which may affect its ability to maintain sufficient supplies of SURFAXIN commercial drug product; 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, (4) other companies' competing products, (5) legal proceedings, and (6) 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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Will Roberts, Vice President, Investor Relations and Corporate Communication: 215.488.9489 or wroberts@discoverylabs.com

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

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2014	2013	2014	2013
Revenues:				
Product sales	\$ 106	\$ –	\$ 176	\$ –
Grant revenue	421	60	1,475	315
Total Revenue	527	60	1,651	315
Operating expenses: ⁽¹⁾				
Cost of product sales	257	–	1,769	–
Research and development	6,471	6,574	18,919	21,909
Selling, general and administrative	4,126	4,299	12,995	12,648
Total expenses	10,854	10,873	33,683	34,557
Operating loss	(10,327)	(10,813)	(32,032)	(34,242)
Change in fair value of common stock warrant liability ⁽¹⁾	173	(1,059)	1,999	1,627
Other income/(expense), net	(1,170)	(352)	(3,390)	(871)
Net loss	\$ (11,324)	\$ (12,224)	\$ (33,423)	\$ (33,486)
Net loss per common share:				
Basic	\$ (0.13)	\$ (0.22)	\$ (0.39)	\$ (0.68)
Diluted	\$ (0.13)	\$ (0.22)	\$ (0.41)	\$ (0.69)
Weighted avg. common shares outstanding:				
Basic	85,209	54,792	85,001	49,235
Diluted	85,209	54,792	86,121	50,377

(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 September 30, 2014 and 2013, the charges for depreciation and stock-based compensation were \$1.1 million (\$0.5 million in R&D and \$0.6 million in S,G&A) and \$0.8 million (\$0.4 million in R&D and \$0.4 million in S,G&A), respectively. For the nine months ended September 30, 2014 and 2013, the charges for depreciation and stock-based compensation were \$2.9 million (\$1.4 million in R&D and \$1.5 million in S,G&A) and \$2.1 million (\$1.1 million in R&D and \$1.0 million in S,G&A), respectively.

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

	September 30, 2014 (Unaudited)	December 31, 2013
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 54,915	86,283
Accounts receivable	22	67
Inventory	429	112
Prepaid expenses and other current assets	357	777
Total current assets	55,723	87,239
Property and equipment, net	1,772	1,656
Restricted cash	325	325
Other assets	489	97
Total Assets	58,309	89,317
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable and accrued liabilities	6,207	6,218
Deferred revenue	95	139
Common stock warrant liability	3,049	5,425
Equipment loans, current portion	76	73
Total Current Liabilities	9,427	11,855
Long-Term Liabilities:		
Long-term debt, net of discount of \$10,736 at June 30, 2014 and \$11,646 at December 31, 2013, respectively	19,768	18,354
Equipment loan, non-current portion	7	69
Other liabilities	142	538
Total Liabilities	29,344	30,816
Stockholders' Equity:	28,965	58,501
Total Liabilities and Stockholders' Equity	58,309	89,317

