
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

August 10, 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 August 10, 2015, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended June 30, 2015, 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 June 30, 2015 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.

The press release referred to in Item 2.02 also provides certain program updates relating to the Company’s AEROSURF® phase 2 clinical development program.

In addition, for the third quarter of 2015, the Company anticipates net cash outflows before financing activities of approximately \$9 million.

Subject to the note relating to the press release contained in Item 2.02 of this Current Report on Form 8-K, the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated August 10, 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 Provides Business Update and Reports Second Quarter 2015 Financial Results

WARRINGTON, PA – August 10, 2015 – Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company focused on developing aerosolized KL₄ surfactant therapies for respiratory diseases, today provided a corporate update, and announced financial results for the second quarter ended June 30, 2015. The Company will host a conference call Tuesday August 11, 2015 at 8:30 AM ET. Conference call details are below.

Key Highlights

In the second quarter of 2015, the Company implemented a plan to focus its resources on the development of its aerosolized KL₄ surfactant for respiratory diseases, beginning with AEROSURF[®] for respiratory distress syndrome (RDS) in premature infants. Updates on AEROSURF development include:

- Reported encouraging top-line data from the initial phase 2a clinical trial to assess safety and tolerability of a single exposure of aerosolized KL₄ surfactant administered in three escalating (15, 30 and 45 minutes) inhaled doses to premature infants 29 to 34 week gestational age (GA). All key objectives of the trial were met including establishment of proof of concept for the Company's technology platform based on physiological data suggesting that aerosolized KL₄ surfactant is being delivered into the lung of premature infants.
- Currently conducting a phase 2a expansion study in 32 premature infants to assess safety and tolerability of higher (60 and 90 minutes) and potentially repeat inhaled doses of aerosolized KL₄ surfactant administered to premature infants 29 to 34 week GA; enrollment of the 60 minute dose group is complete and enrollment of the 90 minute dose group is currently underway; the Company remains on-track to complete this trial in the fourth quarter of 2015.
- Enrollment is expected to begin in August 2015 in a 32 patient phase 2a clinical trial to assess safety and tolerability of escalating (30 and 45 minutes) and potentially repeat inhaled doses of aerosolized KL₄ surfactant administered to premature infants 26 to 28 week GA; completion of this trial is expected in the fourth quarter of 2015.
- The Company plans to initiate in the fourth quarter of 2015 a Phase 2b clinical trial in 200 to 250 premature infants 26 to 32 week GA, with a primary purpose to assess aerosolized KL₄ surfactant administered in two escalating doses, demonstrate evidence of efficacy on an acceptable endpoint, identify the dose regimen(s) to be used in the planned phase 3 clinical program and provide an estimate of the treatment effect (magnitude of benefit); completion of this trial is expected in mid-2016.

As of June 30, 2015, the Company had cash and cash equivalents of \$26.1 million. The Company strengthened its financial position and better aligned its obligations under its \$30 million loan with affiliates of Deerfield Management Company, L.P. (Deerfield) with anticipated AEROSURF development milestones:

- Recently completed a public offering of common stock, warrants and pre-funded warrants, resulting in net proceeds of approximately \$37.6 million, which includes \$5.0 million in non-cash consideration from Deerfield in satisfaction of future interest payments due under the Company's outstanding loan with Deerfield; the Company anticipates that its existing cash will be sufficient to support the AEROSURF phase 2 clinical program and fund operations through first quarter of 2017.
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Amended the \$30 million loan agreement with Deerfield by (i) prepaying \$5.0 million of the outstanding principal amount and (ii) adjusting the principal installments under the loan to eliminate the installment due in February 2017 and adjust the amounts due in each of February 2018 and February 2019 from \$10 million to \$12.5 million.

“The second quarter was a pivotal quarter for our Company as we implemented a new strategy to focus on the development of our aerosolized KL4 surfactant for respiratory diseases. We are encouraged by the results of our recent AEROSURF phase 2a data in premature infants with RDS, and we continue to advance our clinical development plan for this potentially transformative therapy for premature infants,” said John G. Cooper, Discovery Labs' President and Chief Executive Officer. “We anticipate important development milestones in 2015 and 2016.”

Select Financial Results for the Second Quarter ended June 30, 2015

During the second quarter of 2015, the Company recognized \$0.1 million in grant revenue under a previously announced award of \$1.0 million 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. In June 2015, the Company received a second \$1.0 million award under this grant. During the second quarter of 2014, we received and expended \$1.1 million under a \$1.9 million Fast Track Small Business Innovation Research (SBIR) grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the AEROSURF phase 2a clinical trial.

Operating expenses for the second quarter ended June 30, 2015 were \$10.5 million and included a \$2.0 million charge in connection with the plan the Company implemented in April 2015 to voluntarily cease the commercialization of SURFAXIN® (lucinactant) Intratracheal Suspension. Research and development costs included: (1) activities to conduct the Company's AEROSURF phase 2a clinical trial and manufacture capillary aerosol generator (CAG) devices and related components to prepare for the planned AEROSURF phase 2b clinical program; (2) the Company's 50% share of development costs under the collaboration with Battelle to prepare the CAG for a potential AEROSURF phase 3 clinical program and potential commercial activities; and (3) investments in clinical, medical, and aerosolization device expertise to support the AEROSURF clinical program and pipeline development.

The Company reported a net loss of \$11.3 million (\$0.13 per basic share) on 85.8 million weighted-average common shares outstanding for the quarter ended June 30, 2015, compared to a net loss of \$10.6 million (\$0.12 per basic share) on 85.1 million weighted average common shares outstanding for the comparable period in 2014.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 which was filed with the Securities and Exchange Commission on August 10, 2015, which includes discussion 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 August 11, 2015. During the conference call, Discovery Labs' management will discuss the 2015 second 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.

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 10070663 as the replay passcode.

About AEROSURF®

AEROSURF is a novel, investigational drug/device product that combines the Company's proprietary KL4 surfactant and its aerosolization technologies. AEROSURF is being developed to potentially reduce or eliminate the need for intubation and mechanical ventilation in the treatment of premature infants with respiratory distress syndrome (RDS). With AEROSURE, neonatologists may potentially administer aerosolized KL4 surfactant to premature infants supported by nasal continuous positive airway pressure (nCPAP), without subjecting them to invasive intubation and mechanical ventilation (each of which can result in serious respiratory conditions and other complications), which are currently required to administer surfactant therapy to premature infants. By enabling delivery of aerosolized KL4 surfactant using less invasive procedures, AEROSURE, if approved, has the potential to address a serious unmet medical need, provide transformative clinical and pharmacoeconomic benefits, and enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. If surfactant deficiency or degradation occurs, the air sacs in the lungs can collapse, resulting in severe respiratory diseases and disorders. Discovery Labs' technology platform includes a novel synthetic peptide-containing (KL4) surfactant, that is structurally similar to pulmonary surfactant, and proprietary drug delivery technologies being developed to enable efficient delivery of aerosolized KL4 surfactant. Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of aerosolized surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

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 are described in Discovery Labs' filings with the Securities and Exchange Commission (SEC) including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto, including the Quarterly Report on Form 10-Q that was filed with the SEC on August 10, 2015.

Contact Information:

John Tattory, Senior Vice President and Chief Financial Officer: 215.488.9418 or jtattory@discoverylabs.com

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

	Three Months Ended June 30, (unaudited)		Six Months Ended June 30, (unaudited)	
	2015	2014	2015	2014
Revenues:				
Product sales	\$ —	\$ 42	\$ 7	\$ 70
Grant revenue	75	1,051	259	1,054
	75	1,093	266	1,124
Operating expenses: (1)				
Cost of product sales	—	731	929	1,512
Research and development	7,129	6,858	14,211	12,448
Selling, general and administrative	3,383	4,446	6,736	8,869
Total expenses	10,512	12,035	21,876	22,829
Operating loss	(10,437)	(10,942)	(21,610)	(21,705)
Change in fair value of common stock warrant liability (1)	469	1,448	438	1,826
Other income / (expense), net	(1,358)	(1,129)	(2,333)	(2,220)
Net loss	\$ (11,326)	\$ (10,623)	\$ (23,505)	\$ (22,099)
Net loss per common share:				
Basic	\$ (0.13)	\$ (0.12)	\$ (0.27)	\$ (0.26)
Diluted	\$ (0.13)	\$ (0.14)	\$ (0.27)	\$ (0.28)
Weighted avg. common shares outstanding:				
Basic	85,753	85,061	85,671	84,766
Diluted	85,753	85,882	85,671	86,111

(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 June 30, 2015 and 2014, the charges for depreciation and stock-based compensation were \$0.5 million (\$0.3 million in R&D and \$0.2 million in S, G & A) and \$1.0 million (\$0.5 million in R&D and \$0.5 million in S, G & A), respectively. For the six months ended June 30, 2015 and 2014, the charges for depreciation and stock-based compensation were \$1.3 million (\$0.7 million in R&D and \$0.6 million in S, G & A) and \$1.8 million (\$0.9 million in R&D and \$0.9 million in S, G & A), respectively.

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

	June 30, 2015 (Unaudited)	December 31, 2014
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 26,091	\$ 44,711
Inventory	—	27
Prepaid expenses and other current assets	571	821
Total current assets	26,662	45,559
Property and equipment, net	1,245	1,637
Restricted cash	225	225
Other assets	68	78
Total Assets	\$ 28,200	\$ 47,499

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payable and accrued expenses	\$ 2,314	\$ 6,466
Deferred revenue	6,613	43
Common stock warrant liability	820	1,258
Equipment loans, current portion	21	62
Total current liabilities	9,768	7,829
Long-term debt, \$30,000 net of discount of \$8,549 at June 30, 2015 and \$9,698 at December 31, 2014	21,451	20,302
Other liabilities	59	169
Stockholders' Equity	(3,078)	19,199
Total Liabilities and Stockholders' Equity	\$ 28,200	\$ 47,499