**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**

**May 14, 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 8.01. Other Events.**

On May 14, 2015, Discovery Laboratories, Inc. (the "Company") issued a press release announcing the top-line results of its AEROSURF® phase 2a clinical trial, the first in-human study for AEROSURF using the Company's proprietary aerosol delivery technologies, including its capillary aerosol generator (CAG). A slide presentation used in the call has been posted on the Company's website. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

During the conference call, the Company reviewed the objectives of the trial. The primary objective was to demonstrate the safety and tolerability of a single exposure of aerosolized KL4 surfactant administered in escalating inhaled doses to premature infants 29 to 34 week gestational age and receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone. A second objective was to establish proof of concept for the Company's proprietary technology platform based on physiological data suggesting that aerosolized KL4 surfactant is being delivered into the lung of premature infants and acceptable performance of the novel capillary aerosol generator (CAG) technology in the neonatal intensive care unit (NICU). Based on the safety and tolerability profile observed in the trial, the independent Safety Review Committee approved progressing to the next phases of the AEROSURF clinical development program.

The Company reviewed data from the trial related to gas exchange, which appear to suggest that, with AEROSURF, KL4 surfactant is being delivered to the lungs of premature infants with RDS and potentially improving gas exchange. In addition, an assessment of parameters related to the timing and frequency of the need for invasive rescue therapy suggest that a single dose of AEROSURF may delay the time to invasive rescue therapy. Based on this assessment, the Company plans to study whether multiple or increased doses of AEROSURF may have the potential to reduce the need for invasive rescue therapy. In summary, the physiological data assessed, the data related to gas exchange and the requirement for rescue therapy due to nCPAP failure appear to suggest that with AEROSURF, KL4 surfactant is being delivered into the lungs of premature infants with RDS. The Company also reported that the CAG performed as designed. There were no device failures during treatment and no device related adverse events, and the CAG was well accepted by NICU personnel at all study sites.

The Company outlined its plans for additional phase 2 clinical assessment, including a phase 2a dose expansion in 29 to 34 weeks gestational age infants to evaluate increased doses and repeat dosing, which is expected to begin in the second quarter of 2015 and be completed in the fourth quarter of 2015; a phase 2a clinical trial assessing the safety and tolerability of escalating doses of AEROSURF administered to 26 to 28 weeks gestational age infants, with an ability to administer repeat doses, which is expected to begin in July 2015 and be completed in the fourth quarter of 2015; and a phase 2b clinical trial to determine the optimal dose and define the expected efficacy margin of AEROSURF treatment, which is expected to begin in the fourth quarter of 2015 and be completed in mid 2016.

In addition, the Company reaffirms its forecast set forth in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as follows: before any additional financings the Company anticipates that it will have sufficient cash available to support the AEROSURF clinical program as outlined in this Current Report on Form 8-K, pay debt service and fund its operations through the first quarter of 2016.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits:

99.1 Press Release dated May 14, 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.

**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: May 14, 2015

**Exhibit 99.1**

**Discovery Labs Announces Results of Phase 2a Clinical Trial of AEROSURF®**

***Encouraging safety and physiological data suggest that aerosolized $KL_4$ surfactant can be delivered to the lung of premature infants with respiratory distress syndrome***

***Key study objectives achieved; Company advancing AEROSURF phase 2 clinical program***

**Warrington, PA, May 14, 2015 — Discovery Laboratories, Inc. (NASDAQ: DSCO),** a specialty biotechnology company focused on developing aerosolized $KL_4$ surfactant therapies for respiratory diseases, today reported top line data from its recently completed AEROSURF® phase 2a clinical trial in premature infants with respiratory distress syndrome (RDS). Key objectives of the study were achieved, including (1) the primary objective of demonstrating the safety and tolerability of a single exposure of aerosolized $KL_4$ surfactant administered in three escalating inhaled doses to premature infants 29 to 34 week gestational age and receiving nasal continuous positive airway pressure (nCPAP) for RDS, compared to infants receiving nCPAP alone, and (2) establishing proof of concept for the Company's proprietary technology platform based on physiological data suggesting that aerosolized $KL_4$ surfactant is being delivered into the lung of premature infants, and acceptable performance of the novel capillary aerosol generator (CAG) technology in the neonatal intensive care unit (NICU).

"The ability to administer surfactant without invasive endotracheal intubation in the management of premature infants with RDS would represent a significant medical advancement. We are encouraged by the results from this AEROSURF phase 2a clinical trial as it represents a positive indication that our technology has the potential to achieve this goal. While the trial was designed as a safety study and the number of patients was limited, the results suggest that the Company's combination drug/device product has the ability to deliver aerosolized $KL_4$ surfactant to the lungs of premature infants with RDS," commented Steve Simonson, M.D., Discovery Labs' Chief Development Officer. "These results will inform and improve the further development of our AEROSURF clinical program."

AEROSURF is Discovery Labs' combination drug/device product that combines the Company's novel synthetic peptide-containing ($KL_4$) surfactant and its proprietary aerosol delivery technologies, including the CAG, that are designed to enable efficient delivery of aerosolized $KL_4$ surfactant. Currently, the available surfactants (animal-derived) can only be administered using endotracheal intubation with mechanical ventilation, invasive procedures that may each result in serious complications and other respiratory conditions. With AEROSURF, neonatologists potentially will be able to administer aerosolized $KL_4$ surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation.

The AEROSURF phase 2a trial was a multi-center, open-label trial to evaluate safety and tolerability of a single dose of aerosolized $KL_4$ surfactant in premature infants 29 to 34 weeks gestational age who are receiving nCPAP for RDS ("AEROSURF group"; n = 24), compared to infants receiving nCPAP alone ("control group"; n=24). The study evaluated three escalating doses of AEROSURF.

***Discovery Labs' management will host a conference call and live webcast, with a slide presentation including data from the clinical trial, today at 8:00 a.m. Eastern time to review and discuss the results of the trial. See below for details of the call.***

**Safety and Tolerability**

Overall, the safety and tolerability profile of the AEROSURF group in this initial trial was generally comparable to the control group. All reported adverse events and serious adverse events were those that are common and expected among this fragile patient population. The most common adverse events observed included neonatal jaundice, constipation and apnea. The most common serious adverse event observed was pneumothorax, the incidence of which was comparable in the AEROSURF and control groups. The incidence of adverse events and serious adverse events in the AEROSURF and control groups were generally comparable and there was no pattern observed of increasing adverse events or serious adverse events with increasing doses of AEROSURF.

Regarding tolerability of AEROSURF administration, the patient interface was well tolerated in that there were no observed upper airway obstructions. Peri-dosing events, which are common in the administration of surfactants currently, were infrequent in the AEROSURF group.

Based on the safety and tolerability profile observed in this clinical trial, the independent Safety Review Committee approved progressing to the next phases of the AEROSURF clinical development program.

**Physiological Evaluation**

In exploratory analyses of certain safety and tolerability measures to assess whether a single dose of aerosolized $KL_4$ surfactant was being delivered to the lungs of premature infants and potentially having a physiological effect, measurements of gas exchange in the lungs and the timing of or need for endotracheal intubation and delayed (rescue) surfactant therapy due to nCPAP failure were evaluated in both the AEROSURF and control groups.

*Gas Exchange*

Gas exchange parameters were assessed as part of the safety and tolerability profile of AEROSURF. No safety signals were observed with respect to gas exchange. These parameters are physiological measurements that the Company also used to assess whether there is evidence of $KL_4$ surfactant being delivered to the lungs of premature infants.

The fraction of inspired oxygen (FiO2) required by an infant is considered a key measurement of how well the lung is functioning to oxygenate the blood. Healthy lungs can achieve appropriate blood oxygen saturation breathing room air, which is 21% oxygen; however, to achieve the desired level of oxygen saturations, premature infants with RDS frequently require supplemental oxygen. Supplemental oxygen can be toxic, however, so the goal of clinicians is to decrease the amount of supplemental oxygen as quickly as possible.

To evaluate whether AEROSURF was positively impacting oxygenation as assessed by the FiO2 requirement, two measurements were assessed: (i) the need for supplemental oxygen at one hour after either starting the AEROSURF treatment or randomization to the control group (the “one-hour measurement”) and (ii) the FiO2 change from baseline over three hours (the “three-hour measurement”). Results indicate that: (i) at the one-hour measurement, 36% of the AEROSURF group (8/22) were at room air as compared to 14% in the control group (3/22); and (ii) at the three-hour measurement, the AEROSURF group (n=21) had an absolute reduction in FiO2 of approximately 6.5% from the baseline average FiO2 of 32%, compared to an absolute reduction in FiO2 of approximately 1.5% from the baseline average FiO2 of 28% for the control group (n=21).

Carbon dioxide levels in the blood (PCO2) are considered a measure of respiratory function and how efficiently the lungs eliminate carbon dioxide (CO2) from the bloodstream. A known benefit of surfactant replacement therapy for premature infants with RDS is a reduction of CO2 levels in the bloodstream. To evaluate whether AEROSURF may be having a positive impact on CO2 levels, PCO2 was also assessed over three hours after the start of AEROSURF treatment or randomization to control group. In those patients in whom PCO2 was measured (the two higher dose groups and corresponding control patients), a 9 mm of mercury (Hg) decrease in CO2 from the baseline average of 48 mm Hg was observed in the AEROSURF group (n=12), compared to a 1.5 mm Hg decrease from a baseline average of 46 mm Hg for control patients (n=10). This effect is consistent with the action of a surfactant exerting its effect in the lung.

The data related to gas exchange appear to suggest that with AEROSURF, $KL_4$ surfactant is being delivered to, the lungs of premature infants with RDS and potentially improving gas exchange.

*Requirement for Invasive Rescue Therapy due to nCPAP failure*

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, invasive procedures that may each result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists treat infants with less severe RDS by less invasive means, typically nCPAP. Unfortunately, a significant number of premature infants on nCPAP will respond poorly (an outcome referred to as nCPAP failure) and may require delayed surfactant therapy (invasive rescue therapy). Since neonatologists currently cannot predict which infants will experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for those infants who experience nCPAP failure and receive delayed surfactant therapy may be less favorable than the outcomes for infants who received surfactant therapy in the first hours of life.

Parameters associated with invasive rescue therapy were assessed as part of the safety and tolerability profile of AEROSURF. These parameters were also used to assess whether there is evidence of $KL_4$ surfactant being delivered to the lungs of premature infants.

To evaluate whether a single dose of AEROSURF had an impact on the need for invasive rescue therapy (due to nCPAP failure), the time to nCPAP failure was assessed for both the AEROSURF (n=24) and control group (n=24). The results indicate that: (i) at three hours after the start of treatment or randomization to the control group, no AEROSURF patients required rescue therapy compared to 17% of control patients; (ii) at six hours after the start of treatment or randomization to the control group, 13% of patients in the AEROSURF group required rescue therapy compared to 21% in the control group; and, (iii) at 12 hours after the start of treatment or randomization to the control group, nCPAP failure rates in the AEROSURF and control groups were the same at 33%.

Overall, the nCPAP failure rates through 72 hours after the start of treatment or randomization to the control group were comparable between the AEROSURF and control groups. In assessing nCPAP failure rates, the results suggest that inclusion criteria of the phase 2a trial (particularly the FiO2 requirement of at least 25%) resulted in a population at higher risk for nCPAP failure. The overall nCPAP failure rate of the AEROSURF and control groups combined was approximately 58% and was higher than what might be expected in the 29 to 34 weeks gestational age patient population. However, in the AEROSURF groups generally, as the dose increased, the time to nCPAP failure appeared to be prolonged. In addition, the nCPAP failure rate observed in the third (highest dose) AEROSURF group was 38% (3/8), as compared to a 58% (14/24) failure rate in the control group as a whole.

“These data suggest that a single dose of AEROSURF may delay the time to invasive rescue therapy,” continued Dr. Simonson. “Patients receiving endotracheal surfactant therapy often require multiple doses; similarly, multiple or increased doses of AEROSURF may have the potential to reduce the need for invasive rescue therapy. This observation merits further study. Accordingly, our upcoming clinical program will incorporate the ability to administer repeat dosing.”

To summarize the physiological data assessed, the data related to gas exchange and the requirement for rescue therapy due to nCPAP failure appear to suggest that with AEROSURF, $KL_4$ surfactant is being delivered into the lungs of premature infants with RDS.

**Performance of the Novel CAG Technology**

The capillary aerosol generator performed as designed by delivering a high-output, dense aerosol stream that met all output specifications. During the course of the phase 2a trial there were no device failures during treatment or device related adverse events. Overall, the device was well accepted by NICU personnel at all study sites.

**Next Steps in AEROSURF Phase 2 Program**

The Company believes that the achievement of objectives in the initial phase 2a clinical trial will inform and improve the further development of its AEROSURF clinical program for premature infants with RDS. The Company plans the following phase 2 clinical assessments going forward:

- A phase 2a dose expansion in 29 to 34 weeks gestational age infants to evaluate increased doses and repeat dosing. The Company anticipates starting this trial in the second quarter of 2015 with completion in the fourth quarter of 2015.

- A phase 2a clinical trial assessing the safety and tolerability of escalating doses of AEROSURF administered to 26 to 28 weeks gestational age infants, with an ability to administer repeat doses. The Company anticipates initiating this trial in July 2015, with completion in the fourth quarter of 2015.

- A phase 2b clinical trial to determine the optimal dose and define the expected efficacy margin of AEROSURF treatment. The Company anticipates initiating this clinical trial in the fourth quarter of 2015, with completion in mid 2016.

This clinical trial was supported, in part, by a $1.9 million Phase II award of a $2.4 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) under award number 4R44HL107000-02. The content of this press release is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health.

**Conference Call and Webcast Details**
Discovery Labs' management will host a conference call and live webcast, with a slide presentation including data from the clinical trial, today at 8:00 a.m. Eastern time to review and discuss the results of the trial. The live webcast and archive of the conference call can be accessed at http://discoverylabs.investorroom.com/events.

For "listen-only" participants and those who wish to take part in the question and answer portion of the call, dial (888) 346-0767 (domestic) or (412) 902-4251 (international). After placing the call, request to be joined into the Discovery Labs conference call. A replay of the conference call will be accessible through May 22, 2015 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference ID number 10065912.

**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 endotracheal 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 endotracheal 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 $KL_4$ surfactant using less invasive procedures, 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.

Currently in the U.S., the Company estimates that approximately 120,000 to 150,000 premature infants could benefit from surfactant therapy. However, due to the risks associated with endotracheal intubation and mechanical ventilation, only approximately 50,000 to 60,000 of these infants currently are treated with surfactants as the initial therapy for severe RDS. The remaining infants with less severe RDS are usually supported with nCPAP alone. However, a large percentage of these infants are not adequately supported with nCPAP alone (an outcome referred to as nCPAP failure) and thereafter may require delayed surfactant therapy administered by endotracheal intubation and mechanical ventilation

**About Discovery Labs**
Discovery Laboratories, Inc. is a specialty biotechnology company focused on developing aerosolized $KL_4$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 ($KL_4$) surfactant, that is structurally similar to pulmonary surfactant, and proprietary drug delivery technologies being developed to enable efficient delivery of aerosolized $KL_4$ 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***
*Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties, including those affecting Discovery Labs' ability successfully to complete its development programs and realize the potential benefits of its RDS product portfolio, are 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. Any forward-looking statement in this release speaks only as of the date on which it is made. Discovery Labs assumes no obligation to update or revise any forward-looking statements.*

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