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 12, 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 CFR240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On November 12, 2015, Discovery Laboratories, Inc. (the “Company” or "Discovery Labs"), issued a press release announcing that it would host a conference call and live webcast to review of the top line data from its recently completed AEROSURF® phase 2a clinical program in premature infants 29 to 34 week gestational age receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS). A copy of the presentation materials is attached as Exhibit 99.1 hereto.

Pursuant to General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 hereto are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise be subject to the liabilities of that section, nor is it incorporated by reference into any filing of Discovery Laboratories, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On November 12, 2015, the Company issued a press release announcing that it would host a conference call and live webcast review of the top line data from its recently completed AEROSURF® phase 2a clinical program in premature infants 29 to 34 week gestational age receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS). The two-part program enrolled a total of 80 premature infants including 40 in five AEROSURF dose groups and 40 control infants on nCPAP alone. The Company previously announced top line data from the initial trial in May 2015. During the webcast, the Company will report data on the overall phase 2a program in premature infants 29 to 34 week gestational age including the recently completed phase 2a expansion study. A copy of the press release is attached as Exhibit 99.2 hereto and incorporated herein by reference.

In addition, the Company reaffirms its forecast set forth in the Quarterly Report on Form 10-Q for the quarter ended September 30, 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 2017, including net cash outflows of approximately $8 million in the fourth quarter of 2015.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits:

99.1 Slide Presentation dated November 12, 2015.
99.2 Press Release dated November 12, 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: November 12, 2015

Exhibit 99.1

AEROSURF® Phase 2 Program Update

Investor Conference Call

November 12, 2015

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Inspired Innovation

Forward Looking Statement

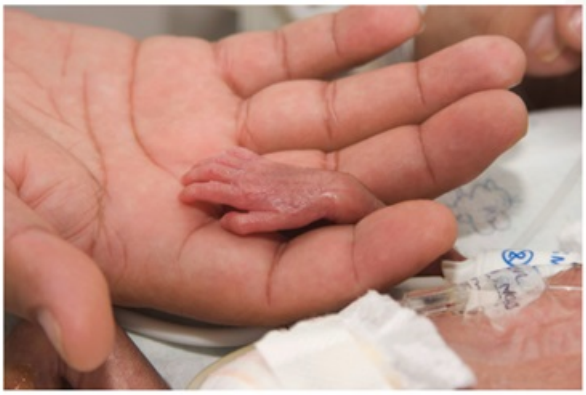
To the extent that statements in this presentation are not strictly historical, including statements about the Company's business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, or 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 presentation are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. These risks are further described in the Company's periodic filings with the Securities and Exchange Commission (SEC), including the most recent reports on Forms 10-K, 8-K and 10-Q, and any amendments thereto ("Company Filings").

Respiratory Distress Syndrome (RDS)

Primary characteristic is surfactant deficiency in underdeveloped lungs of premature infants (born with a lack of natural lung surfactant required for open airways and proper gas exchange – O_2 in and CO_2 out)

American Academy of Pediatrics guidelines recommend providing surfactant replacement within the first hours of life[1]

Neonatologists believe the highest unmet need in RDS is the ability to deliver surfactant non-invasively to patients[2]



1. AAP guidelines, 2013
2. Discovery Labs' primary market research (2014)

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AEROSURF® Aerosolized Surfactant for RDS

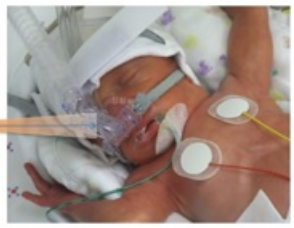
Proprietary Synthetic KL4 Surfactant

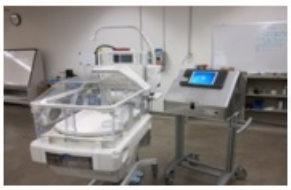
Designed to be structurally similar to human lung surfactant

SURFAXIN® - Liquid KL4 surfactant (intratracheal instillate) for RDS approved by the FDA

Innovative Aerosol Delivery Technology

Designed specifically for the capability to aerosolize and deliver surfactant





Potential to transform the treatment of premature infants with RDS by making surfactant therapy available through non-invasive delivery technology.

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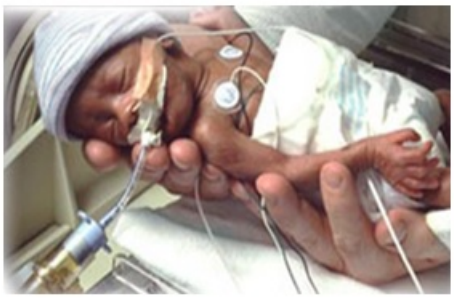
Current Treatment of RDS: Intubate or Not?

Invasive Intubation



Surfactant replacement therapy (SRT) - requires intubation and mechanical ventilation (MV); available surfactants are animal-derived

Invasive intubation and MV can result in serious respiratory conditions and other complications, such as higher risk of infection and bronchopulmonary dysplasia (BPD)

Nasal continuous positive airway pressure (nCPAP)

Considered less invasive but does not address underlying condition – surfactant deficiency

Many infants respond poorly and require delayed rescue SRT via intubation and MV ("nCPAP failure")

Earlier SRT produces better outcomes compared to late SRT[1]

1. AAP guidelines, 2013

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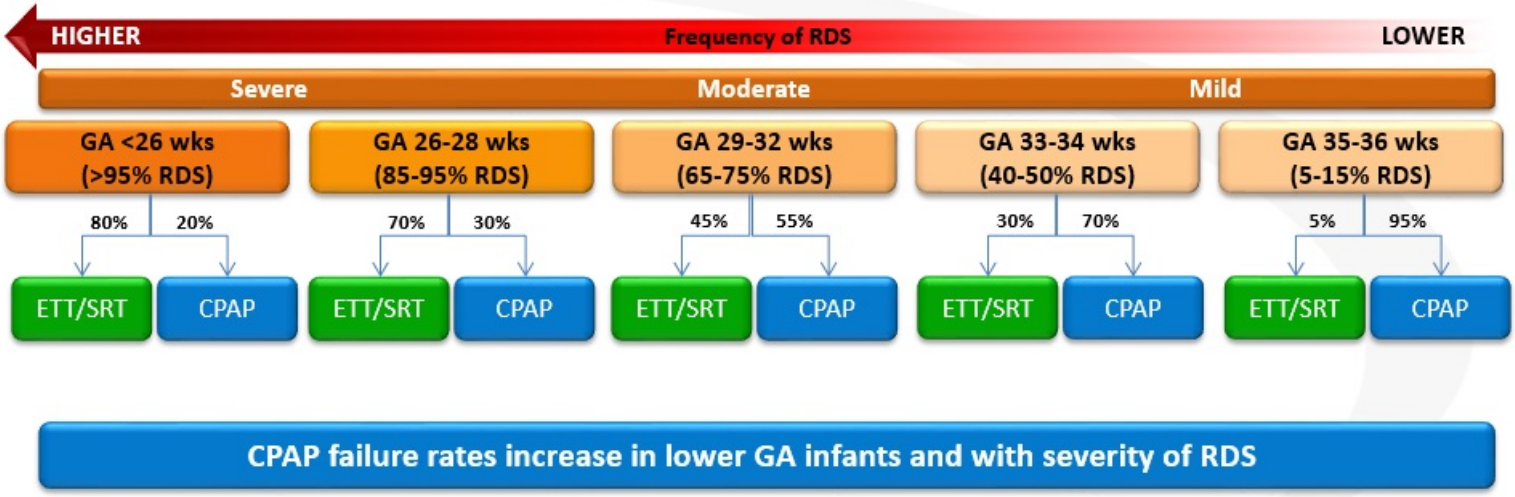
Current Treatment of RDS: nCPAP Used Across All Gestational Ages and Severity of RDS



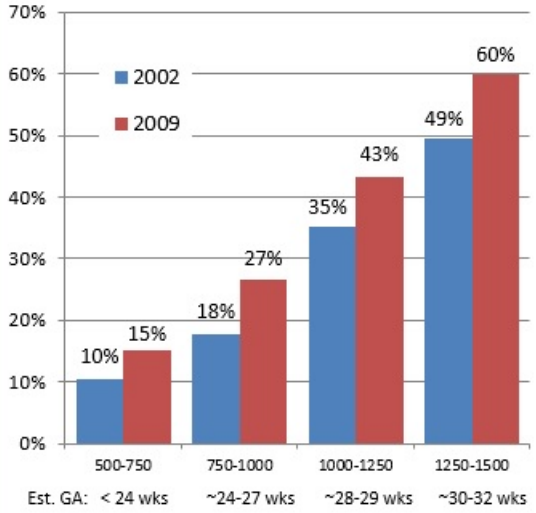
CPAP failure rates increase in lower GA infants and with severity of RDS

Note: ETT/SRT – administration of surfactant replacement therapy via intubation with an endotracheal tube

Source: Discovery Labs' primary market research (2014); IMS MIDAS data (2012); CDC National Vital Statistics, 2014, Healthcare Costs and Utilization Project (HCUP), 2013; Agency for Healthcare Research and Quality (AHRQ), 2012; Births by birth weight (CDC Website).

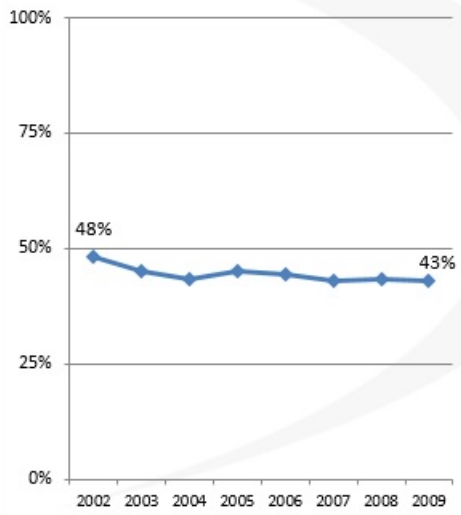
Current Treatment of RDS: Trends in Non-Invasive Care of Neonates – Increasing Use of nCPAP to Avoid Intubation

First-line nCPAP use has been trending up across all gestational ages up to 32 weeks GA



Source: Soll, Obstetric and Neonatal Care Practices for Infants 501 to 1500 g From 2000 to 2009; *Pediatrics; July 2013*

However, still experience high nCPAP failure rates



Source: Soll, Obstetric and Neonatal Care Practices for Infants 501 to 1500 g From 2000 to 2009; *Pediatrics; July 2013*

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RDS: Clinicians seeking a non-invasive way to deliver SRT

What is wanted[1]:

- ✓ An approach that effectively delivers surfactant without intubation or mechanical ventilation
- ✓ Possibility of repeat doses
- ✓ Avoids clinical instability associated with bolus administration
- ✓ Administration by non-specialist staff
- ✓ Reduce cost of treating premature infants

"…optimization of less invasive method of surfactant administration will be one of the most important subjects for research in the field of surfactant therapy of RDS in coming years".

Kribs A. How best to administer surfactant to VLBW infants. Arch Dis Child Fetal Neonatal Ed 2011;doi:10.1136.

1. Pillow & Minocchieri: Neonatology, 2012

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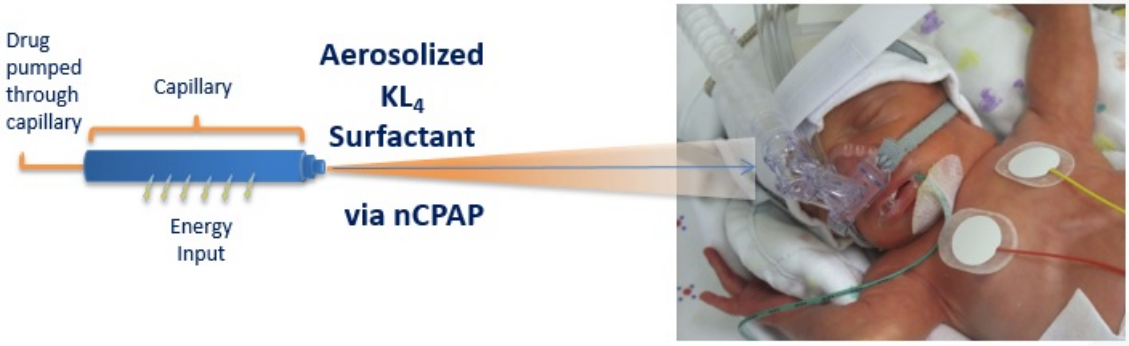
AEROSURF® Potential to Transform Management of RDS

Goal is to administer surfactant without invasive intubation and early in the management of RDS in premature infants



We are conducting the AEROSURF® development program with the goal of establishing AEROSURF as the first aerosolized surfactant therapy to address RDS

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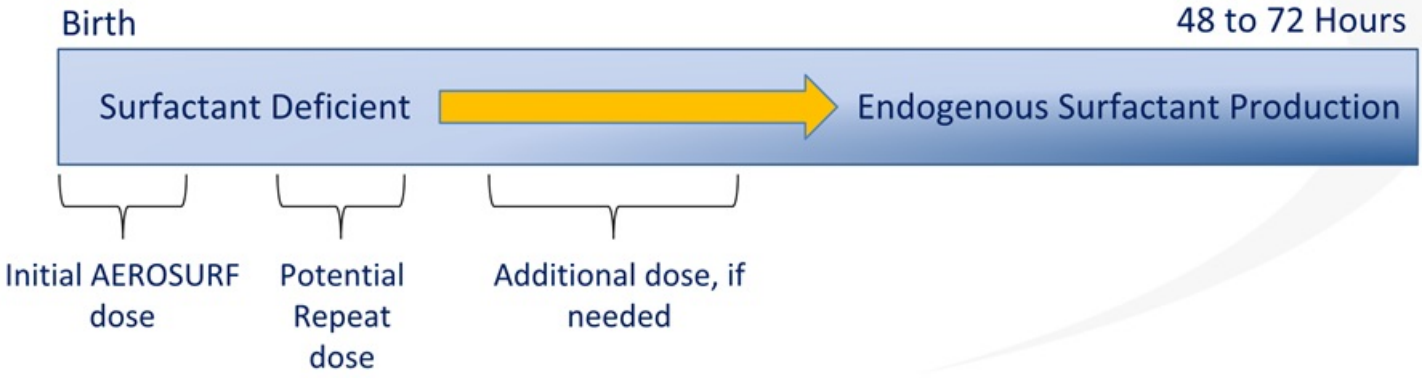
AEROSURF® Bridge the Surfactant / RDS Gap in the First 72 Hours

Goal

- Provide surfactant therapy to premature infants until they can produce their own endogenous surfactant
- Allow for single or repeat non-invasive doses of aerosolized surfactant with nCPAP



Phase 2 development program is primarily to assess safety and understand the proper dosing regimen to support premature infants to surfactant self-sufficiency

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AEROSURF® Comprehensive Phase 2 Program

	Phase 2a	Phase 2a Expansion	Phase 2a	Phase 2b
Gestational Age (wks)	29 – 34		26 - 28	26 – 32 (Begin with 29 – 32)
Dose Groups	15 min; 30 min; 45 min (25, 50, 75 TPL mg/kg) (8 active, 8 control per group) Single dose	60 min; 90 min (100 and 150 TPL mg/kg) (8 active, 8 control per group) Primarily single dose	30 min; 45 min (50 and 75 TPL mg/kg) (8 active, 8 control per group) Up to two doses	25 min; 50 min; Control (40 and 80 TPL mg/kg) Up to 3 doses
# of patients	48	32	32	Up to 250
Objective(s)	Safety and tolerability Physiological data suggesting delivery of KL_4 surfactant to the lungs Performance of aerosol delivery system	Safety and tolerability of higher doses and determine therapeutic index (safety window) Continue physiological assessment	Safety and tolerability Physiological assessment	Provide evidence of efficacy on an acceptable endpoint Identify dose regimens for phase 3 study Provide estimate of effect size
# of sites	Initiated with 3; increased to 8 (US)	12 (US)	Up to 20 (US)	50+ (US, EU, Canada, LATAM)
Timeline / Milestones	**Completed May 2015; key objectives achieved**	**Completed Oct 2015**	Initiated; results expected Q1 2016	Expect to initiate Q4 2015; target enrollment completion – mid - 2016

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Phase 2a Clinical Program (29 to 34 weeks GA)

Top-Line Data Review

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Phase 2a Study (29 to 34 wks GA)
Study Design

AEROSURF®

Evaluate the safety and tolerability of aerosolized KL4 surfactant (lucinactant 30 mg TPL/ml) for inhalation, administered to preterm neonates 29 to 34 weeks post-menstrual age (PMA) receiving nCPAP for RDS, compared to neonates receiving nCPAP alone.

Design

- Multicenter, randomized, controlled, dose-escalation study
- Preterm neonates within the first 21 hours after birth and who have had implementation of controlled nCPAP within 1 hour of birth.
- 8 control and 8 active per dose group (80 total: 40 active; 40 pooled control)

Treatment Groups

- Dose Group 1 – 15 min (25 mg TPL/kg) single dose
- Dose Group 2 – 30 min (50 mg TPL/kg) single dose
- Dose Group 3 – 45 min (75 mg TPL/kg) single dose
- Dose Group 4 – 60 min (100 mg TPL/kg) single dose*
- Dose Group 5 – 90 min (150 mg TPL/kg) single dose*

* *Dose Groups 4 & 5 could have repeat doses if oxygen requirement was ≥ 0.35 at least 2 hours after dosing*

Method of Administration

- Reconstituted lyophilized KL4 surfactant aerosolized by the investigational device (capillary aerosol generator), and introduced into the nCPAP circuit.

Phase 2a Study (29 to 34 wks GA)
Study Design (cont'd)

AEROSURF®

Inclusion Criteria

- Gestational age 29 to 34 weeks PMA
- Implementation of controlled nCPAP within 60 minutes after birth
- Spontaneous breathing
- Chest radiograph consistent with RDS
- Within the first 21 hours after birth, requires the following to maintain SpO_2 of 88% - 95%
  - nCPAP of 5 to 6 cm H_2O
  - FiO_2 of 0.30 to 0.50 for at least 60 minutes
  - FiO_2 of 0.25 to 0.50 for at least 120 minutes (amendment)
  - FiO_2 of 0.25 to 0.50 for at least 30 minutes (amendment)

Exclusion Criteria

- Hemodynamically unstable
- Major congenital / chromosomal abnormalities
- Recurrent apnea

Primary Objective

Safety and tolerability of AEROSURF® compared to nCPAP alone

Other Key Objectives

Assess physiological data indicating that aerosolized KL4 surfactant is being delivered into the lungs of premature infants

- Gas exchange: FiO_2 requirements and changes in CO_2
- Need for rescue therapy and requirement for invasive respiratory support

Acceptable performance of the AEROSURF Delivery System in the NICU

Phase 2a Study (29 to 34 wks GA)
Safety & Tolerability – Administration & Peri-Dosing

AEROSURF®

Complications of patient interface	All AEROSURF (N=40)
Bleeding	0
Apparent obstruction of the nares	0
Bi-nasal prongs occlusion requiring removal and replacement	0
Nasal irritation	2
Anatomic limitation required a mask	1

The nasal interface and nasal prongs were well tolerated

Upper airway obstruction was not observed

Peri-Dosing Event	All AEROSURF (N=40)
Bradycardia	0
Desaturation	5 (16%)
Vomiting	2 (6%)

Peri-dosing events were infrequent with AEROSURF® administration

Phase 2a Study (29 to 34 wks GA)
Safety & Tolerability - Adverse Events

AEROSURF®

Co-morbidities and adverse events occur frequently in this patient population

Adverse Event Observations:

The most common adverse events in the AEROSURF® and control groups were:

- Neonatal jaundice
- Constipation
- Apnea
- Anemia

All observed adverse events were as expected for this patient population

Incidence of adverse events was generally comparable between AEROSURF and control groups

There was no pattern of increased adverse events with increasing AEROSURF dose

Phase 2a Study (29 to 34 wks GA)
Adverse Events - Incidence of Air Leak

AEROSURF®

Types of Air Leak	Control (N=40)	AEROSURF® (N=40)
Pneumothorax/Pneumomediastinum	5 (13%)[1]	9 (23%)[2, 3]
Pulmonary Interstitial Emphysema	2 (5%)	1 (3%)
Total Number of Infants[4]	7 (18%)	9 (23%)

[1] Includes 4 patients with an SAE and one non-serious PTX
[2] Includes 1 AEROSURF patient inappropriately enrolled in the trial
[3] One AEROSURF patient was found to have an air leak prior to dosing
[4] All chest x-rays for patients in this study are being reviewed by an independent radiologist for severity of RDS at baseline and to assess the course of RDS

The incidence of air leak in this trial is not unexpected and comparable to what has been reported in the literature for infants in this age group 23-47%[5]

There was no pattern of increased incidence of air leaks with increasing AEROSURF dose

AEROSURF Dose Groups	1	2	3	4	5
Number of Infants with Air Leak	2	2	1	2	2

[5] Dargaville et al. 2013

Phase 2a Study (29 to 34 wks GA)
Safety & Tolerability - Serious Adverse Events (SAE)

AEROSURF®

SAE	Control (N=40)	AEROSURF® (N=40)
Apnea	0	1 (3%)
Oxygen saturation decreased	0	1 (3%)
Necrotising enterocolitis	1 (3%)	2 (5%)
Cardio-respiratory arrest	1 (3%)	1 (3%)[1]
Hydrocephalus	1 (3%)	0
Pneumothorax/Pneumomediastinum	4 (10%)	9 (23%)[2, 3]
Pulmonary Hemorrhage	1 (3%)[1]	0
Death	1 (3%)	1 (3%)

[1] SAEs associated with mortality - both considered unrelated to study drug or trial procedures
[2] Includes 1 AEROSURF patient inappropriately enrolled in the trial
[3] One AEROSURF patient was found to have an air leak prior to dosing and the SAE

These are SAEs that you would expect to see in this population

There was no pattern of increased incidence of SAEs with increasing AEROSURF dose

All air leaks resolved without complication.

Phase 2a Study (29 to 34 wks GA)
Safety and Tolerability - Summary

AEROSURF®

The adverse events seen in this trial were expected for this patient population

The adverse events and complications of prematurity were generally comparable between AEROSURF® and control groups

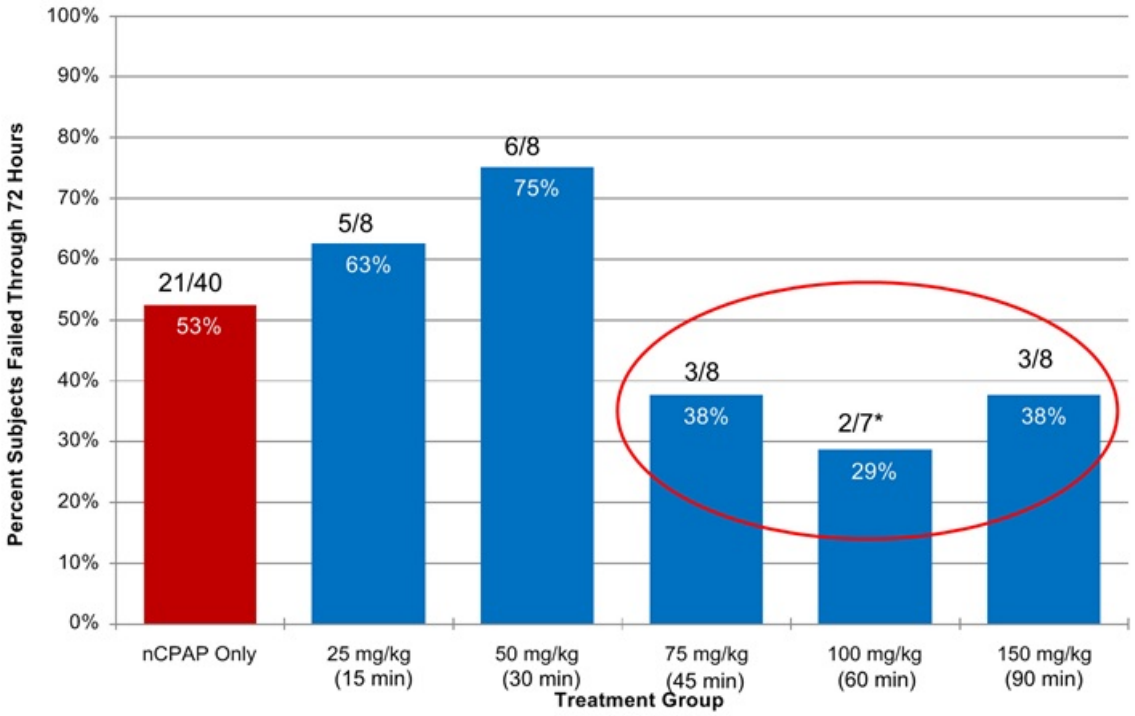
There was no pattern of increased adverse events or serious adverse events with increasing AEROSURF dose

The AEROSURF Delivery System delivered KL4 surfactant to the infants in a way that was generally safe and well tolerated

The Independent Safety Review Committee supports proceeding to the next studies in our program

Phase 2a Study (29 to 34 wks GA)
nCPAP Failure by Treatment Group through 72 hours

AEROSURF®

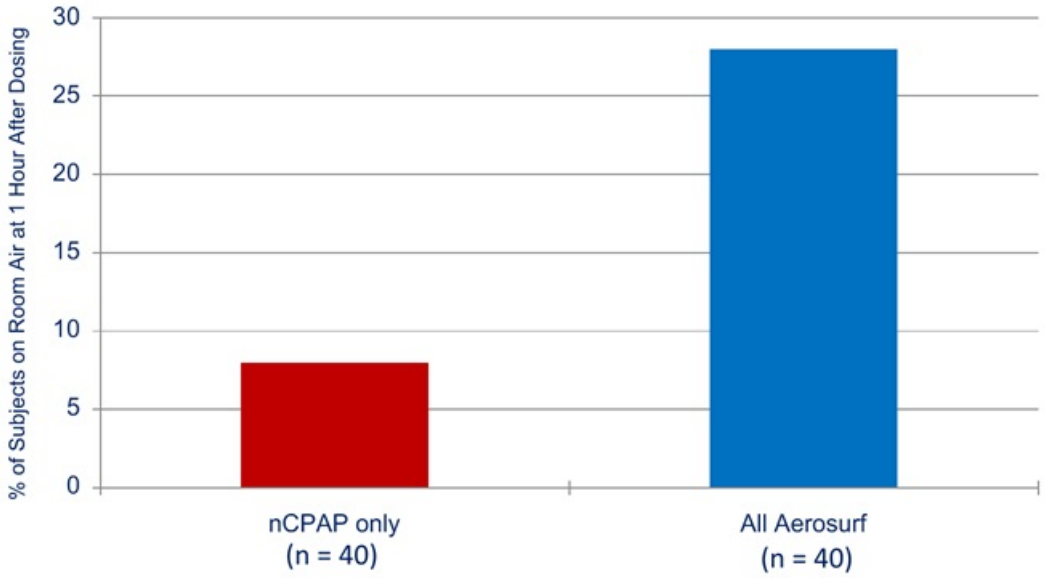


* One intubated patient excluded due to being inappropriately enrolled

AEROSURF treatment, primarily in single doses of 45 minutes and greater, appears to be associated with lower rates of nCPAP failure.

AEROSURF® Phase 2a Study (29 to 34 wks GA)

Patients on Room Air at 1 Hour Post Start of Treatment[1]



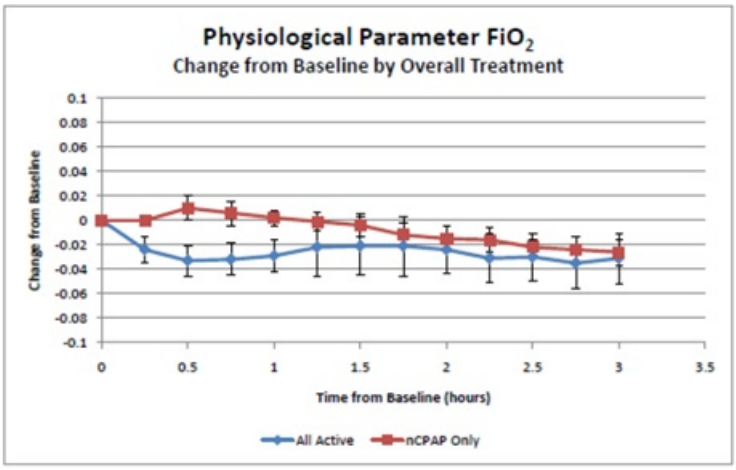
At 1 hour after start of treatment, 28% of all AEROSURF® patients were at 21% O_2 (room air) compared to 8% of control patients.

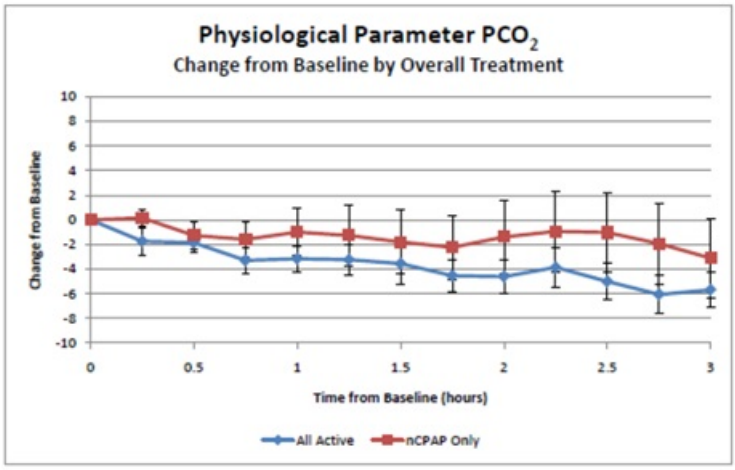
[1] For control patients time is 1 hour after randomization

Phase 2a Study (29 to 34 wks GA)

Gas Exchange – Change in FiO_2 and CO_2 (at 3 hrs)

AEROSURF®



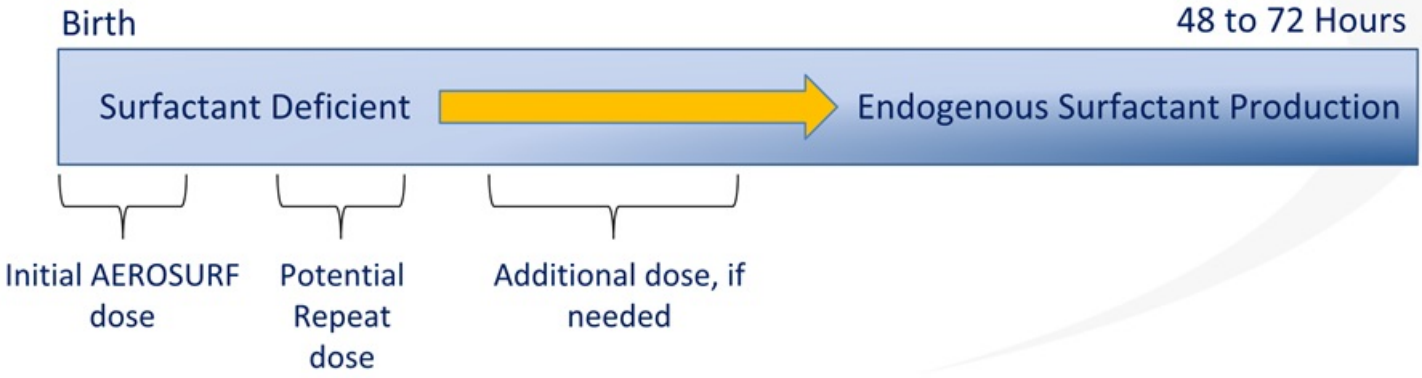


The data suggest that AEROSURF is associated with a decrease in FiO_2 shortly after initiation of treatment and numerically greater change in PCO_2 levels compared to control, suggesting that aerosolized KL4 surfactant is being delivered to the lungs

AEROSURF® Bridge the Surfactant / RDS Gap in the First 72 Hours

Goal

- Provide surfactant therapy to premature infants until they can produce their own endogenous surfactant
- Allow for single or repeat non-invasive doses of aerosolized surfactant with nCPAP



Phase 2 development program is primarily to assess safety and understand the proper dosing regimen to support premature infants to surfactant self-sufficiency

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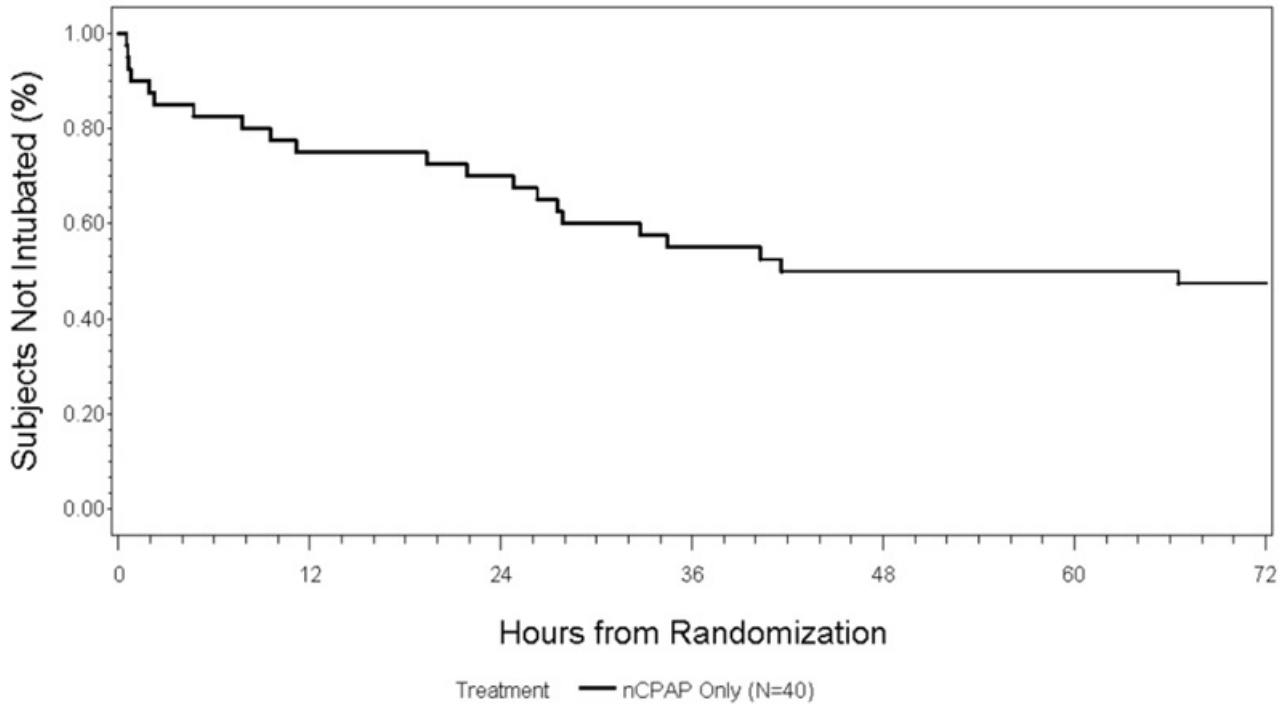
Phase 2a Study (29 to 34 wks GA)

Time to Intubation for nCPAP Failure for Control Group

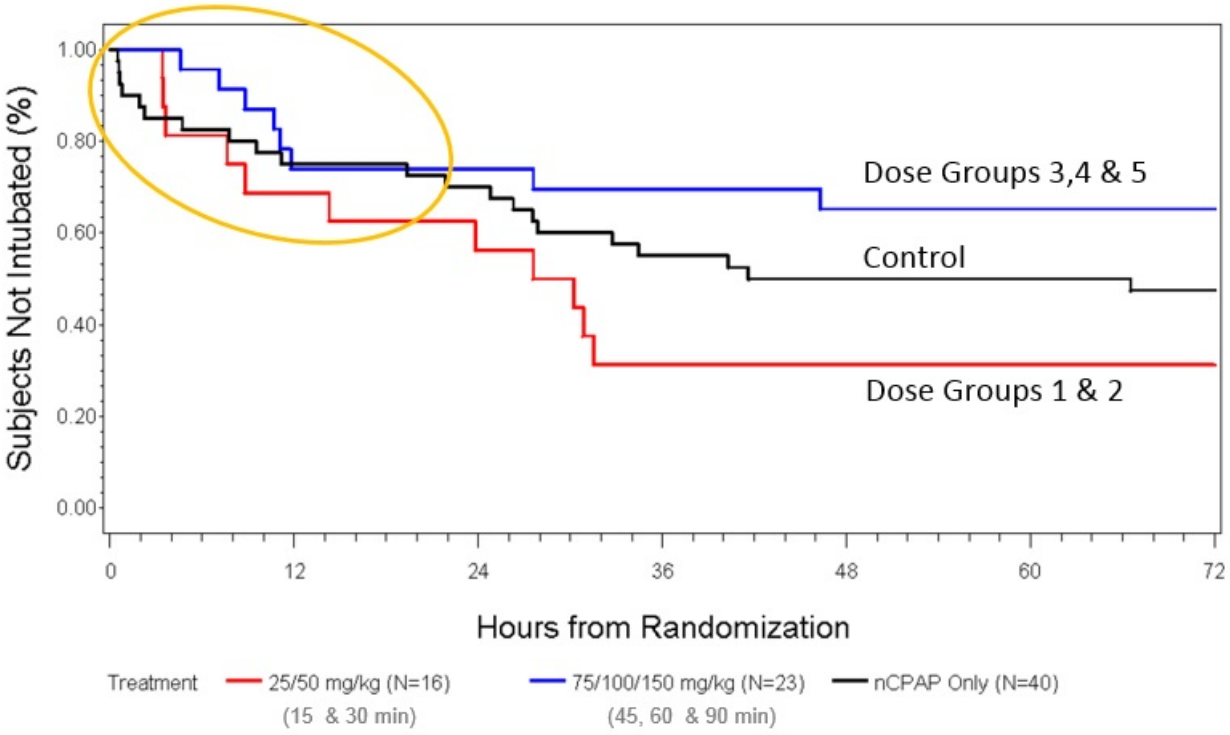
AEROSURF®



nCPAP failures due to RDS normally occur within 72 hours; in the control group (n=40) majority of nCPAP failures occurred within 48 hours of life

Phase 2a Study (29 to 34 wks GA)

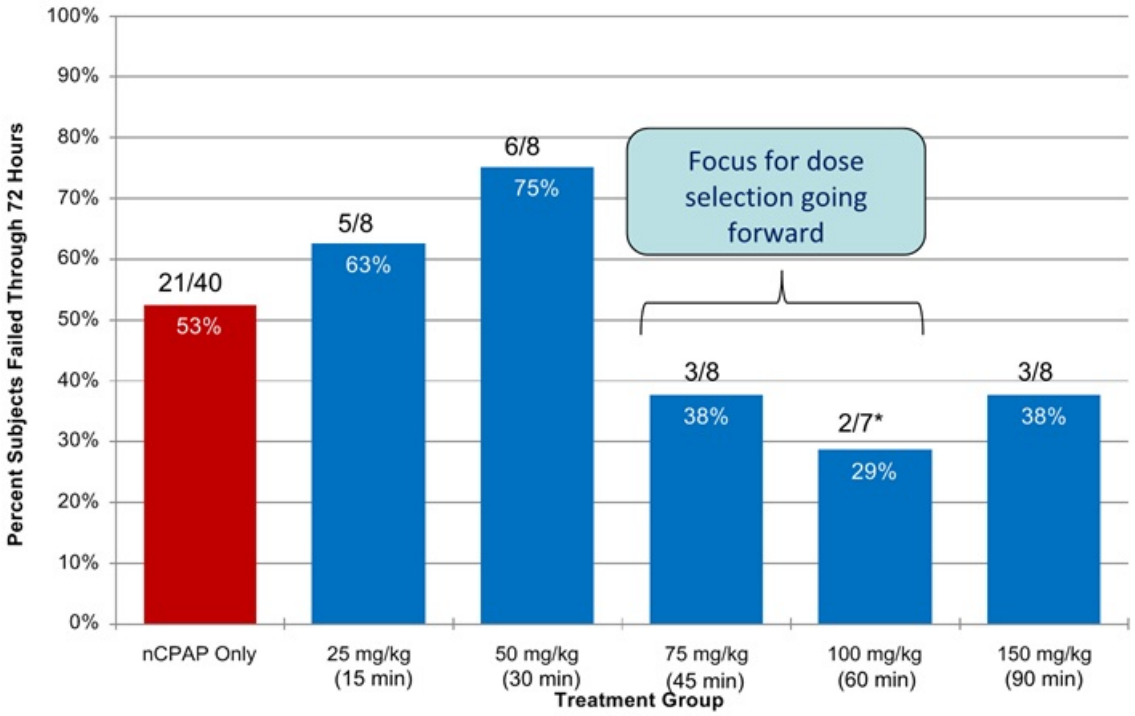
Time to Intubation for nCPAP Failure by Treatment Group



AEROSURF may prolong the time to intubation; repeat dosing may be important to extend this effect to surfactant self-sufficiency

Phase 2a Study (29 to 34 wks GA)
nCPAP Failure by Treatment Group through 72 hours

AEROSURF®

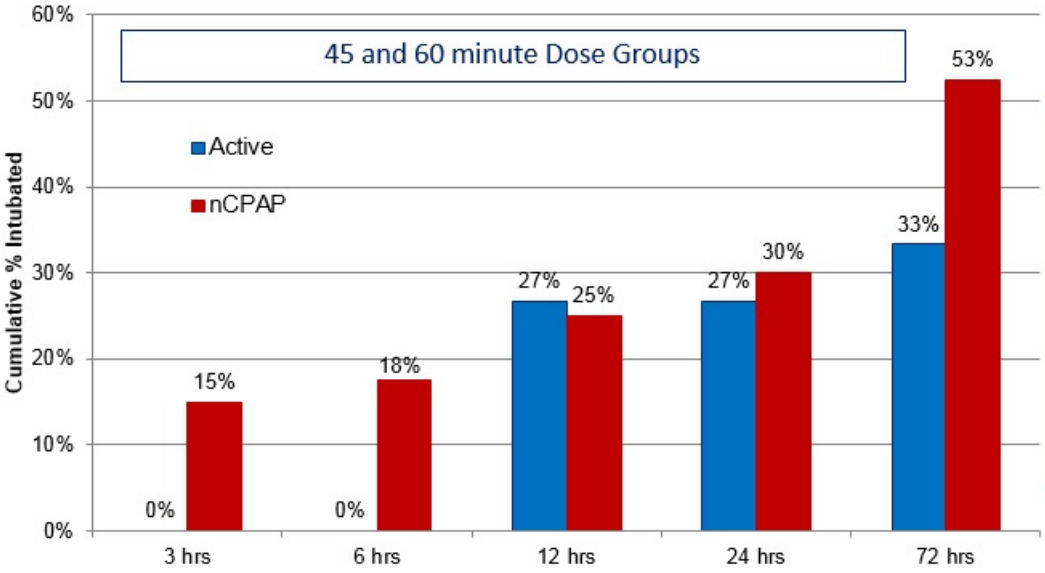


* One intubated patient excluded due to being inappropriately enrolled

AEROSURF treatment, primarily in single doses of 45 minutes and greater, appears to be associated with lower rates of nCPAP failure

Phase 2a Study (29 to 34 wks GA)

45 and 60 Minute Dose Groups - nCPAP Failure through 72 hours



At 72 hours post-dosing, 33% (5/15*) of AEROSURF patients in the 45 and 60 minute dose groups required intubation compared to 53% (21/40) in the control group, or a relative reduction in nCPAP failure of 38%

- No AEROSURF patients in the 45 and 60 minute dose groups required intubation at 3 or 6 hours post-dosing compared to 18% (7/40) of control patients
- AEROSURF 45 and 60 minute doses may be reducing the rates of intubation and also prolonging the time to intubation -- repeat dosing may be important to extend this effect to surfactant self-sufficiency

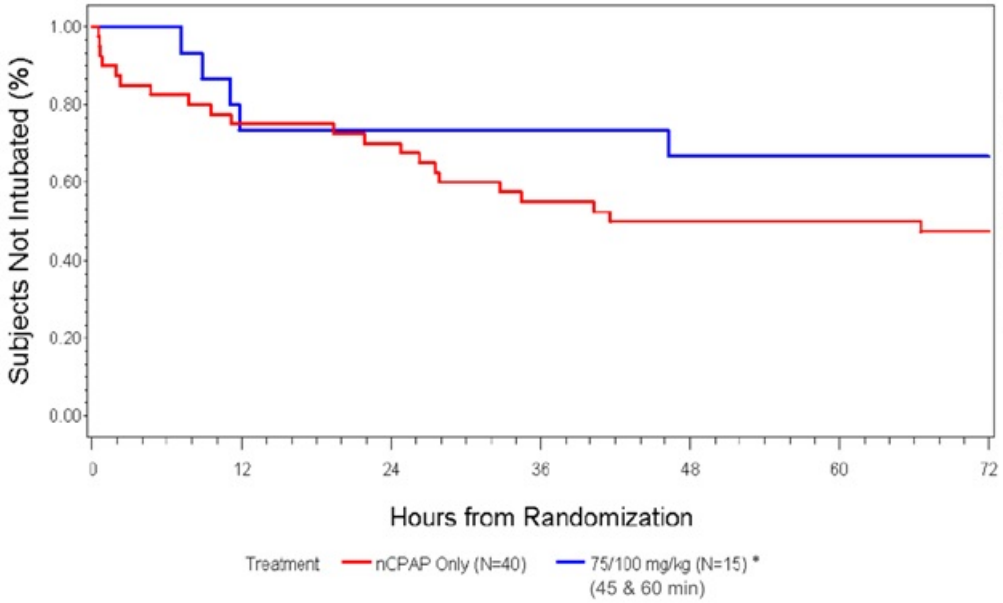
* One intubated patient excluded due to being inappropriately enrolled

Phase 2a Study (29 to 34 wks GA)

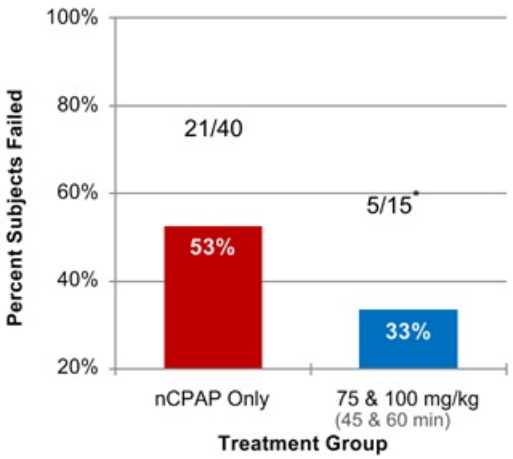
45 and 60 Minute Dose Groups - nCPAP Failure through 72 hours

AEROSURF®

Time to nCPAP Failure



nCPAP Failure



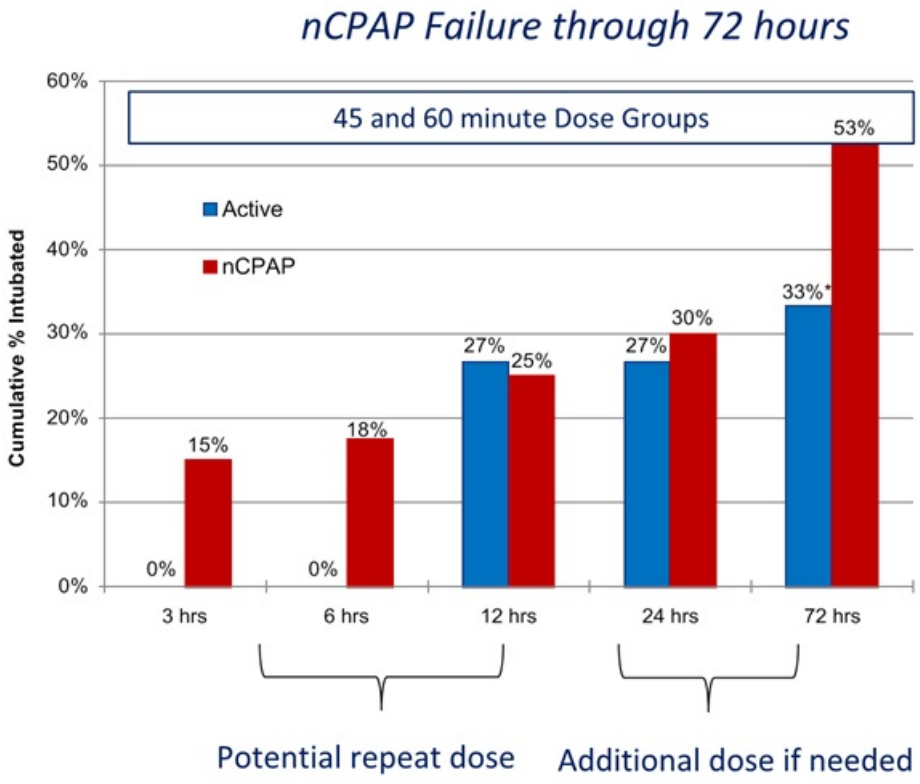
AEROSURF treated patients experienced a 20% absolute reduction or a 38% relative reduction in nCPAP failure compared to control

* One intubated patient excluded due to being inappropriately enrolled

DiscoveryLabs

Phase 2a Study (29 to 34 wks GA)
Moving Forward – Window for Repeat Dosing

AEROSURF®



* One intubated patient excluded due to being inappropriately enrolled

DiscoveryLabs

Phase 2a Study (29 to 34 wks GA)
Summary to Date

AEROSURF®

- Overall, the safety and tolerability profile of the AEROSURF group in the trial was generally comparable to the control group
- There was acceptable performance by the novel aerosol delivery technology in the NICU
- Aerosolized surfactant produces physiological changes that are expected with surfactant replacement therapy
- The goal of decreasing nCPAP failure and intubations appears achievable - data to date suggest that AEROSURF may be decreasing nCPAP failure and the need for intubation
- Repeat dosing may be important to enhance the reduction in nCPAP failures
- Results from the phase 2a program in 29-34 week GA premature infants has informed the phase 2b study in premature infants 29-32 week GA and the phase 2a study in 26-28 week GA premature infants

AEROSURF® Comprehensive Phase 2 Program

	Phase 2a	Phase 2a Expansion	Phase 2a	Phase 2b
Gestational Age (wks)	29 – 34		26 - 28	26 – 32 (Begin with 29 – 32)
Dose Groups	15 min; 30 min; 45 min (25, 50, 75 TPL mg/kg) (8 active, 8 control per group) Single dose	60 min; 90 min (100 and 150 TPL mg/kg) (8 active, 8 control per group) Primarily single dose	30 min; 45 min (50 and 75 TPL mg/kg) (8 active, 8 control per group) Up to two doses	25 min; 50 min; Control (40 and 80 TPL mg/kg) Up to 3 doses
# of patients	48	32	32	Up to 250
Objective(s)	Safety and tolerability Physiological data suggesting delivery of KL_4 surfactant to the lungs Performance of aerosol delivery system	Safety and tolerability of higher doses and determine therapeutic index (safety window) Continue physiological assessment	Safety and tolerability Physiological assessment	Provide evidence of efficacy on an acceptable endpoint Identify dose regimens for phase 3 study Provide estimate of effect size
# of sites	Initiated with 3; increased to 8 (US)	12 (US)	Up to 20 (US)	50+ (US, EU, Canada, LATAM)
Timeline / Milestones	**Completed May 2015; key objectives achieved**	**Completed Oct 2015**	Initiated; results expected Q1 2016	Expect to initiate Q4 2015; target enrollment completion – mid - 2016

DiscoveryLabs. Inspired Innovation

AEROSURF® Phase 2 Program Update

Investor Conference Call

November 12, 2015

DiscoveryLabs
Inspired Innovation

Exhibit 99.2

Discovery Labs Announces Top Line Results of AEROSURF® Phase 2a Clinical Program in Premature Infants 29 to 34 Weeks Gestational Age

Encouraging phase 2a data suggest that aerosolized KL4 surfactant delivered to premature infants with RDS may decrease nCPAP failure and the need for intubation

Data provides foundation and direction for AEROSURF phase 2b clinical trial

Warrington, PA, November 12, 2015 — Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, today reported top line data from its recently completed AEROSURF® phase 2a clinical program in premature infants 29 to 34 week gestational age (GA) receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS). The two-part program enrolled a total of 80 premature infants including 40 infants in five AEROSURF dose groups and 40 control infants on nCPAP alone. The Company previously announced top line data from the initial trial in May 2015. The Company is now reporting data on the overall phase 2a program in premature infants 29 to 34 week GA including the recently completed phase 2a expansion study. The data are encouraging and suggest that aerosolized KL4 surfactant delivered to premature infants with RDS is generally safe and well tolerated and may decrease nCPAP failure and the need for intubation. The Company is now advancing AEROSURF to a phase 2b clinical trial beginning with enrollment of premature infants 29 to 32 week GA.

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.

Key objectives of the program were achieved, including (1) the primary objective of evaluating the safety and tolerability of aerosolized KL4 surfactant, compared to nCPAP alone; (2) proof of concept for the Company's proprietary technology platform based on physiological data suggesting that aerosolized KL4 surfactant is being delivered into the lungs of premature infants; and, (3) acceptable performance of the novel aerosol delivery technology in the neonatal intensive care unit (NICU). Key observations from the data include:

- Overall, the safety and tolerability profile of the AEROSURF group in this phase 2a program was generally comparable to the control group. All reported adverse events and serious adverse events were those that are common and expected among premature infants with RDS. Based on the safety and tolerability profile observed in the program, the Company is progressing to the AEROSURF phase 2b clinical trial.

- Data suggest that AEROSURF may be reducing the incidence of nCPAP failure (the need for intubation and delayed surfactant therapy). Through 72 hours after the start of treatment, AEROSURF treated patients, predominantly receiving a single dose, had lower rates of nCPAP failure compared to control in each of the last three dose groups studied. nCPAP failure rates were 53% in the control group compared to 38%, 29% (excluding one patient who was inappropriately enrolled) and 38% in the 45, 60 and 90 minute AEROSURF dose groups, respectively.

  The Company has focused its planning for the phase 2b clinical trial on the 45 and 60 minute dose groups. The combined data for these groups indicate that, through 72 hours after the start of treatment, AEROSURF treated patients had a 33% nCPAP failure rate compared to 53% in the control group. This represents a 20% absolute reduction or a 38% relative reduction in nCPAP failure compared to control.

- The phase 2a program in premature infants 29 to 34 week GA has provided a foundation and direction for the AEROSURF phase 2b trial in premature infants 26 to 32 week GA. The Company expects to initiate the phase 2b trial in the fourth quarter of 2015. The phase 2b trial will include the ability to administer repeat doses, if necessary. Enrollment will begin with premature infants 29 to 32 week GA, followed by enrollment of premature infants 26 to 28 week GA.

“Premature infants with RDS are born with immature lungs and are frequently unable to produce their own endogenous surfactant for up to 48 to 72 hours of life. With AEROSURF, we potentially have an opportunity to administer aerosolized KL_4 surfactant non-invasively to support premature infants until they are able to produce their own surfactant.” commented Steve Simonson, M.D., Discovery Labs’ Chief Development Officer. “The data from the phase 2a program to date are very encouraging. We are seeing signals that suggest our goal of reducing nCPAP failures and intubations with AEROSURF appears achievable. If we are successful, we believe AEROSURF will represent a transformational change in the management of RDS.”

Phase 2a Clinical Program in Premature Infants 29 to 34 Weeks GA

Study Design

The phase 2a clinical studies were multicenter, randomized, open-label, controlled studies in 80 premature infants 29 to 34 weeks GA receiving nCPAP for RDS, and designed to evaluate the safety and tolerability of aerosolized KL_4 surfactant administered in five dose groups (15, 30, 45, 60 and 90 minute), compared to infants receiving nCPAP alone. In addition to safety and tolerability, another objective of the study was to establish 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 aerosol delivery technology in the NICU.

Safety and Tolerability

Overall, the safety and tolerability profile of the AEROSURF group in the studies 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, apnea and anemia. The most common serious adverse events were air leaks (pneumothorax and pneumomediastinum). 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.

Air leaks (including pneumothorax, pneumomediastinum and pulmonary interstitial emphysema) were the most common complication of prematurity in both the AEROSURF and control groups. There were a total of nine patients with air leaks in the AEROSURF group and seven patients with air leaks in the control group. One AEROSURF treated infant was found to have an air leak prior to study drug administration. One other infant in the AEROSURF group was inappropriately enrolled in the study, received only a brief exposure to study drug and has been excluded from the analysis of all of the physiological evaluations below. The incidence of air leaks was not unexpected and comparable to what has been reported in the literature (23-47%) for infants in this age group (*Dargaville et al., 2013*). All air leaks were resolved without complication and there was no pattern of increased incidence of air leaks with increasing AEROSURF dose.

Regarding tolerability of AEROSURF administration, the patient interface was well tolerated. Peri-dosing events, which are common in the endotracheal administration of surfactants currently, were infrequent in the AEROSURF group.

Physiological Evaluation

In exploratory analyses of certain safety and tolerability measures to assess whether 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.

Requirement for Invasive Rescue Therapy due to nCPAP failure

Parameters associated with delayed surfactant therapy and nCPAP failure were assessed as part of the safety and tolerability profile of AEROSURF. These data were also used to evaluate whether AEROSURF had an impact on the need for intubation and delayed surfactant therapy due to nCPAP failure.

Overall, the nCPAP failure rates through 72 hours after the start of treatment or randomization to the control group were 63% (15 min), 75% (30 min), 38% (45 min), 29% (60 min) and 38% (90 min) for the five AEROSURF groups compared to 53% in the control group. AEROSURF treatment of 45 minutes and greater (primarily single doses) appears to be associated with lower rates of nCPAP failure representing a 28% (45 and 90 min) and 45% (60 min) relative reduction in nCPAP failure compared to control.

These data, combined with the favorable safety profile, have formed the basis for dose selection in the phase 2b program. The Company has focused on two dose groups (45 and 60 minutes) to define the appropriate upper dose to take into the phase 2b study. In doing so, the Company combined the data in the 45 min and 60 min AEROSURF dose groups (n=15) and assessed nCPAP failure compared to the control group (n=40). The results suggest that: (i) at six hours after the start of treatment or randomization to the control group, 18% of control patients required intubation and delayed surfactant therapy compared to no AEROSURF patients; and, (ii) at 72 hours after the start of treatment or randomization to the control group, 53% in the control group required intubation and delayed surfactant therapy compared to 33% of patients in the AEROSURF group. This represents a 20% absolute reduction or a 38% relative reduction in nCPAP failure compared to control.

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. 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; however, premature infants with RDS frequently require supplemental oxygen. 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.

The data for all five dose groups suggest that AEROSURF is associated with a decrease in FiO2 shortly after initiation of treatment and numerically greater change in PCO2 levels compared to control. The changes in these parameters are consistent with the effects that one would expect to see with a surfactant delivered to the lung.

Performance of the Novel Aerosol Delivery Technology

The aerosol delivery technology 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-related adverse events. Overall, the device was well accepted by NICU personnel at all study sites.

The clinical trials in 29 to 34 week GA premature infants 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 November 20, 2015 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference ID number 10076116.

About AEROSURF®

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. 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.

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 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.

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