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

October 24, 2016
Date of Report (Date of earliest event reported)

Windtree Therapeutics, 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 7.01. Regulation FD Disclosure.

On October 25, 2016, Windtree Therapeutics, Inc. (the "Company") will host a conference call and live webcast at 8:00 a.m. to review: (i) distribution data from a lung deposition study in non-human primates (NHP); (ii) an update on the ongoing AEROSURF® (lucinactant for inhalation) phase 2 clinical program in premature infants 26 to 32 week gestational age receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to nCPAP alone, and (iii) a financial update. A copy of the presentation materials is attached as Exhibit 99.1 to this Current Report on Form 8-K.

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 Windtree Therapeutics, 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.

Reference is made to Item 7.01. On October 25, 2016, the Company will host a conference call and live webcast to review the following: (i) distribution data from a lung deposition study in non-human primates (NHP), (ii) an update on the ongoing AEROSURF phase 2a clinical trial in premature infants 26 to 28 week gestational age and the AEROSURF phase 2b clinical trial in premature infants 29 to 32 week gestational age, and (iii) a financial update.

Results of NHP Study

On October 24, 2016, the Company issued a press release announcing results from the NHP study, which demonstrated that the Company's proprietary aerosol delivery system (ADS) is capable of delivering aerosolized KL4 surfactant throughout all regions of the NHP lung. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

The NHP Study was conducted with three non-human primates, cynomolgus macaques, using the same model ADS that is being studied in the ongoing phase 2 clinical program for AEROSURF in premature infants. The Company believes that the results of the NHP Study, when combined with other studies assessing the ADS, confirm that the ADS is capable of producing aerosolized KL4 surfactant with a particle size in the optimal 1µm to 3 µm respirable range for lung deposition. Moreover, the Company believes that the ADS represents a potential transformative technology that when combined with the Company's KL4 surfactant could address a significant unmet medical need in RDS.

AEROSURF Phase 2 Clinical Program Update

AEROSURF is the Company's novel, investigational drug/device combination product that combines the Company's proprietary KL4 surfactant with its proprietary ADS. AEROSURF is being developed to potentially reduce or eliminate the need for endotracheal intubation and mechanical ventilation in the treatment of premature infants with RDS.

Initial AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age

The Company previously completed and announced the results of a phase 2a clinical trial in 80 premature infants 29 to 34 week gestational age, including 40 in five AEROSURF dose groups and 40 control infants being supported on nCPAP alone. The key objectives of that trial were achieved, including

- the primary objective of evaluating the safety and tolerability of aerosolized KL4 surfactant. Overall, the safety and tolerability profile of the AEROSURF group was generally comparable to the control group; the most common adverse events observed included neonatal jaundice, constipation, apnea and anemia; the most common serious adverse events (SAE) were air leaks (pneumothorax and pneumomediastinum). The incidence of adverse events and SAE in the AEROSURF and control groups were generally comparable and there was no pattern observed of increasing adverse events or SAE with increasing doses of AEROSURF;

- assessment of available physiological data suggesting that aerosolized KL4 surfactant is being delivered into the lungs of premature infants: 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 KL4 surfactant being delivered to the lungs of premature infants. 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 (45, 60 and 90 minutes) studied. In the 45 and 60 minute dose groups combined, (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 27% of patients in the AEROSURF group. This represents a 26% absolute reduction, or a 49% relative reduction, in nCPAP failure compared to control; and
- acceptable performance of the novel aerosol delivery technology in the neonatal intensive care unit (NICU).

These data, combined with the favorable safety profile, formed the basis for dose selection in the phase 2b program. The Company determined to focus on two dose groups (45 and 60 minutes) to define the appropriate upper dose to take into the phase 2b study.

AEROSURF phase 2a clinical trial in premature infants 26 to 28 week gestational age

Following the initial phase 2a clinical trial in the older premature infants, the Company initiated a phase 2a multicenter, randomized, open-label, controlled clinical study in 32 premature infants 26 to 28 week gestational age receiving nCPAP for RDS. This study is designed to evaluate safety and tolerability of aerosolized KL4 surfactant administered in two escalating (30 and 45 minutes) doses, with potential repeat doses, compared to infants receiving nCPAP alone. Based on the results of the initial phase 2a clinical trial, the Company expected that infants 26 to 28 week gestational age could be included in the ongoing phase 2b trial if the safety and tolerability profile from the first two dose groups of the phase 2a trial was adequate and there were no other factors that made such an action imprudent. To assure flexibility in the event that 2 dose groups are not adequate, the study protocol also provided for two additional doses (60 and 90 minutes), if required.

In addition to the primary objective of assessing safety and tolerability, the Company is assessing the performance of the ADS and available physiological and clinical outcome data for information indicating that aerosolized KL4 surfactant is being delivered to the lungs and potentially reducing or delaying the time to invasive surfactant therapy due to nCPAP failure. The Company initially anticipated completing enrollment in this trial in the second quarter of 2016, but execution required additional time, due in part to a longer initiation process than expected at a number of clinical sites. In addition, lower gestational age is generally associated with greater surfactant deficiency, a higher incidence and severity of RDS and other non-respiratory complications of prematurity, causing a greater proportion of this already-smaller patient population to be more quickly intubated than expected, even in the delivery room, resulting in fewer infants eligible for enrollment. In August 2016, the Company announced that it anticipated completing enrollment in the third quarter of 2016 and releasing top-line results in September or early October 2016. The Company has since maintained a rate of enrollment in line with that adjusted guidance.

The second dose group (45 minutes) was completed in September 2016. The Safety Review Committee has met as required after each dose group (twice) to assess the available data and the appropriateness of proceeding to the next dose escalation. The emerging safety profile to date for AEROSURF in premature infants 26-28 week gestational age has been characterized by the following preliminary observations:

- the safety and tolerability profile of the AEROSURF groups was generally comparable to the control group;
- the adverse events and SAE seen were expected for this population and generally comparable between AEROSURF and the control groups; and

- there was no pattern of increased adverse events or SAE with increasing doses of AEROSURF.

Based on Safety Committee review, this age group would meet the safety criteria to be included in the phase 2b clinical trial.

In assessing the data, the Company has observed an early effect on prolonging time to intubation. However, after assessing two doses, the Company has not yet observed a durable effect sufficient to achieve the desired reduction of nCPAP failure rates through 72 hours. The data suggests that younger gestational age infants may potentially require higher doses of surfactant due to a greater surfactant deficiency and more variable inhalation characteristics. Accordingly, the Company plans to continue this phase 2a clinical trial and has progressed to a third dose group (60 minutes), after which it plans to further assess and determine whether it is appropriate to continue to a fourth dose group (90 minutes). As a result of the delay in completing this trial, instead of enrolling the younger infants in the ongoing phase 2b clinical trial, the Company plans to assess these infants in a blinded clinical trial after assessing the additional dose(s) in premature infants 26-28 week gestational age and after obtaining blinded data on older 29-32 week gestational age infants in the ongoing phase 2b clinical trial.

AEROSURF phase 2b clinical trial in premature infants 26 to 32 week gestational age

The ongoing AEROSURF phase 2b clinical trial is a multicenter, randomized, controlled study with masked treatment assignment in up to approximately 240 premature infants and is designed to evaluate the safety and tolerability of aerosolized KL4 surfactant (including with up to two potential repeat doses) administered in two dose groups (25 and 50 minutes) compared to infants receiving nCPAP alone. The key objectives of this trial are:

- to identify an acceptable endpoint by evaluating the following endpoints to find evidence of efficacy:
    - time to nCPAP failure (defined as the need for intubation and delayed surfactant therapy),
    - incidence of nCPAP failure, and
    - physiological parameters indicating the effectiveness of lung function;
- to identify the dose regimen for the planned phase 3 clinical program; and
- to provide an estimation of the expected efficacy margin of AEROSURF treatment.

The Company plans to conduct this trial in approximately 50 clinical sites in the U.S., Canada, Europe and Latin America. Under the recent clinical projections, enrollment was expected to include 180 premature infants 29 to 32 week gestational age, and, after completion of the ongoing phase 2a clinical trial, 60 premature infants 26 to 28 week gestational age. The Company anticipated releasing top-line results in the first quarter of 2017.

Because the phase 2a clinical trial in premature infants 26 to 28 week gestational age has been extended, as discussed above, the Company no longer plans to enroll the younger infants in this phase 2b clinical trial. Instead, the Company is planning to implement the following adjustments to the phase 2b clinical plan:

- the trial will continue to enroll only premature infants 29 to 32 week gestational age and will focus on this larger market segment of the total population,
- the Company will continue to study a total of up to approximately 240 premature infants (instead of 180 older infants as originally planned), to maintain a similar current statistical power and provide an opportunity for a stronger data set and potentially statistically better results to better support regulatory efforts and potential business development and financing opportunities,
- the trial is expected to take approximately 90 additional days to complete, and
- the Company expects to release top line results in mid-year 2017.

The Company believes that the approach outlined in this Form 8-K, including the investment of additional time in both ongoing clinical trials, provides the opportunity for a stronger data set and potentially a statistically better phase 2b result to support future regulatory activity and potential business development and financing opportunities.

The AEROSURF phase 2b clinical trial has been supported in part by a Phase II Small Business Innovation Research (SBIR) grant valued up to $2.6 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), and an initial $1.0 million award under a grant valued at up to $2.6 million, award number 2R44HL107000-03. The content of this Current Report on Form 8-K is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health.

Financial Update

In addition, the Company reports that at September 30, 2016, cash and cash equivalents were $12.4 million, and long-term secured debt was $25 million ($12.5 million principal due in each of February 2018 (subject in certain specified event to deferral) and February 2019). For the quarter ended September 30, 2016, the Company's net operating cash outflows were $8.4 million offset by $0.4 million of net proceeds from financings under the Company's at-the-market equity sales (ATM) Program with Stifel, Nicolaus & Company, Incorporated. Regarding the third quarter ATM financings, the Company sold 159,051 shares at a net average price of approximately $2.64 per share. 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 February 2017.

The Company continues its efforts to secure the additional capital that will be required to continue our AEROSURF development program and fund our operations. The Company is actively pursuing all or a combination of potential strategic alliances, collaboration agreements and other strategic transactions and also may seek additional capital through public or private equity offerings (including under the ATM Program). In May 2016, the Company received a deficiency letter from Nasdaq that it is no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. The Company submitted its plan and was granted an extension of time until November 15, 2016 to regain compliance with the listing requirement. If the Company has not regained compliance on that date, the Staff of Nasdaq will issue a delisting notice and the Company will be entitled to appeal the Staff's determination to a Listing Qualifications Panel. In that event, we would expect that a hearing would be scheduled in late December 2016 or January 2017. There can be no assurance that we will be successful in implementing our plan to regain compliance with the minimum stockholders' equity rule.

The Company believes that with the progress observed to date in the AEROSURF phase 2 clinical program, the recent Fast Track designation granted by the [FDA] and other potential developments, it will be successful in securing the additional capital required to complete its AEROSURF phase 2 clinical program and to fund its operations going forward. However, there can be no assurance that the Company will be successful in securing any such capital when needed, if at all.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits:

99.1 Slide Presentation dated October 25, 2016.
99.2 Press Release dated October 24, 2016.

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.

Windtree Therapeutics, Inc.

By: /s/ Craig Fraser
Name: Craig Fraser
Title: President and Chief Executive Officer

Date: October 25, 2016

WINDTREE THERAPEUTICS™

Investor Conference Call
October 25, 2016

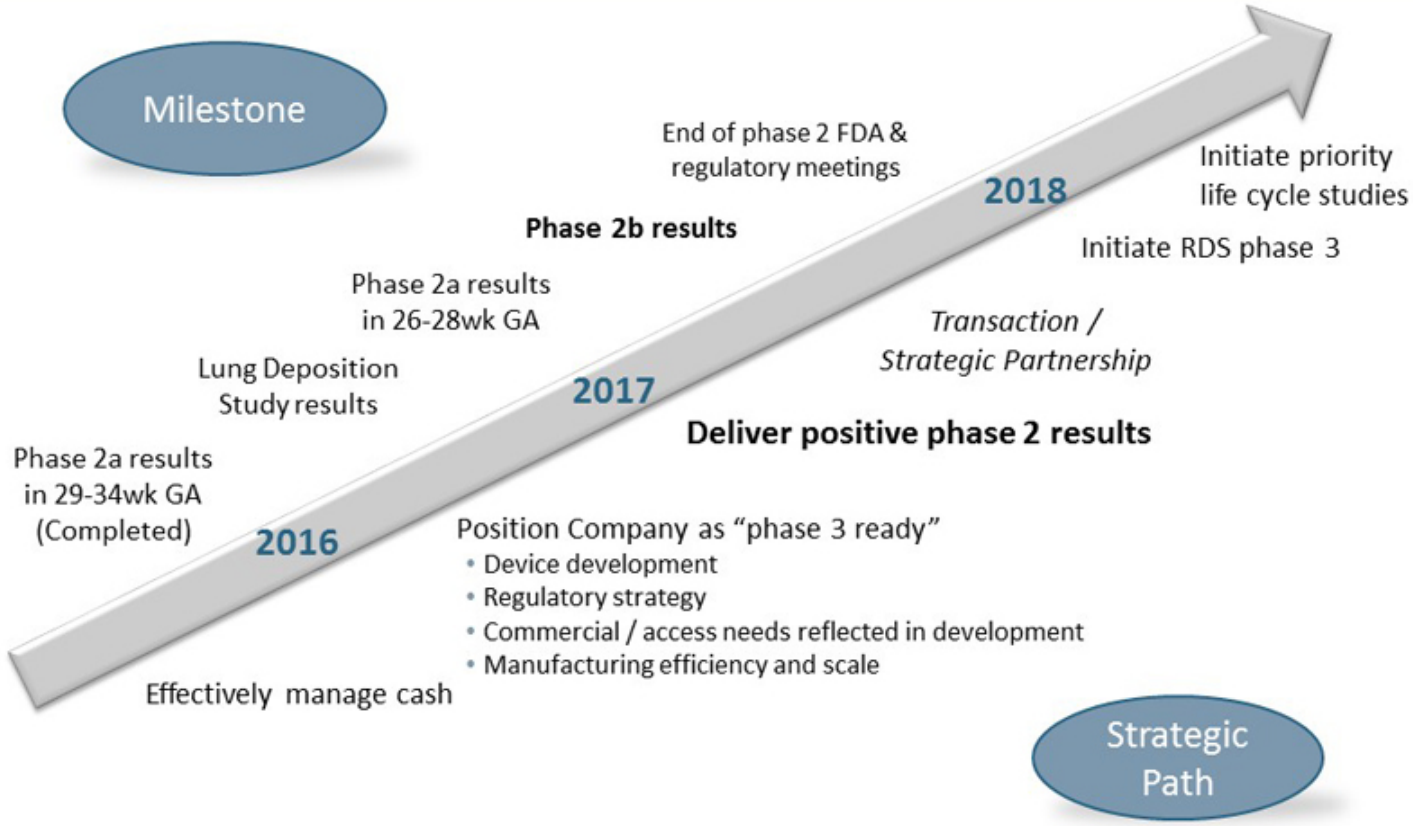
NASDAQ:WINT

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").

This presentation under no circumstances shall be construed as an offer to sell or as a solicitation of an offer to buy any of the Company's securities. In addition, the information presented in this deck is qualified in its entirety by the Company Filings. The reader is encouraged to refer to the Company Filings for a fuller discussion of the matters presented here.

Focus on Execution for Value Creation



WINDTREE THERAPEUTICS

Agenda

- Lung Deposition Study in Non-Human Primates
- AEROSURF® Phase 2a Study (26-28 week gestational age) Update
- AEROSURF Phase 2b Study Update
- Financial Update
- Summary

Lung Deposition Study in Non-Human Primates

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Pulmonary Drug Delivery Through Inhalation

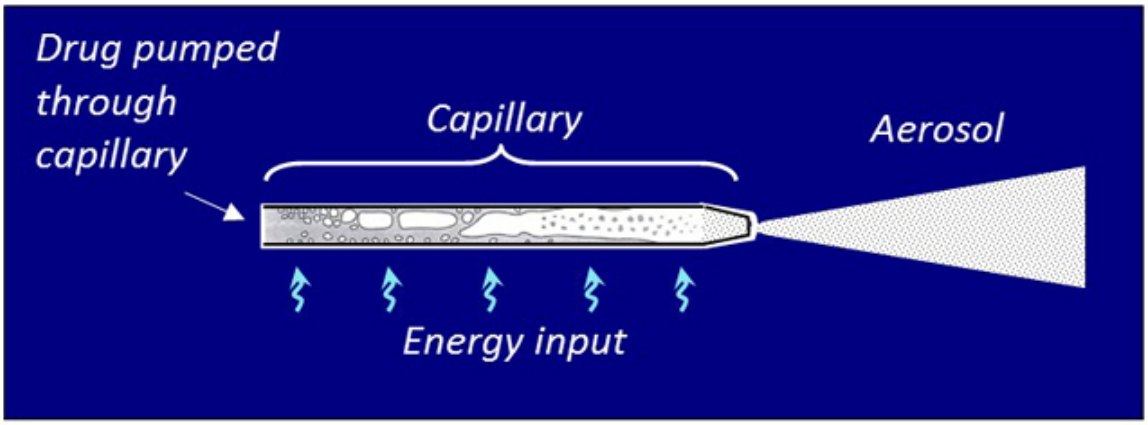
Pulmonary drug delivery through inhalation can be very advantageous but comes with significant challenges:

- Creating the appropriate particle size and aerosol concentration
- Producing consistent drug output from the aerosol device
- Delivering the drug through the patient's anatomy and other breathing apparatus
- Delivering the drug in different breathing characteristics

Aerosolizing surfactant has been a particularly daunting task

- Currently available liquid surfactants are generally effective for treating RDS but are administered via invasive intubation, which increases the risk of serious complications – thus the pursuit for a noninvasive approach
- Surfactant characteristics make it a particularly challenging substance to aerosolize due to:
  - High viscosity; tendency to foam and bubble
  - The need to avoid clogging or obstruction in the delivery system
  - The need to deliver an adequate dose in the right particle size in a reasonable amount of time
- Many have tried but there has been little success in aerosolizing surfactants and there are no commercially available devices
- Given the characteristics of RDS and of premature infants, as well as the heightened need for efficacy and safety in this fragile patient population, the performance standard is high

Windtree's Proprietary Aerosol Delivery System (ADS) is a Novel Approach

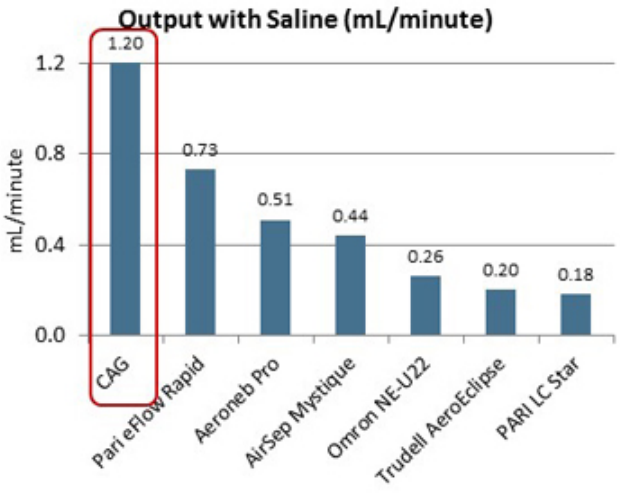


- Delivering surfactant under pressure through a heated capillary has been shown to successfully create a consistent, controllable aerosol with particle sizes appropriate for distal lung delivery in volumes that are clinically relevant
- KL4 surfactant has been shown to retain its physicochemical properties after aerosolization using this process
- Windtree holds exclusive patent rights covering this unique ADS technology

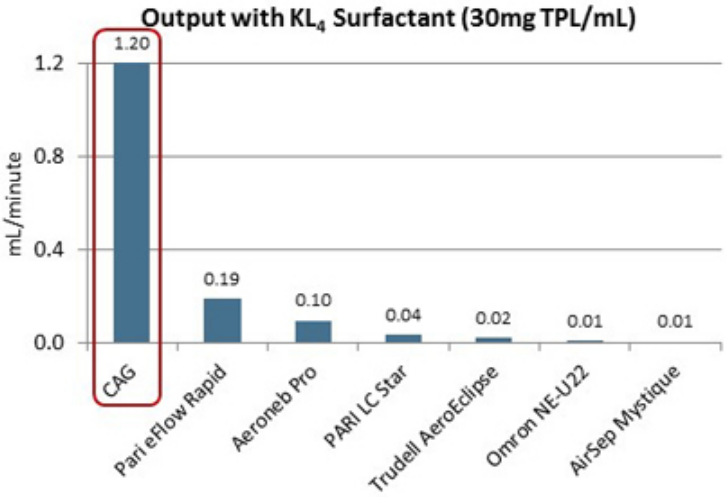
Aerosol Delivery System (ADS) Performance is Different

ADS technology provides better output rate

Aerosol output rate



Saline output of ADS technology is close to double the next best technology tested



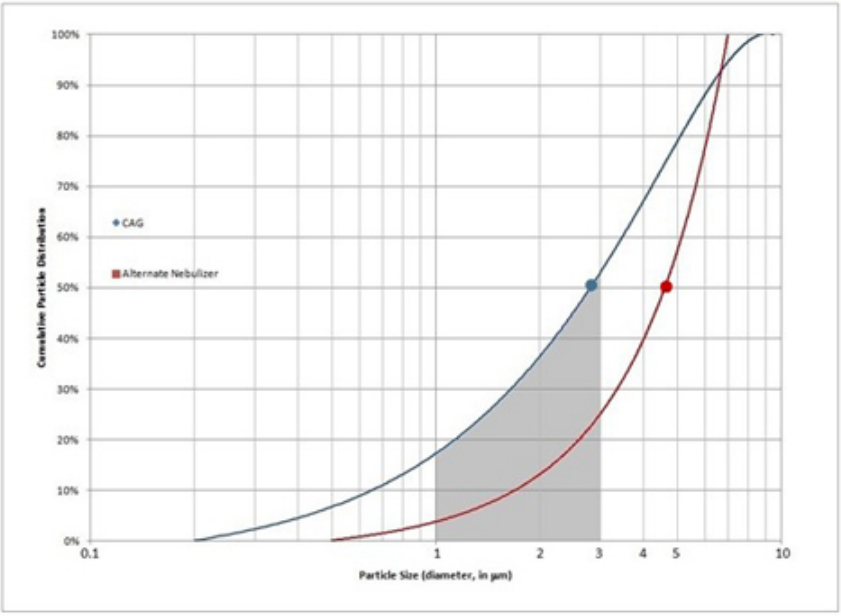
KL_4 surfactant output of ADS technology is six times the next best technology tested

Additionally, unlike other available aerosolization technologies, the ADS technology delivers a consistent surfactant output minute by minute, device after device

WINDTREE THERAPEUTICS

Source: Windtree - Data on file.

Aerosol Delivery System (ADS) Technology Delivers Optimal Particle Size



ADS system produces more particles in the optimal 1 to 3µm range than a commercially available vibrating mesh nebulizer

- ADS aerosol particle size optimized for lung delivery deposition: MMD = 2.8µm
- Comparator nebulizer aerosol particle size larger (MMD = 4.6µm)
- Larger particles more likely to impact before getting to the distal airway

WINDTREE THERAPEUTICS

Source: Windtree - Data on file

Aerosol Delivery System
Summary

Aerosol Delivery System allows for a very well controlled and consistent KL4 surfactant delivery system:

- *High output*
- *Pre- and post-aerosolization characteristics of KL4 surfactant are comparable*
- *Consistent output rate and particle size from device to device*
- *Consistent of output rate and particle size throughout the dosing period*

Controlled and reproducible experience

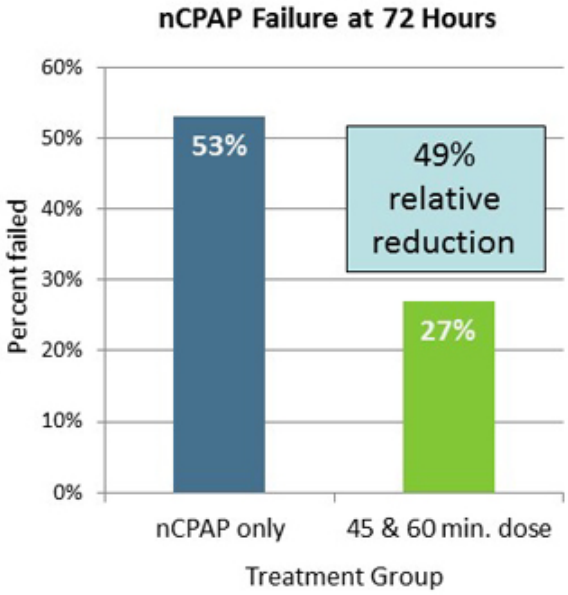
A solid platform for life-cycle advancements

WINDTREE THERAPEUTICS

Noninvasive Surfactant Delivery in the AEROSURF® 2a Clinical Trial

Phase 2a Clinical Trial (29 to 34 wk GA)
Initial Physiological and Efficacy Data Summary

- AEROSURF produces clinical and physiological changes that are expected with surfactant therapy
- AEROSURF may reduce the rate of nCPAP failure as well as prolong the time to nCPAP failure, providing initial clinical evidence suggesting that AEROSURF is getting into the lungs where it needs to act
- The safety and tolerability profile of AEROSURF was generally comparable to the control group



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Objective: Obtain Direct Evidence of Successful KL4 Surfactant Delivery Using the Aerosol Delivery System (ADS)

Can we demonstrate that aerosolized KL4 surfactant is actually getting into the lung?

Rationale:

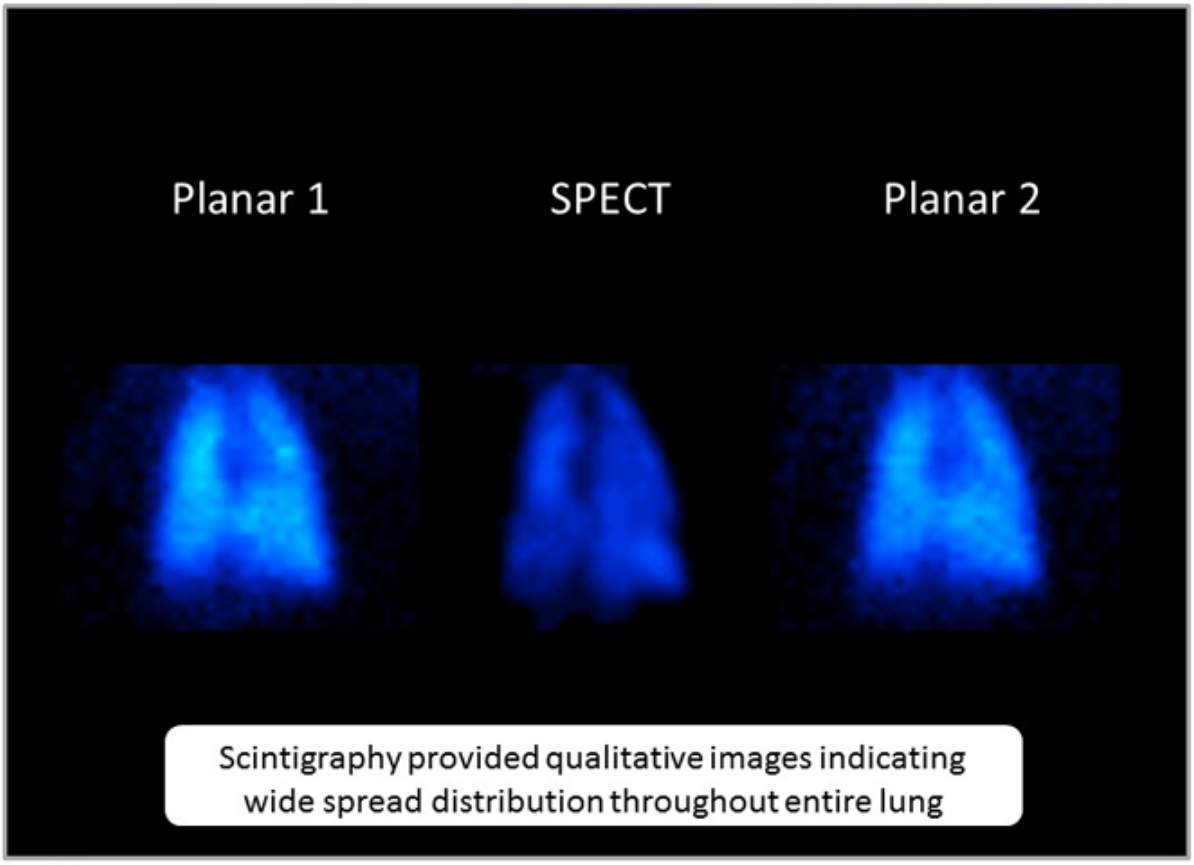
- Use of non-human primates (cynomolgus macaques)
  - Nose, throat, & lung anatomy comparable to infants
  - Respiratory function similar to preterm infants
  - Lightly anesthetized, spontaneously breathing via nasal cannula
- Use of technetium-99m
  - Capture images using gamma scintigraphy
  - Short radioactive half-life: does not require sacrifice and allows for re-use
- Ability to deliver aerosolized KL4 surfactant via nCPAP using the ADS

Lung Deposition Study
Protocol Summary

- *In vitro* studies performed to validate that admixed technetium-99m (^{99m}Tc) travels with the aerosolized KL4 surfactant in a measurable and consistent manner
- Radiolabeled KL4 surfactant aerosolized using Aerosol Delivery System (ADS), delivered via nasal cannula in 3-10 min exposures
- Radiolabeled KL4 surfactant inhaled from a nCPAP circuit (3 L/min aerosol flow & 3 L/min CPAP flow) by 3 cynomolgus macaques
- Measured total & regional pulmonary deposition by a series of gamma images
  - Acquisition of a 2-D planar image followed immediately by a 3-D SPECT image, then a repeat second planar image
  - Images analyzed to determine the pulmonary & extra pulmonary (nasal, throat, trachea and stomach) deposition
  - SPECT data used to determine regional lung deposition using a quantitative model

Lung Deposition Study - Distribution Information

nCPAP: NHP-3 Gamma Images



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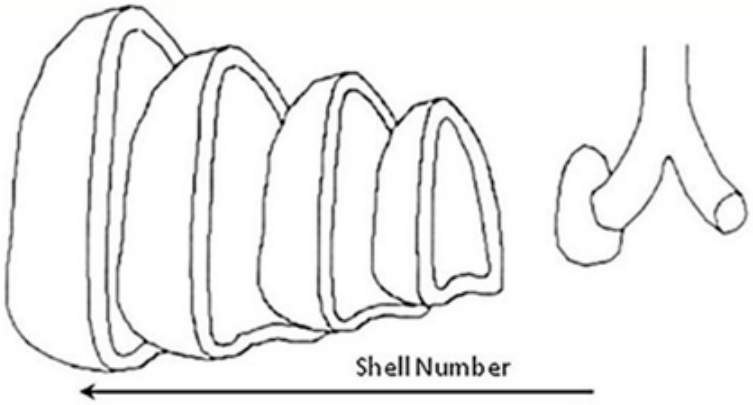
Lung Deposition Study – Quantitative Analysis of Distribution

Model divides the lung into 10 equal volume shells



Transverse view | Coronal view | Sagittal view

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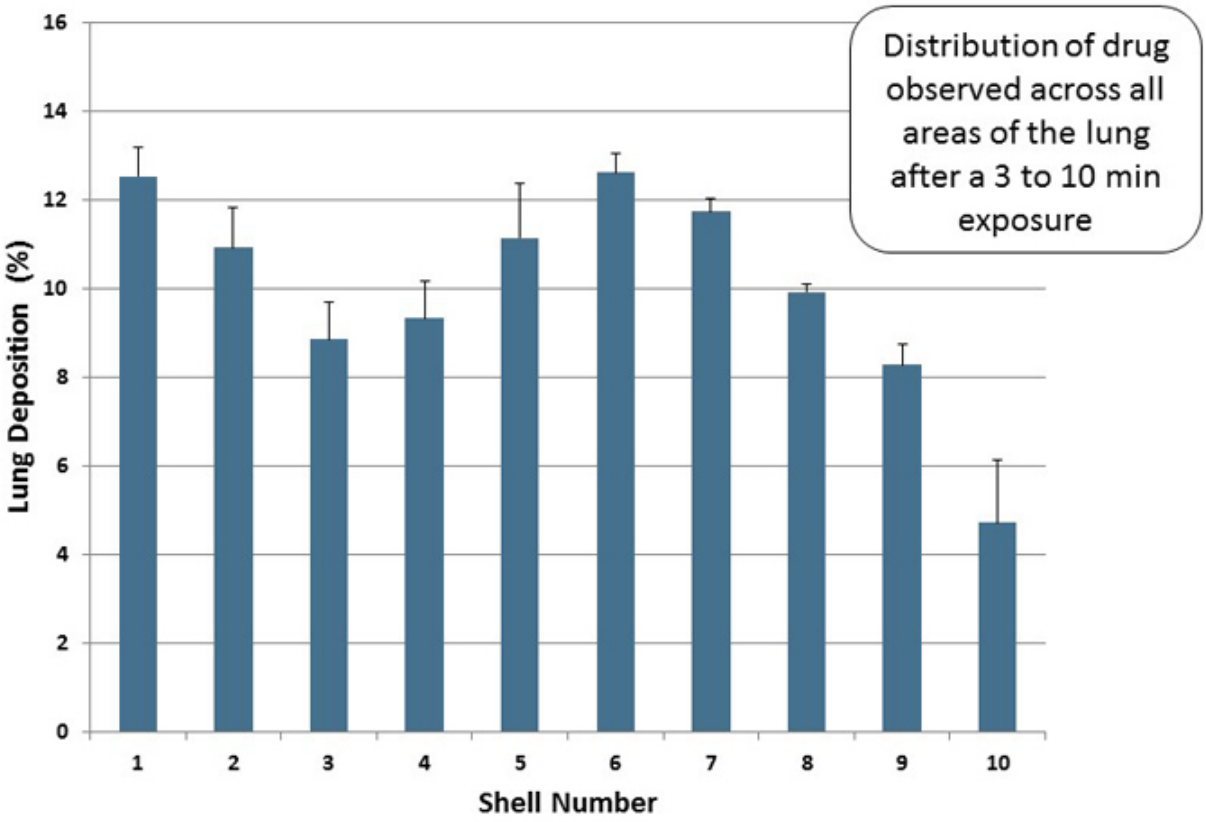
Fleming et al, J Aerosol Med Pulm Drug Del. 2012; 25(Suppl 1) S29-S51

Lung Deposition Study – Quantitative Analysis of Distribution

Total Deposition Across 10 Equal Shells



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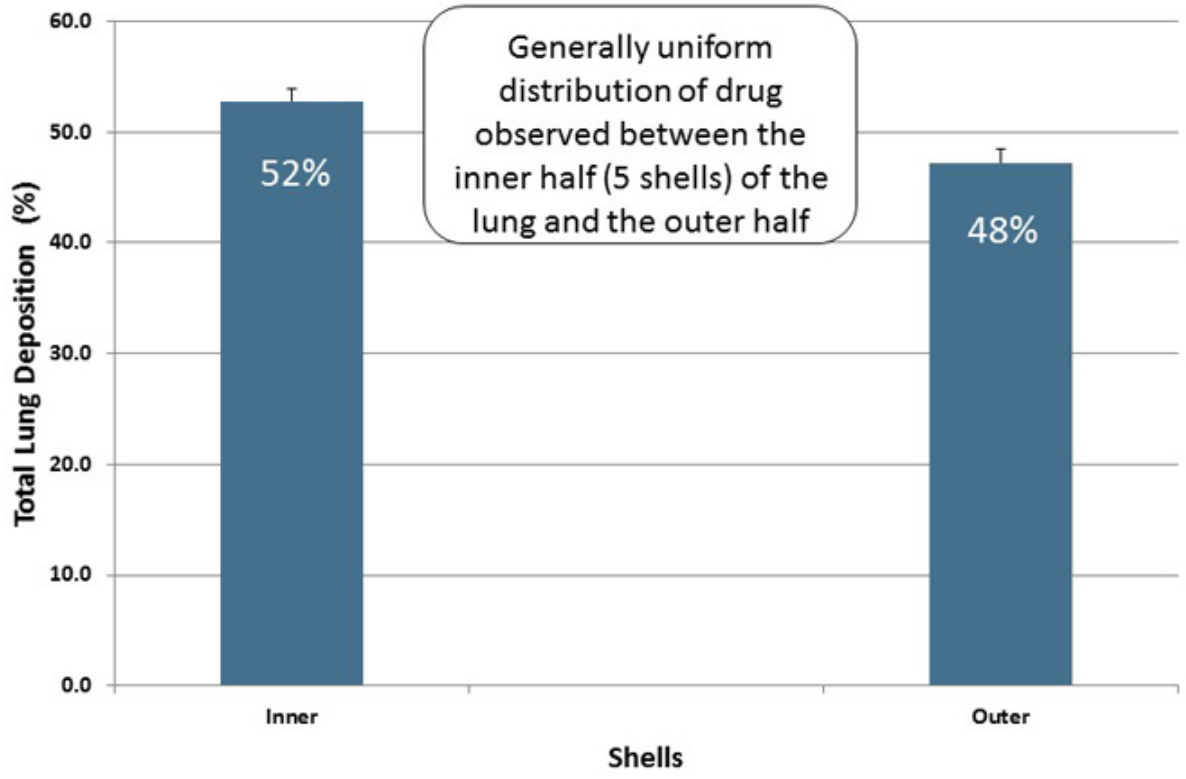
Lung Deposition Study – Quantitative Analysis of Distribution

Total Deposition By Inner and Outer Shell



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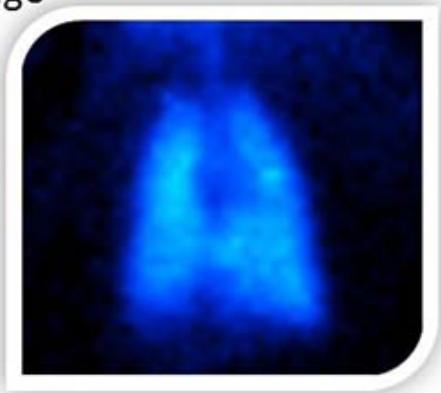
Lung Deposition Study
Summary

- The portion of aerosolized KL_4 surfactant, delivered to the lungs using the Aerosol Delivery System (ADS) via nCPAP, is deposited throughout the lungs of NHPs within a few minutes
- The aerosol is observed to be homogeneously deposited in all regions of the lungs
- These results are complemented by the clinical evidence seen in our 2a trial in premature infants 29 to 34 weeks gestational age
- This study, along with other testing and studies, should serve as a validation of our ADS ability to effectively aerosolize and deliver KL_4 surfactant



WINDTREE THERAPEUTICS

Windtree as a Platform Company

KL4 surfactant + the innovative Aerosol Delivery System (ADS) technology enable a platform strategy that could enable potential prevention / protection, treatment, and delivery of therapeutics in an array of diseases

		Program Focus	Potential Application
RDS	Phase 2b		
ALI - Radiation	Preclinical development	Prevention of acute & chronic changes (fibrotic)	Metastatic Breast & Lung Rad.Onc; Biodefense
ALI - Viral	Preclinical	Mitigate lung injury, prevent vent. / ECMO	SARS, H1N1, MERS, Viral pneumo (peds), etc.
ALI - Chemical	Preclinical	Mitigate lung injury, prevent vent. / ECMO	Defense, industrial
Drug Delivery	Preclinical	Better delivery drugs to lungs / higher concentration	Antivirals, Antibiotics, chemo agents, anti-fibrotic...

Planned Assessment & Prioritization in Q4'16

Cystic Fibrosis	ECMO Liberation	Post Surgical Adhesion	COPD
Acute Asthma	Severe Pneumonia	Chronic Sinusitis	Lung Transplant

+ Others?

RDS Clinical Program Update

WINDTREE THERAPEUTICS

AEROSURF® Fast Track Designation

- In September 2016, Windtree announced that it had received a Fast Track designation by the FDA for its AEROSURF RDS program
- The Fast Track program was created by the FDA to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical needs
  - benefit from more frequent communications and meetings with FDA to review the drug's development plan
  - may qualify for priority review to expedite the FDA review process, if relevant criteria are met
- This designation underscores the significant need to reduce the use of invasive intubation and mechanical ventilation, which are currently required to administer life-saving surfactant therapy to premature infants with RDS

RDS Development Program

- Phase 2a 29-34 week gestational age (GA), 80 patients - completed
- Phase 2b 29-32 week GA, up to 240 patients - ongoing
- Phase 2a 26-28 week GA, up to 64 patients - ongoing
- Lung Deposition Study - completed

Rationale for Separate Phase 2a Study in 26-28 week GA

Gestational age (GA) has an important influence on many factors

FDA recommended the younger GA group be studied separately

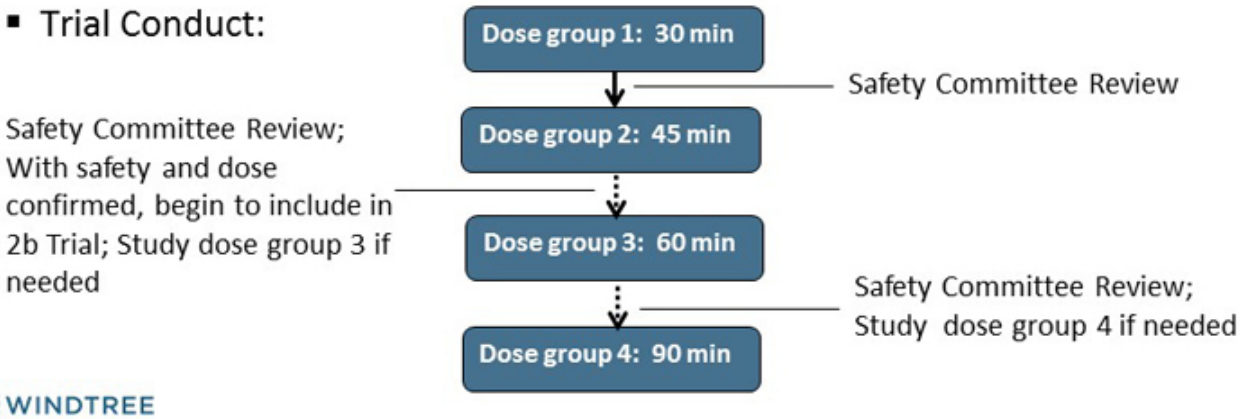
The lower the GA (e.g. 26 weeks), the greater the incidence of complications of prematurity

- Respiratory failure
  - higher incidence and severity of RDS
  - greater surfactant deficiency
- Apnea of prematurity is more common
- Non-respiratory complications of prematurity, such as NEC and IVH are more common

Younger premature infants 26 to 28 week GA may require potentially higher doses of surfactant due to a greater level of surfactant deficiency and smaller inhalation volume

Phase 2a Trial in 26-28 Week Gestational Age (GA) – Trial Design

- Objectives:
  - Safety and tolerability
  - Physiological data assessment for data indicating that aerosolized KL4 surfactant is being delivered to the lung and potentially reducing or delaying nCPAP failure
- Design:
  - 30 min; 45 min (50 and 75 TPL mg/kg) - 8 active, 8 control per group
  - As needed, 60 min; 90 min (90 and 140 TPL mg/kg) - 8 active, 8 control per group
- Trial Conduct:



WINDTREE THERAPEUTICS

Phase 2a Trial in 26-28 Week Gestational Age (GA)

Enrollment Update

Trial has taken longer than initially expected:

- 26-28 week GA infants only represent an estimated 10% - 15% of RDS infants[1]
  - Greater proportion of these infants are quickly intubated (even in delivery room)
- Site start-up has taken longer than initially expected

Enrollment trends on track with previously announced adjusted timelines:

- Dose Group 2 – completed in September
- Dose Group 3 – ongoing
- Dose Group 4 – if needed

1. Windtree primary market research (2014) applied to IMS Midas data (2012); CDC National Vital Statistics, 2014; Healthcare Costs and Utilization Project (HCUP), 2013; Agency for Healthcare Research and Quality, 2012; Births by birth weight (CDC website). Represents U.S. only.

Phase 2a Trial in 26-28 Week Gestational Age (GA)

Safety and Tolerability Assessment for Two Dose Groups (30 and 45 min)[1]

- The safety and tolerability profile of AEROSURF® remains generally comparable to the nCPAP control group
- The adverse events and serious adverse events (SAE) seen were expected for this population and generally comparable between AEROSURF and nCPAP control group
- There was no pattern of increased adverse events or SAE with increasing doses of AEROSURF
- Based on Safety Review Committee review, this age group would meet the safety requirements to be included in the phase 2b trial

1. Preliminary and unaudited data

Phase 2a Trial in 26-28 Week Gestational Age (GA)

Observations to Date

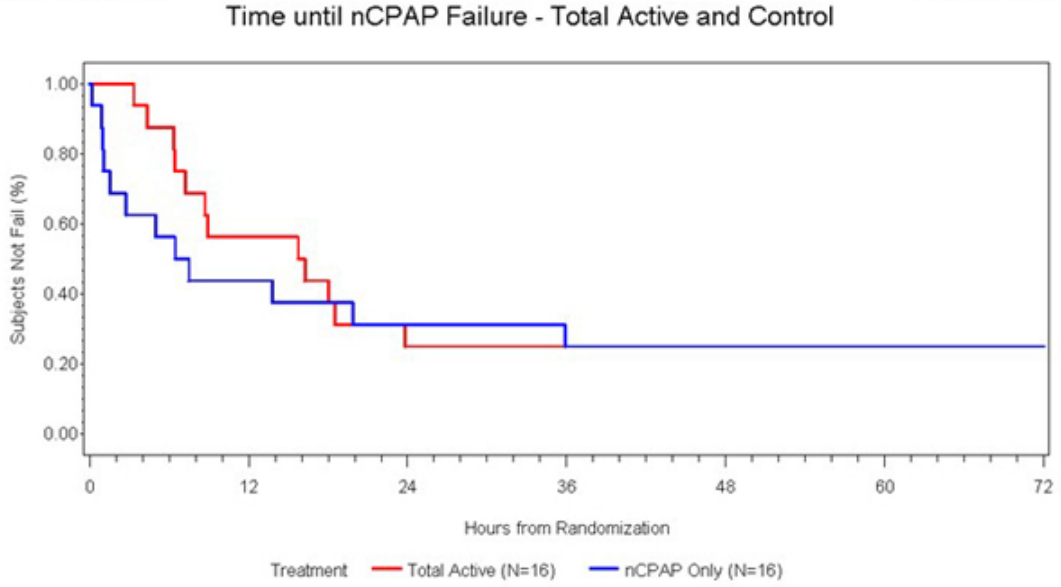
- We have observed a positive early effect on prolonging the time to intubation but a more durable effect is needed to reduce nCPAP failure rates at 72 hours
- Other Observations
  - High nCPAP failure rates in the control group – in line with expectations
  - Small numbers thus far – 16 treated, 8 per dose
  - Site variability and complications of prematurity create a study background which can be somewhat challenging with small study patient numbers
- We have not yet identified the dose(s) necessary to support moving into phase 2b and beyond at this point

Phase 2a Trial in 26-28 Week Gestational Age (GA)

Time to nCPAP Failure for Two Dose Groups (30 and 45 min)[1]

Safety Review Committee
Protocol 03-CL-1401

Data: 10/17/2016



AEROSURF® doses of 30 and 45 minutes may have an early impact on prolonging time to nCPAP failure but a more durable effect is needed to reduce the rate of nCPAP failure rates at 72 hours

1. Preliminary and unaudited data

WINDTREE THERAPEUTICS

Lessons learned in the phase 2a trial in 29-34 week gestational age

- We observed a positive early effect on prolonging the time to intubation in all five dose groups
- While all doses delayed early intubation, the effect on rates of intubation were not observed in the first two dose groups
- The three higher dose groups (45, 60 and 90 min) resulted in a reduction in the rate of intubation at 72 hours and formed the basis for dose selection in the phase 2b trial
  - As noted, 26-28 week gestational age (GA) babies may potentially require higher doses to exhibit a similar effect
- We may potentially be seeing a similar pattern as we observed in our previous phase 2a trial in 29-34 week GA, however studying more patients at higher doses will provide the answer

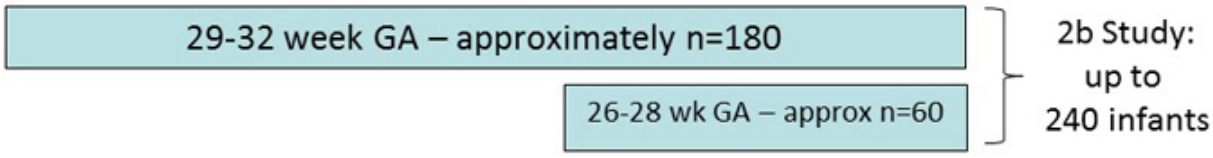
Phase 2a Trial in 26-28 Week Gestational Age (GA)

Path Forward

Study is ongoing: Continue with more infants at the pre-designated higher dose(s)

- Continue dose finding and confirmation through dose group 3 (and possibly dose group 4)
  - Assessment after dose group 3 expected later this quarter / early next quarter
- We do not plan to include this 26-28 week GA sub-group in the ongoing Phase 2b
- We plan to study the 26-28 week GA sub-group in a blinded manner after obtaining data on the older premature infants in the ongoing phase 2b trial

Original Plan: Phase 2b Trial in 26-32 Week Gestational Age (GA)



- Objectives:
  - Provide evidence of efficacy on an acceptable endpoint
  - Identify dose regimens for phase 3 study
  - Provide estimation of effect size
- Design and Execution:
  - Blinded trial in approximately 50 centers globally
  - 25 min; 50 min (40 and 80 TPL mg/kg) + control; 80 infants per group
  - Up to 3 doses
  - Given the previous large 2a study experience and results, start with 29-32 week GA and later open to 26-28 week GA infants once safety and dose finding was completed in the ongoing phase 2a study in 26–28 week GA premature infants.
  - Top line results by the end of Q1 '17 from a pooled analysis of up to 240 infants

Phase 2b Trial Moving Forward

29-32 week GA – approximately n= 240

- Complete phase 2b with 29-32 week GA infants
  - focused solely on the larger market segment (older infants)
- Maintain current statistical power by continuing to study this group in up to 240 subjects:
  - Provides the opportunity for a stronger data set and statistically better results (as compared to ending the trial at 180 infants) to support future regulatory activity and potential business development and financing opportunities
- Trial execution extends approximately 90 days
- Top line results expected in mid-year 2017

Financial Update

- Cash and cash equivalents of $12.4 million as of September 30, 2016
  - Q3'16 net operating cash burn of $8.4 million offset by $0.4 million of net proceeds from financings under the at-the-market (ATM) facility (159.1K common shares at an average price of $2.64 per share)
- $25 million of long-term debt : $12.5 million due in February 2018 (subject to potential deferral) and in February 2019
- The Company anticipates that existing cash (before any additional financings) is sufficient to fund operations through February 2017
- The Company is in active discussions with respect to potential strategic and other transactions to secure additional capital and ensure adequate financial resources through phase 2b data with a modest cushion

Conference Call Summary

- Lung Deposition Study in Non-Human Primates
- AEROSURF® Phase 2a Study (26-28 week gestational age)
- AEROSURF Phase 2b Study
- Financial
- AEROSURF Fast Track designation

High Value-Creating Potential

WINDTREE THERAPEUTICS™

- ✓ Well characterized asset and target application in RDS
- ✓ Potentially transformative therapy for the important, acute neonatology market that has a clear unmet need and is growing
- ✓ Building data base of potential safety, clinical effect and benefit information
- ✓ Opportunity to build a positive health economic position
- ✓ Broad IP with the potential to build a pipeline of aerosolized surfactant therapies to address a variety of respiratory diseases
- ✓ Experienced management team focused on rigorous clinical execution and effective cash management
- ✓ Significant near-term milestones

Q&A

"Striving to deliver Hope for a Lifetime!"

Exhibit 99.2

Windtree Releases Data from Lung Deposition Study in Non-Human Primates Demonstrating Uniform Distribution of Aerosolized KL_4 Surfactant in all Regions of the Lung

Study Provides Further Validation of Company's Proprietary Aerosol Delivery Technology

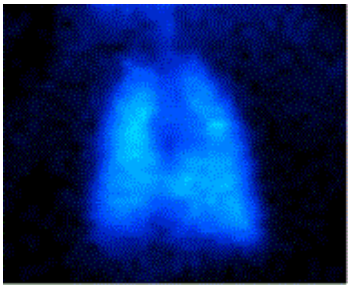
Management to Discuss Results on a Conference Call, Tuesday, October 25, 2016 at 8:00 a.m.

Warrington, PA – October 24, 2016 - Windtree Therapeutics, Inc. (Nasdaq: WINT), a biotechnology company focused on developing aerosolized KL_4 surfactant therapies for respiratory diseases, today released data from a lung deposition study conducted in non-human primates (NHPs) that demonstrates the Company's proprietary aerosol delivery system (ADS) is capable of delivering aerosolized KL_4 surfactant throughout all regions of the lung. The study consisted of a series of experiments in NHPs designed to assess the distribution and deposition of aerosolized KL_4 surfactant in the lung when administered using the ADS. The Company is developing the ADS as part of its lead development program, AEROSURF® (lucinactant for inhalation). AEROSURF is currently being studied in a phase 2b clinical trial as a potential noninvasive treatment for respiratory distress syndrome (RDS) in premature infants. The Company will host a conference call and live webcast on Tuesday, October 25, 2016 at 8:00 a.m. EDT to provide additional details of the study results as well as provide an update on the AEROSURF phase 2 program.

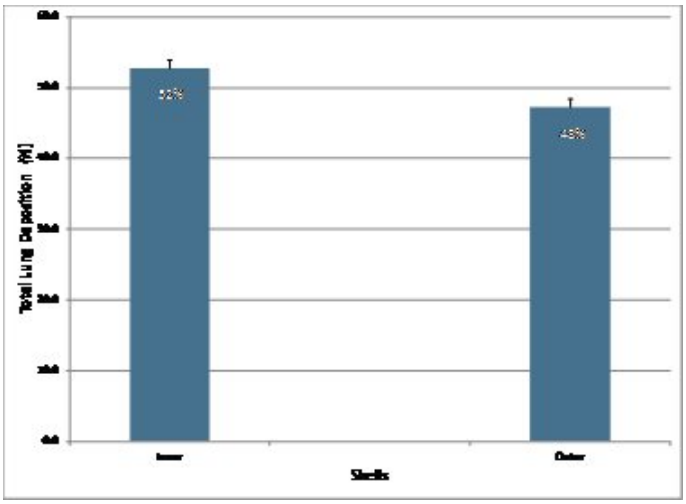
"These study results confirm the ability of our aerosol delivery technology to overcome the barriers of successfully aerosolizing and delivering a surfactant with particle sizes appropriate for deep lung delivery with uniform distribution across all regions of the lung," commented Craig Fraser, President and Chief Executive Officer. "These results not only support the premise of our AEROSURF RDS program, but also complement the clinical evidence seen in our phase 2a trial in premature infants 29 to 34 week gestational age and provide further insight into other potential applications of this novel technology in the future."

Data from this lung deposition study were generated from an *in vivo* distribution study using three NHPs, cynomolgus macaques, which received three-to-ten minute exposures of technetium-labeled KL_4 surfactant that was aerosolized using the same model ADS currently being used in the AEROSURF phase 2b clinical program. After administration, researchers immediately acquired 2-D planar images followed by 3-D SPECT images and then a second 2-D planar image to assess overall pulmonary distribution. Additionally, the 3-D SPECT lung data were analyzed using a quantitative methodology whereby regional distribution was assessed across ten equally sized shells (or layers) of the lung, from the innermost shell through the outermost shell.

Results from the analysis of the 2-D planar and 3-D SPECT images show that aerosolized KL_4 surfactant, delivered using the ADS via constant flow nasal continuous positive airway pressure (nCPAP), was generally uniformly deposited in all regions of the NHPs lungs.



Results from a quantitative analysis further demonstrated that there was generally uniform distribution in all regions of the lung, with an average total lung distribution of 52 percent in the five inner shells and 48 percent in the five outer shells.



“We are extremely pleased with the results of this study because, along with other work we have done, it serves as yet another validation of the potentially transformational capabilities of our ADS device, which aerosolizes our KL_4 surfactant in a consistent and controlled flow and delivers it throughout the lungs to the areas where a surfactant needs to reach to produce its beneficial effects.” commented Steve Simonson, M.D, Senior Vice President and Chief Development Officer.

Conference Call and Webcast Details
The Company will host a conference call and webcast (including a slide presentation) at 8:00 a.m. EDT on Tuesday, October 25, 2016 to provide updates on the AEROSURF® phase 2 clinical program and the lung deposition study in non-human primates.

To participate in the live call and take part in the question and answer session, dial (844) 802-2436 (domestic) or (412) 317-5129 (international). The live webcast, including a slide presentation, can be accessed at http://windtreetx.investorroom.com/events.

A replay of the conference call will be accessible one hour after completion through November 1, 2016 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference number 10095419. An archive of the webcast can be accessed on the Company’s website at http://windtreetx.investorroom.com/events.

About AEROSURF®
Windtree's lead product candidate is AEROSURF (lucinactant for inhalation), a novel, investigational combination drug/device product that combines the Company's proprietary KL_4 surfactant and 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). Enrollment is ongoing in a phase 2b clinical trial to study AEROSURF administered to premature infants receiving nasal continuous positive airway pressure (nCPAP) for RDS, compared to infants receiving nCPAP alone. The phase 2b trial is a global trial with clinical sites in North America, Europe and Latin America.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is a clinical-stage biotechnology company focused on developing novel surfactant therapies for respiratory diseases and other potential applications. Windtree's proprietary technology platform includes a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to endogenous pulmonary surfactant and novel drug-delivery technologies being developed to enable noninvasive administration of aerosolized KL_4 surfactant. Windtree is focused initially on improving the management of respiratory distress syndrome (RDS) in premature infants and believes that its proprietary technology may make it possible, over time, to develop a pipeline of KL_4 surfactant product candidates to address a variety of respiratory diseases for which there are few or no approved therapies.

For more information, please visit the Company's website at www.windtreetx.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 to differ materially from the statements made. Examples of such risks and uncertainties include those risks related to Windtree's aerosolized KL_4 surfactant development programs, including for AEROSURF, which may involve time-consuming and expensive clinical trials that may be subject to potentially significant delays or regulatory holds, or fail; risks related to the development of aerosol delivery systems (ADS) and related components; risks related to the manufacture by contract manufacturers or suppliers of drug products, drug substances, ADS and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including those of the U.S. Food and Drug Administration or other regulatory authorities that 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 Windtree's products; and other risks and uncertainties described in Windtree'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.

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