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

November 5, 2015
Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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))

Item 2.02. Results of Operations and Financial Condition.

On November 5, 2015, Discovery Laboratories, Inc. (the "Company") issued a press release highlighting the results of operations for the quarter ended September 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 September 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.

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 November 5, 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 the Company in this Current Report on Form 8-K is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company 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 5, 2015

Exhibit 99.1

Discovery Labs Provides Business Update and Reports Third Quarter 2015 Financial Results

WARRINGTON, PA – November 5, 2015 – Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company focused on developing aerosolized KL_4 surfactant therapies for respiratory diseases, today provided a business update and financial results for the third quarter ended September 30, 2015.

Key Highlights

The Company continued to make progress in its AEROSURF® phase 2 clinical program:

- The Company recently completed enrollment in the phase 2a expansion trial in 32 premature infants 29 to 34 week gestational age (GA) receiving nasal continuous positive airway pressure (nCPAP) for RDS, the primary purpose of which was to assess safety and tolerability of higher doses of aerosolized KL_4 surfactant administered to two dose groups (60 and 90 minutes), compared to nCPAP alone.

  This trial expands upon the knowledge gained in the initial phase 2a clinical trial in 48 premature infants 29 to 34 week GA receiving nasal continuous positive airway pressure (nCPAP) for RDS, which assessed the safety and tolerability of a single exposure of aerosolized KL4 surfactant administered to three dose groups (15, 30 and 45 minutes), compared to nCPAP alone. All key objectives in the initial trial were met, including establishment of proof of concept based on physiological data suggesting that aerosolized KL_4 surfactant appears to be delivered into the lungs of premature infants.

  The Company has now completed its planned phase 2a clinical trials in premature infants 29 to 34 GA. The Company is finalizing its analysis of the expansion trial data and plans to release top-line results of the overall phase 2a clinical trials of premature infants 29 to 34 week GA and hold an investor conference call on November 12, 2015.

- The Company expects to initiate a phase 2b clinical trial in up to 250 premature infants 26 to 32 week GA in the fourth quarter of 2015. The trial is designed to evaluate premature infants receiving aerosolized KL_4 surfactant (including the ability for infants to receive repeat doses) compared to nCPAP alone. Two dose groups will be evaluated. The primary objective of the trial is to demonstrate evidence of efficacy and, if successful, inform the design of a phase 3 clinical program. The phase 2b trial will begin with enrollment of premature infants 29 to 32 week GA, followed by enrollment of premature infants 26 to 28 week GA after completion of the phase 2a trial in this age group. Enrollment for the phase 2b clinical trial is expected to be completed in mid – 2016.

- The Company has initiated a phase 2a clinical trial in 32 premature infants 26 to 28 week GA receiving nCPAP for RDS, the primary purpose of which is to assess safety and tolerability of aerosolized KL_4 surfactant (including the ability for infants to receive repeat doses) compared to nCPAP alone. Two dose groups will be evaluated (30 and 45 minutes). The Company anticipates releasing top-line results of this phase 2a trial in the first quarter of 2016.

John G. Cooper, Discovery Labs' President and Chief Executive Officer commented, “Our goal with AEROSURF is to provide neonatal medical practitioners with a means to administer aerosolized KL_4 surfactant without invasive endotracheal intubation and, if we are successful, potentially transform the management of premature infants with RDS. The continued advancement of the AEROSURF clinical program and the steps taken in the third quarter to strengthen the Company’s financial position represent important milestones towards achieving our goal.”

As of September 30, 2015, the Company had cash and cash equivalents of $46.3 million. During the third quarter of 2015, the Company strengthened its financial position as follows:

- In July 2015, entered into amendments to the $30 million loan agreement with affiliates of Deerfield Management Company, L.P. (Deerfield) to (i) prepay $5.0 million of the outstanding principal amount of the loan, and (ii) adjust the remaining principal installments under the loan to eliminate the amounts due in February 2017 and increase the amounts due in each of February 2018 and February 2019 from $10 million to $12.5 million. The Company believes these changes better align its payment obligations under the loan with anticipated AEROSURF development milestones.

- Also in July 2015, 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.

Select Financial Results for the Third Quarter ended September 30, 2015

For the quarter ended September 30, 2015, the Company reported an operating loss of $8.4 million compared to $10.3 million for the comparable period in 2014. Net cash outflows before financing activities for the quarter ended September 30, 2015 were $7.5 million.

During the third quarter of 2015, the Company recognized $0.1 million in grant revenue from 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 over a three-year period to support the development of the Company's aerosolized KL_4 surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. During the third quarter of 2014, we received $0.4 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 initial AEROSURF phase 2a clinical trial.

Operating expenses for the quarter ended September 30, 2015 were $8.5 million. Research and development costs of $6.5 million included: (1) activities to conduct the Company's AEROSURF phase 2a expansion 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.

The Company reported a net loss of $21.6 million ($0.20 per basic share) on 105.7 million weighted-average common shares outstanding for the quarter ended September 30, 2015, compared to a net loss of $11.3 million ($0.13 per basic share) on 85.2 million weighted average common shares outstanding for the comparable period in 2014.

As a result of the prepayment and restructuring of the Deerfield debt, the Company recognized an $11.8 million non-cash loss on extinguishment of debt and a non-cash write-off of previously capitalized debt discount costs of $0.7 million (classified as interest expense).

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 which is expected to be filed with the Securities and Exchange Commission on or before November 9, 2015, which includes discussion about the Company's business plans and operations, financial condition and results of operations.

About AEROSURF®

AEROSURF is a novel, investigational drug/device product that combines the Company's proprietary KL_4 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 AEROSURF, neonatologists may potentially administer aerosolized KL_4 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. AEROSURF, 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 include: risks related to Discovery Labs' AEROSURF development program and other development programs that we may undertake in the future, which may involve 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; 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 transactions (including strategic partnerships and other transactions) that would provide funding and support product development, regulatory and, if approved, commercialize our products, or to access debt or equity financings, which could result in substantial equity dilution; risks related to maintaining continued compliance with The Nasdaq Capital Market listing requirements; risks related to Discovery Labs' efforts to maintain and protect the patents and licenses related to its products; 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, Senior Vice President and Chief Financial Officer: 215.488.9418 or jtattory@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)	
	2015	2014	2015	2014
Revenues:				
Product sales	$ –	$ 106	$ 7	$ 176
Grant revenue	66	421	325	1,475
	66	527	332	1,651
Operating expenses: (1)				
Cost of product sales	–	257	929	1,769
Research and development	6,452	6,471	20,663	18,919
Selling, general and administrative	2,057	4,126	8,793	12,995
Total expenses	8,509	10,854	30,385	33,683
Operating loss	(8,443)	(10,327)	(30,053)	(32,032)
Change in fair value of common stock warrant liability (1)	139	173	577	1,999
Loss on debt extinguishment	(11,758)	–	(11,758)	–
Other income / (expense), net	(1,494)	(1,170)	(3,827)	(3,390)
Net loss	$ (21,556)	$ (11,324)	$ (45,061)	$ (33,423)
Net loss per common share:				
Basic	$ (0.20)	$ (0.13)	$ (0.49)	$ (0.39)
Diluted	$ (0.20)	$ (0.13)	$ (0.49)	$ (0.41)
Weighted avg. common shares outstanding:				
Basic	105,696	85,209	92,420	85,001
Diluted	105,696	85,209	92,420	86,121

(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, 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 $1.1 million ($0.5 million in R&D and $0.6 million in S,G & A), respectively. For the nine months ended September 30, 2015 and 2014, the charges for depreciation and stock-based compensation were $1.8 million ($1.0 million in R&D and $0.8 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 Sheets
(in thousands)

ASSETS	September 30, 2015 (Unaudited)	December 31, 2014
Current Assets:		
Cash and cash equivalents	$ 46,308	$ 44,711
Inventory	–	27
Prepaid interest, current portion	1,986	–
Prepaid expenses and other current assets	433	821
Total current assets	48,727	45,559
Property and equipment, net	1,186	1,637
Restricted cash	225	225
Prepaid interest, non-current portion	2,594	–
Other assets	–	78
Total Assets	$ 52,732	$ 47,499
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 9,289	$ 6,466
Deferred revenue	–	43
Common stock warrant liability	497	1,258
Equipment loans, current portion	–	62
Total current liabilities	9,786	7,829
Long-term debt, $25,000 at September 30, 2015 and $30,000 net of discount of $9,698 at December 31, 2014	25,000	20,302
Other liabilities	56	169
Stockholders' Equity	17,890	19,199
Total Liabilities and Stockholders' Equity	$ 52,732	$ 47,499