UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

August 27, 2018
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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

Executives of Windtree Therapeutics, Inc. (the "Company") have updated the Company's corporate presentation and plan to present to potential investors and post on the Company's website the information contained in the presentation which is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits:

99.1 Windtree Therapeutics, Inc. Corporate Presentation dated August 2018.

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, potential strategic transactions and collaboration agreements, the success of the Company's product development activities, the timing of planned clinical trials, cash flows, future revenues, 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. The Company undertakes 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: August 27, 2018

Exhibit 99.1

WINDTREE THERAPEUTICS™

Corporate Presentation
August 2018

OTCQB:WINT

Forward-looking Statement

To the extent that statements in this presentation are not strictly historical, including statements about the Company's clinical development programs, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, 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")

Under no circumstances shall this presentation 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 should refer to the Company Filings for a fuller discussion of the matters presented here.

Windtree Therapeutics

- Public, small cap biopharmaceutical / medical device company
- Based in Warrington, PA with 27 employees
- Focused on acute markets with a lead program expected to address a significant need and significantly expand the Respiratory Distress Syndrome (RDS) in premature infants market (currently valued at ~$400 million*)
- Windtreetx.com

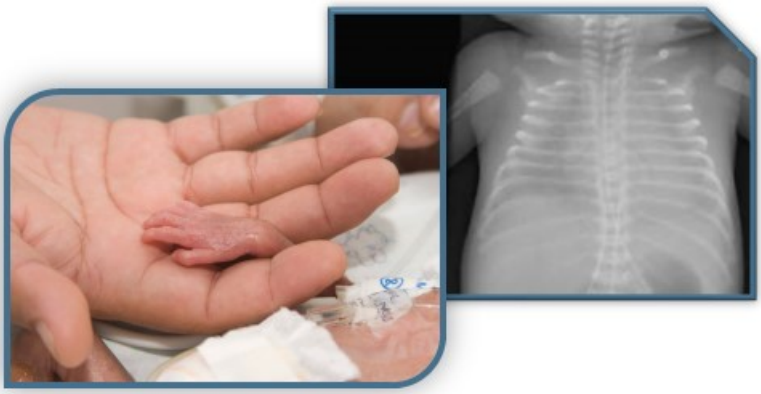
*IMS MIDAS data

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 noninvasively** to patients[2]

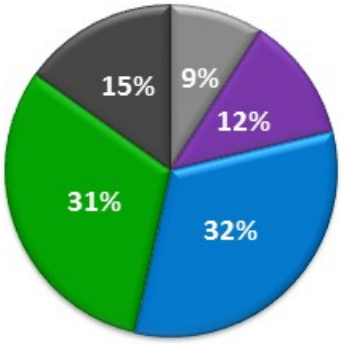


WINDTREE THERAPEUTICS

1. AAP guidelines, 2013
2. WINDTREE primary market research (2014)

Prevalence of RDS Spans Across Gestational Ages / Severity

% of RDS Population



RDS Prevalence	
<26 weeks GA	>95%
26-28 weeks GA	85-95%
29-32 weeks GA	65-75%
33-34 weeks GA	40-50%
35-36 weeks GA	5-10%

AEROSURF® Clinical Development Program

LOWER **Size of Sub-Population** *HIGHER*

GA 26-28 wks	GA 29-32 wks	GA 33-34 wks
30% nCPAP 1st line	55% nCPAP 1st line	70% nCPAP 1st line

HIGHER **Severity of RDS & Incidence of CPAP Failure Rate** *LOWER*

Source: WINDTREE 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).

WINDTREE THERAPEUTICS

Current RDS Treatment Pathways

Initial treatment options include invasive and non-invasive methods:

~40%

~60%

Surfactant Therapy + Invasive mechanical ventilation (IMV)	nCPAP Support until presumptive endogenous surfactant production
• Animal-derived surfactant • Delivered via intubation, usually in combination with mechanical ventilation • Requires sustained intubation • Supports breathing until patient can be weaned	• Non-invasive nasal delivery of continuous positive airway pressure (nCPAP) • Supports breathing until the infant can be weaned

TRADE-OFFS

Timely therapy delivery vs. Exposure to known significant complications

Avoid exposure to known significant complications vs. Cannot deliver surfactant and risk failure

nCPAP failure

>50% are intubated and ventilated

WINDTREE THERAPEUTICS

Source: Windtree and third-party market research

Clinicians Seeking a Noninvasive Way to Deliver Surfactant

What is wanted[1]:

- ✓ Avoid the risks and complications associated with delivery of surfactant therapy via intubation and mechanical ventilation
- ✓ Possibility of repeat doses
- ✓ Avoid clinical instability associated with administration of liquid surfactant bolus administration
- ✓ Enable 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.

WINDTREE THERAPEUTICS

1. Pillow & Minocchieri: Neonatology, 2012

Windtree Technology Platform - AEROSURF®

Potential to Provide Both Non-Invasive and Invasive Solutions to Treat RDS

Proprietary Synthetic KL4 Surfactant

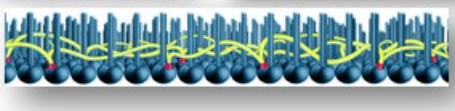
+

Proprietary Innovative Aerosol Delivery System (ADS)

Designed to be structurally similar to human lung surfactant

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

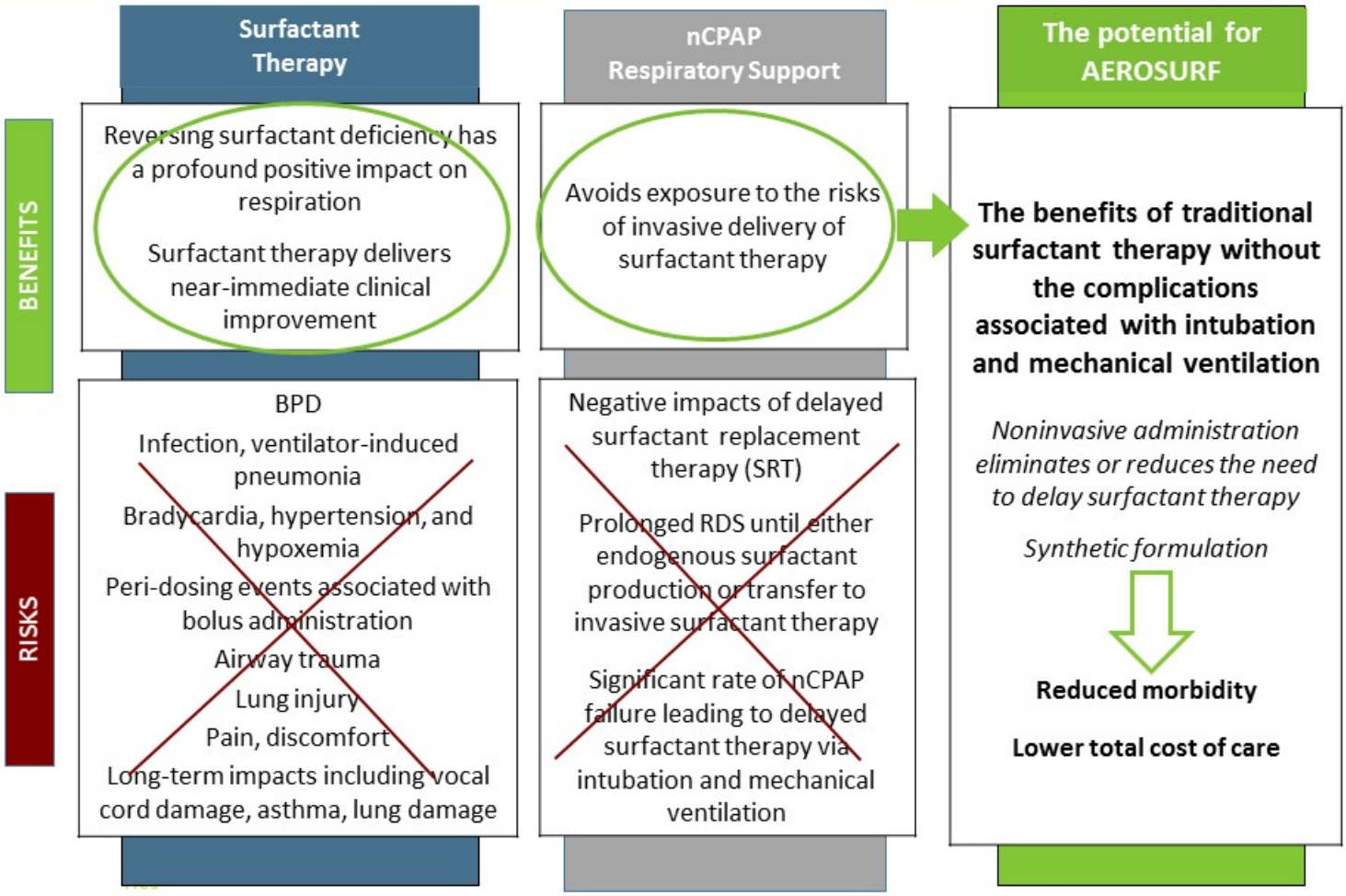
Lyophilized (freeze-dried) KL4 surfactant – currently being developed for AEROSURF®



Designed specifically to aerosolize and deliver KL4 surfactant

WINDTREE THERAPEUTICS

Transformative Potential of AEROSURF®



Potential Drivers of AEROSURF® Opportunity

#1
stated unmet need in RDS

"Noninvasive surfactant delivery" = 54% top, unaided response (3x higher than next response)[1]

20-30%
reduction in nCPAP failure is meaningful

Results in >40% reported, expected patient share[1]

⬆Price
(but ⬇Total Hospital Cost)

Potential for positive health economics related to noninvasive approach, cost avoidance, etc.[2]

Market Expansion

Potential to bring surfactant therapy to new, lower skilled and less certified hospitals and geographies due to noninvasive , less specialized delivery[3]

1. **N=278 Neonatalogists**, US & EU; WINDTREE primary market research (2014)
2. WINDTREE primary market research (2014)
3. Windtree research and estimates

WINDTREE THERAPEUTICS

Significant RDS Global Revenue Opportunity

U.S. Market Example:
~385,000 preterm infants per year,
~134,000 with RDS
China Market:
~1.2-1.4MM preterm,
~500,000 -635,000 with RDS

Regions	Estimated 2016 Annual Revenue Invasive surfactant therapy only[+]
US	$90 million
EU/ME	$85 million
LATAM	$95 million
China / Asia	$115 million
GLOBAL	**~$400 million**

- **Globally, only 50% to 60% of RDS patients currently treated** with surfactant therapy
- Opportunity to **expand treatment population due to easier, non-invasive approach** may enable delivery in less specialized centers
- Positive pharmacoeconomic **value** as well as **capturing cost of respiratory device costs (not just drug) supports higher price**

$800MM - $1B AEROSURF® Potential

WINDTREE THERAPEUTICS

CDC National Vital Statistics; UNICEF data; Windtree market research; IMS MIDAS data; private companies with access to government purchasing records for Latin America, China and Middle East

China Opportunity – License with Lee's Pharm

- Currently, the top animal-derived surfactant sales market, but still very underpenetrated
- 16-19MM births / year (compared to 4MM in the U.S.)
  - About 1.2- 1.4MM are premature and 500,000-600,000 have RDS
- New second child policy promoted by China government is expected to increase the birth rate approx. 20% (with more of these being later in age and higher risk)
- New health policy, increased investment, more of the population under medical care with a focus on babies
- Importantly, a non-invasive approach may allow for surfactant administration by lower skilled healthcare personnel and expand the market to second-line city and rural hospitals
- The potential for additional indications is significant – particularly in acute respiratory care such as anti-viral, severe pneumonia, lung radiation oncology, etc.
- Taiwan and Thailand are other territories of value with a good neonatal network
- In addition to AEROSURF®, with regulatory and manufacturing strategy in China, we may potentially leverage our FDA-approved SURFAXIN® asset and develop and market for SURFAXIN LS™ (lyophilized KL4 surfactant) for non-aerosolized applications, including RDS

Sources: IMS, Population Reference Bureau.org; Lee's primary research 2017; CIA.gov population growth; MarchofDimes.org

Medical Device and Device Studies

WINDTREE THERAPEUTICS

Innovative Aerosol Delivery System (ADS)

Proprietary Innovative Aerosol Delivery System (ADS)

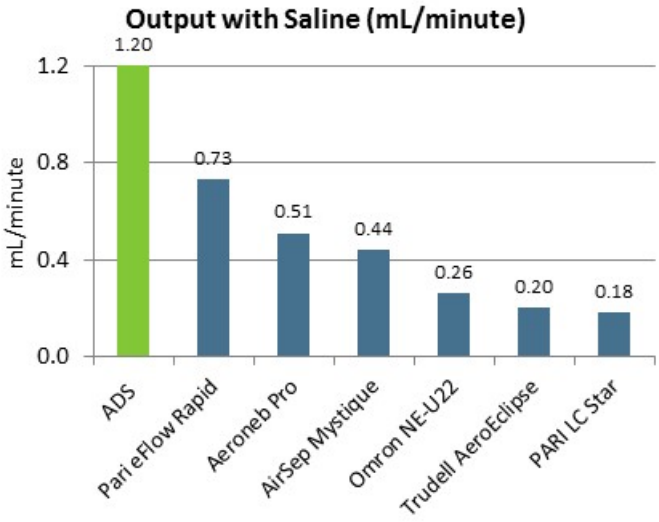
Designed specifically to aerosolize and deliver KL4 surfactant

- AEROSURF® innovation made possible by novel medical device
- Unique aerosol delivery system (ADS) technology utilizing pressure and heated capillary has demonstrated ability to break through the barrier to effectively aerosolize KL4 surfactant
- Controlled, effective and reproducible performance validated in bench comparative studies and in the lung deposition study
- Developed in partnership with Battelle Memorial Institute

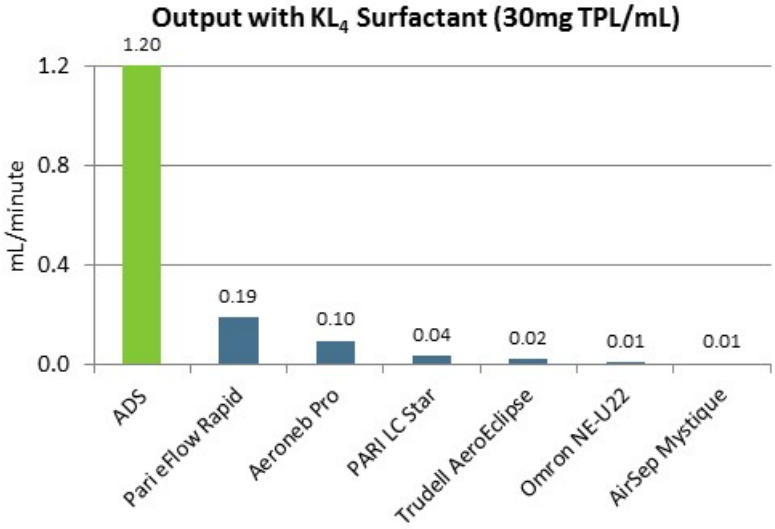
ADS Technology Provides Better Output Rate

Aerosolizes surfactant as well as saline

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

Unlike other available aerosol technologies, the **ADS system produces more particles in the optimal 1 to 3µm range** than a commercially available vibrating mesh nebulizer, and delivers a **consistent KL4 surfactant aerosol output**, minute by minute, device after device

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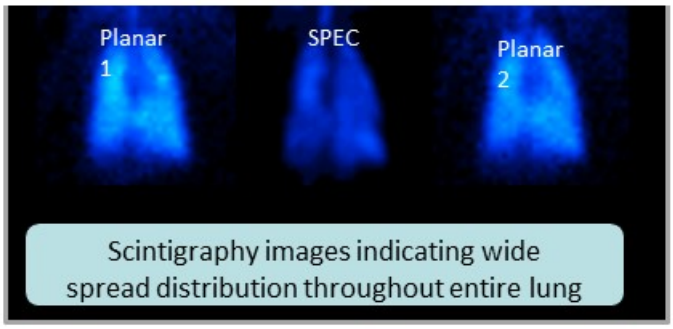
Source: Windtree - Data on file; tests conducted using prototype ADS.

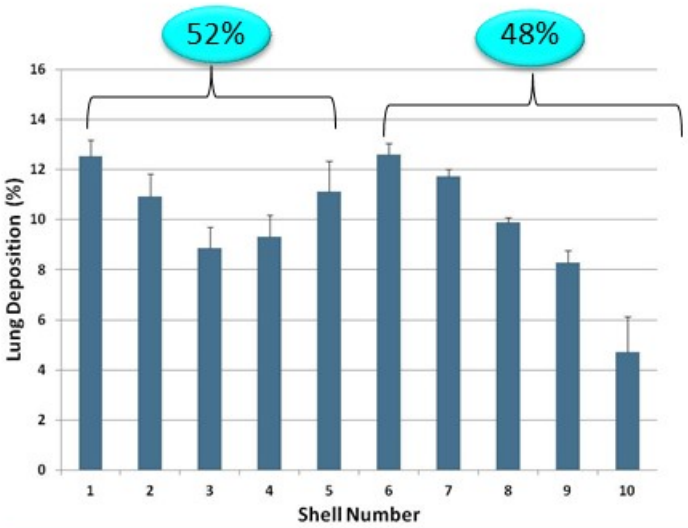
Lung Deposition Study in Non-Human Primates

- Use of non-human primates (cynomolgus macaques) - Nose, throat, & lung anatomy comparable to infants; respiratory function similar to preterm infants
- Radiolabeled KL4 surfactant aerosolized using prototype Aerosol Delivery System (ADS), delivered via nasal cannula in 3-10 min exposures inhaled from a nCPAP circuit
- Measured total & regional pulmonary deposition by a series of gamma images with SPECT data used to determine regional lung deposition using a quantitative model



Scintigraphy images indicating wide spread distribution throughout entire lung

Total Deposition Across 10 Equal Volume Shells



Drug deposition observed across all areas of the lung after 3 to 10 min of inhalation demonstrating generally uniform distribution of drug between the inner half and the outer half of the lungs

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Windtree data on file

AEROSURF®
Clinical Studies

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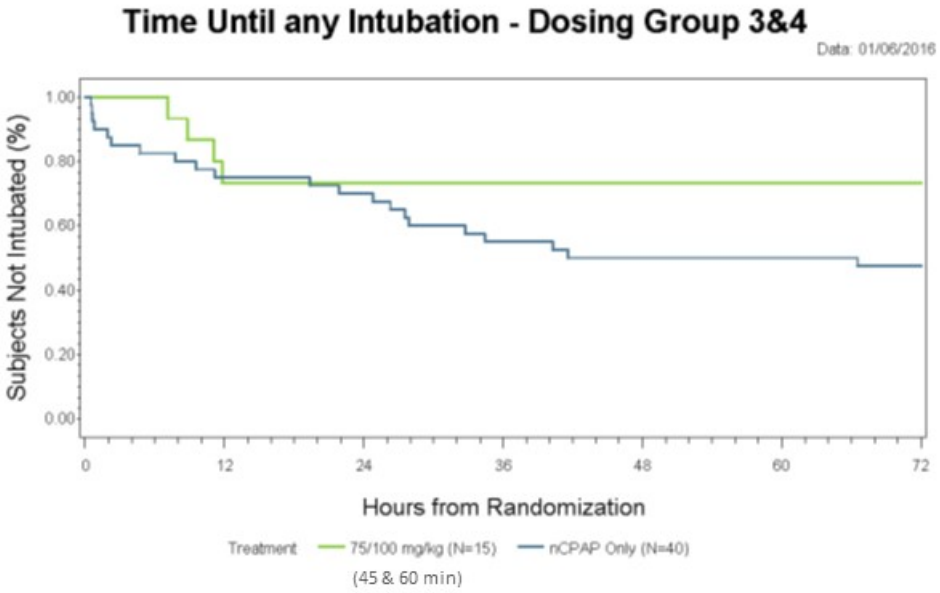
AEROSURF® Phase 2 Program Components

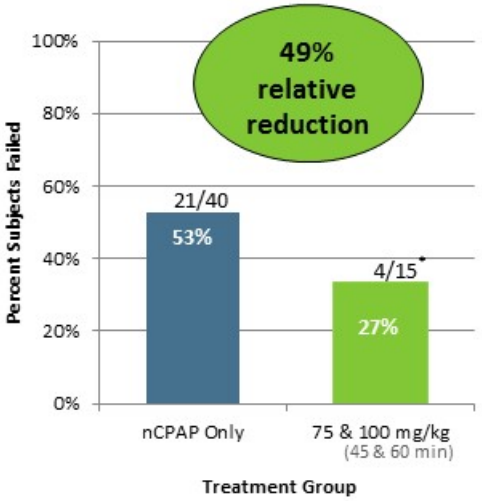
Study / Activity	Rationale / Objective	Status
Phase 2a	Initial safety & tolerability (29-34 wk gestational age (GA))	Completed
2a Expansion	Extending the dose range in 29-34 wk GA	Completed
Phase 2a	Safety and tolerability in 26-28 wk GA	Completed
Phase 2b	28 – 32 wk GA - Dose and evidence of clinical effect	Completed
Other Studies:		
Observational Study	Understand treatments and outcomes for our target population	>2000 pts data collection complete
Lung Deposition Study	Assess inhaled surfactant distribution in non-human primate lungs	Completed
Other Activities:		
Licensing in Asia	Access ex-US opportunity and development support with Lee's	Completed
Device Development	Design verification, validation (DV) and clinical experience with next generation, phase 3 and commercial device	DV on Track for mid 2018
FDA Interaction	Confirm strategic direction and operational approach	Successful Type C meetings as well as Fast Track Designation

Phase 2a Study (29 to 34 wk GA)

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

Time to nCPAP Failure





At 72 hours post-dosing, 27% of AEROSURF® patients in the combined 45 and 60 minute dose groups required intubation compared to 53% in the control group; a relative reduction in nCPAP failure of 49%

* One intubated patient excluded due to being inappropriately enrolled

AEROSURF® Phase 2a Study in 26-28 week GA

Safety and Tolerability Assessment

- The FDA requested that we conduct a separate safety study in smaller premature infants before including them in blinded studies
- Multicenter, randomized, open-label, controlled study in 48 premature infants 26 to 28 weeks GA receiving nCPAP for RDS to evaluate the safety and tolerability of aerosolized KL4 surfactant administered in three escalating doses (8 treatment, 8 control per dose group)
- The primary objective of the study was successfully met. The safety and tolerability profile of AEROSURF® remains generally comparable to the nCPAP control group across gestational ages
  - The safety profile of AEROSURF in younger GA neonates allows this group to be included in AEROSURF trials going forward
  - 26-27 week GA neonates are more surfactant deficient and may require additional surfactant administration. The phase 2 safety profile will allow us to administer more surfactant to babies that need it
- Despite limited treatment numbers, we observed a positive early effect on prolonging the time to intubation (a consistent finding across studies) as well as dose related signs that nCPAP failure can be reduced in this GA range when dosed as intended. Based on this study, we believe we have a dose identified to produce the desired effect in clinical studies moving forward

AEROSURF® Phase 2a in 26-28 week GA - Potentially Important Observation Related to Bronchopulmonary Dysplasia (BPD)

BPD	Rate	Patients
AEROSURF	0%	0/24
Control	25%	6/24

- Bronchopulmonary Dysplasia (BPD) or chronic lung disease of the newborn is one of the most common complications of prematurity and RDS treatments. It occurs in up to 40% of infants born at or before 28 week GA who have required intubation, mechanical ventilation and oxygen therapy.
- BPD is associated with ongoing pulmonary disease, neurodevelopmental impairment and increased healthcare utilization.
- Despite its importance, effective prevention and treatment strategies for BPD have been elusive and there are no approved treatment.
- BPD contributes to substantial patient morbidity and healthcare costs.
- Decreasing BPD would address a significant unmet medical need and represents an upside scenario in our outlook. Additional study is warranted within our future RDS trials.

JAMA 2016; 316 (6); 611-624; JAMA Pediatric 2015; 169 (8); 731-739

AEROSURF® Phase 2b Study (28 to 32 wk GA)

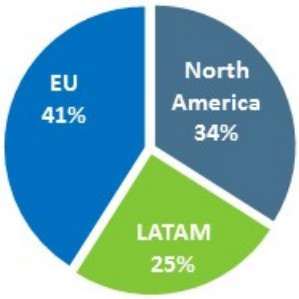
Trial Objectives

- Evaluate safety and tolerability
- Demonstrate efficacy
- Determine effect size for phase 3 planning
- Dose(s) selection for phase 3
- Evaluate and further develop our Phase 2 prototype device performance

Trial Design

- 3 dose groups:
  - ✓25 minute, 40mg/kg (up to 2 repeat doses)
  - ✓50 minute, 80mg/kg (up to 2 repeat doses)
  - ✓nCPAP alone Control
- Treatment assignment was blinded
- Infants with RDS between 28-32 wk GA

221 Patients Enrolled



47 sites enrolled:

• US	17
• Canada	3
• Poland	9
• Netherlands	1
• Hungary	6
• Ireland	1
• Chile	7
• Colombia	3

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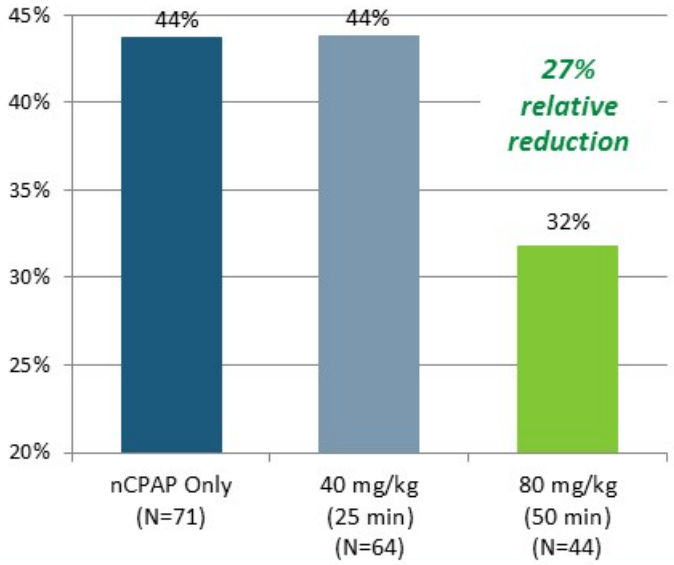
AEROSURF® Phase 2b Incidence of nCPAP Failure

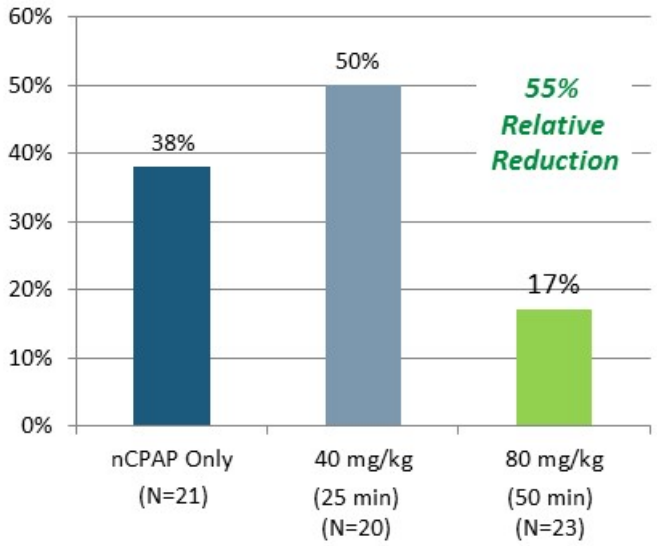
Preplanned mITT Without Treatment Interruptions Demonstrates Targeted Reduction [1]

All Sites



AEROSURF® treated patients in the 50 min dose group without treatment interruptions experienced a 12% absolute reduction or a **27% relative reduction** in nCPAP failure compared to control

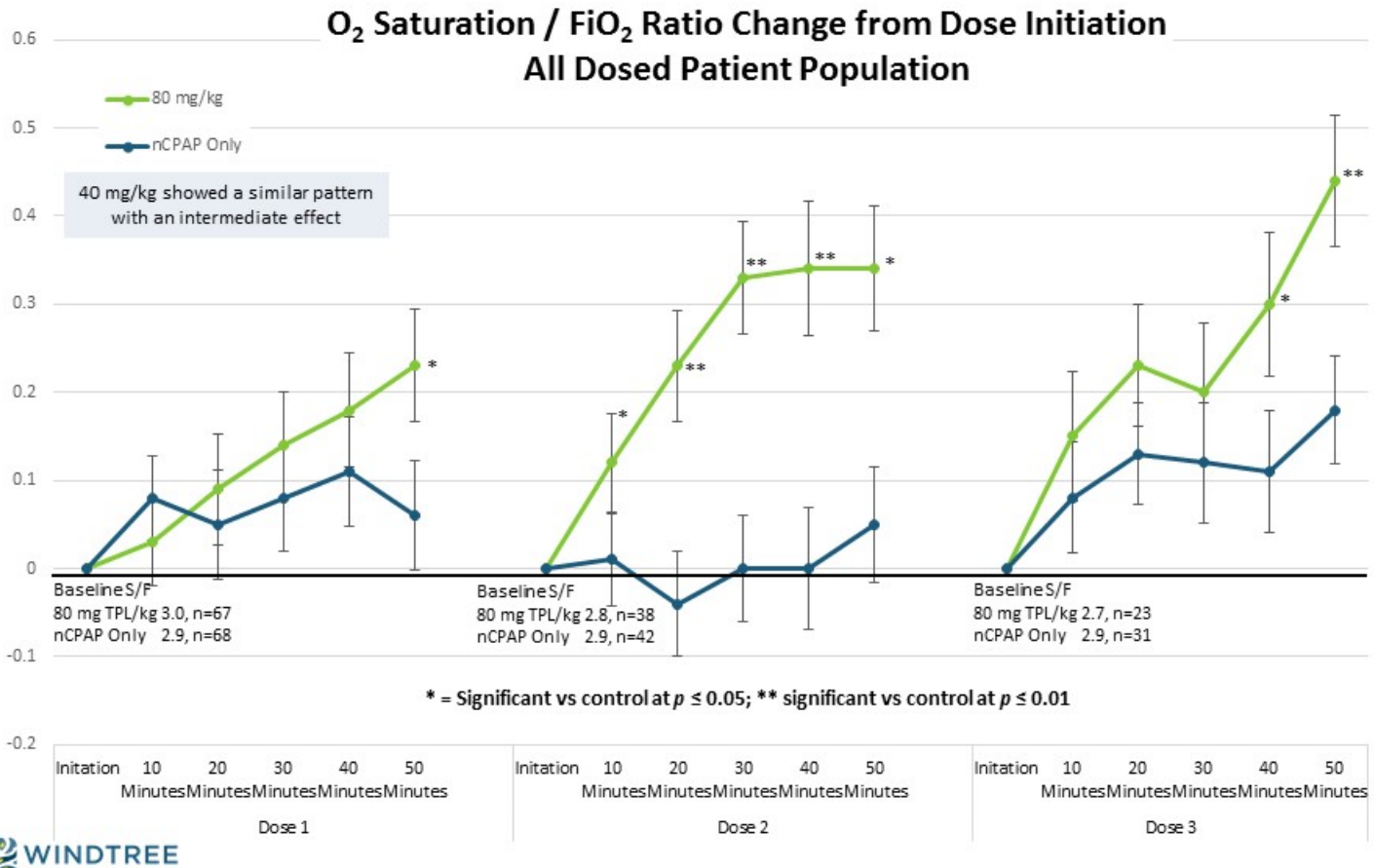
US Only (to compare with 2a)



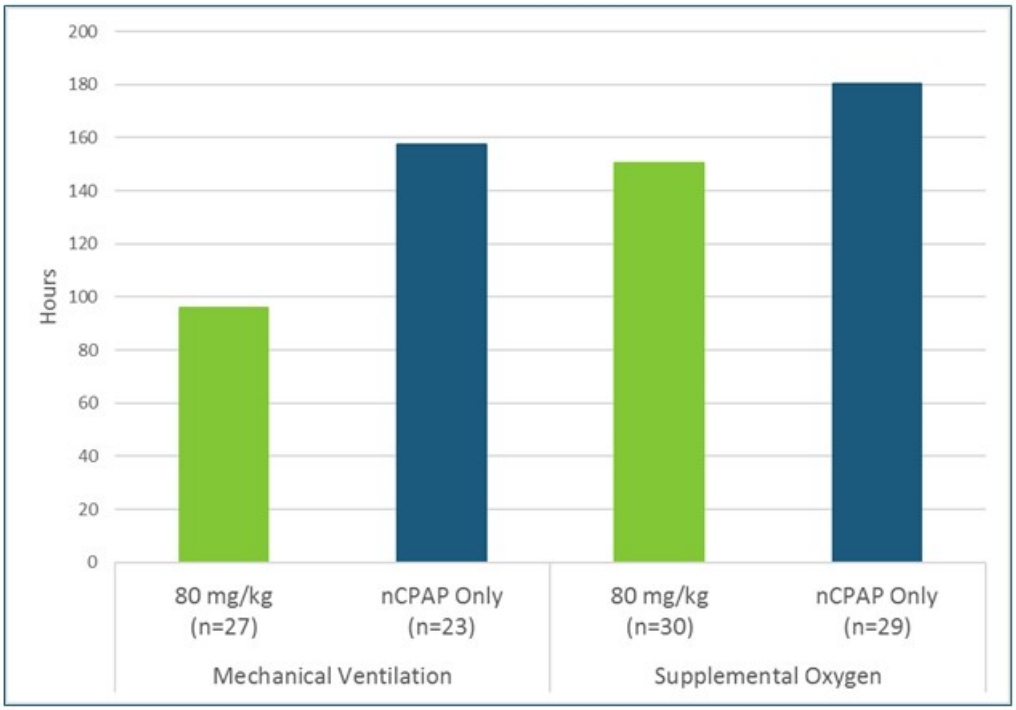
AEROSURF treated patients in the 50 min dose group experienced a 21% absolute reduction or a **55% relative reduction** in nCPAP failure compared to control

1) The planned top line analysis of the primary endpoint did not show the intended effect due in large part to treatment interruptions in certain patients caused by specific lots of disposable cartridge filters used in the phase 2 prototype device that had a higher tendency to clog

AEROSURF® Phase 2b – Significantly Improved Key Respiratory Parameters



AEROSURF® Phase 2b - Potential for Reduced Respiratory Support in Patients Who Failed nCPAP When on AEROSURF



In patients who failed nCPAP and required intubation and mechanical ventilation, AEROSURF treated patients appeared to require shorter duration of mechanical ventilation and time on supplemental oxygen

Phase 2b - Safety & Tolerability Profile

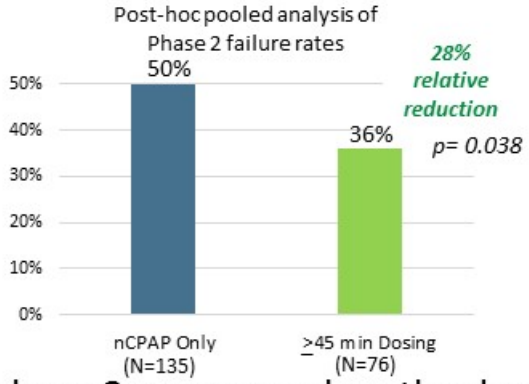
Similar for Treatment and Control Populations

- The adverse event and serious adverse event profile was similar across the 3 groups
- Complications of prematurity were also similar

	40 mg/kg (25 min)	80 mg/kg (50 min)	nCPAP Only
Acquired Sepsis	12 (17%)	13 (18%)	16 (23%)
Air Leak	7 (10%)	6 (8%)	10 (14%)
Apnea	31 (44%)	27 (38%)	28 (39%)
PVL	1 (1%)	1 (1%)	1 (1%)
PDA	18 (26%)	24 (33%)	24 (34%)
IVH	8 (11%)	10 (14%)	11 (15%)
NEC	1 (1%)	7 (10%)	6 (8%)
ROP	3 (4%)	6 (8%)	3 (4%)
BPD	7 (10%)	7 (10%)	10 (14%)
Alive without BPD	62 (89%)	64 (89%)	59 (83%)

Summary of Efficacy Signals in the Phase 2 Program

- Post-hoc pooled analysis of patients in the phase 2 program (3 studies) treated in doses ≥ 45 minutes dosed as intended (uninterrupted) shows a notable reduction in nCPAP failure with AEROSURF® treatment compared to nCPAP controls



- Beneficial effects reproduced across the phase 2 program when the dose is delivered as intended
  - 2b results are consistent with previous data from the 2a study in 29-34 week GA infants (49% relative reduction in nCPAP failure for combined 45 and 60 minute doses)
- Phase 2a in 26-28 week GA infants also observed an important potential effect on development of BPD with 0% (0 of 24) in treated infants versus 25% (6 of 24) in control as well as a potential reduction of BPD in phase 2b
- AEROSURF patients in the phase 2b study failing nCPAP required less time on oxygen and fewer days on mechanical ventilation

Accomplished - Evolution of Aerosolized Delivery System (ADS) from Phase 2 to the Phase 3 / Commercial Device

Phase 2 Prototype

- 2012 – 2017
- Developed in conjunction with Battelle Memorial Institute (Battelle)
- Designed and used in prior phase 2 clinical experience
- Battelle assembled for phase 2 trials

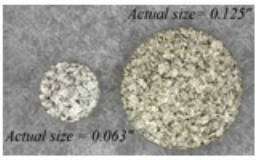
Current ADS is our Phase 3 and intended Commercial Device

- Designed to utilize the same aerosol delivery technology to provide comparable key aerosol characteristics of emitted dose and particle size of the phase 2 device for bridging of device and data
- Enhanced ergonomics and user interface:
  - Faster start-up and change-over
  - Built in step by step instructions with detailed images
- Simplified disposable set up to help prevent incorrect assembly and inadvertent re-use
- Enhanced controls and dose monitoring
- Modular design for easier maintenance, etc.

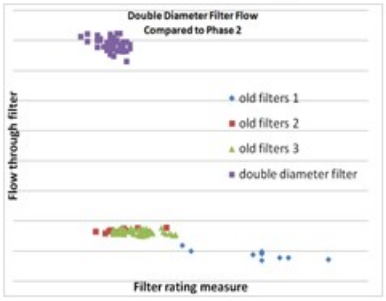
WINDTREE THERAPEUTICS

Addressed Filter Issue Through Design Enhancements, Quality Systems and Assembly. Demonstrating in a Performance Study

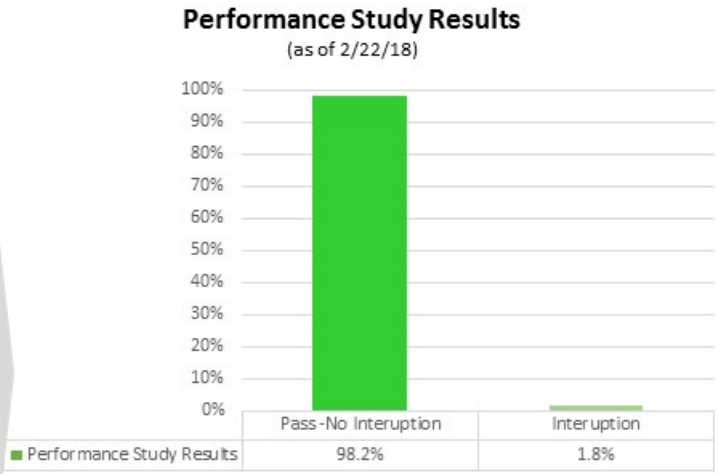
- ✓ Filter diameter doubled, surface cross section increased by 4x



- ✓ New material quality specifications and tests for flow through filter



- ✓ Modified design and assembly to reduce restrictions
- ✓ Transferring to a device manufacturer with strong quality systems and track record



Performance Study executed at 50 minute dose has a 98.2% pass rate with 84% (57 of planned 68) tests completed

*This one interruption was due to software programming in a test device

WINDTREE THERAPEUTICS

AEROSURF® Clinical Development Next Steps

Generate the strongest possible position and transition to phase 3

Execute a Bridge Study to transition the new, Phase 3 / Commercial ADS device in order to meet the following objectives:

1. Demonstrate adequate, consistent performance with the new ADS
   - Beyond Device Design Verification and bench performance study, Windtree learns from actual "in-clinic" experience to ensure no issues
2. Sites gain experience with procedure and new device prior to FPI phase 3
3. Generate additional supportive high dose data (with more intensive dosing)
   - Fourth data set at high dose is expected to provide data on safety of more intensive dosing and to augment phase 2b data that was impacted by removal of treatment interruptions in the pre-planned mITT

AEROSURF® Bridge Study

- Blinded study; nCPAP alone as control versus adding AEROSURF® treatment
- GA range: 26-32 weeks
- N=70 planned (35 per group) in a design similar to phase 2b
- ~20-25 select sites
  - represent the best previous study sites for enrollment and execution in phase 2 (predominately U.S. sites)
- Planned Timing: ~3 quarters study duration starting in late Q4 2018 / Q1 of 2019

- Dose: Initial 100 min dose for all infants; with up to 3 repeat doses of 50 min (determined by infant FiO_2); minimum 20 minute assessment between doses
  - Ph2b was 50 min. high dose, 2 repeats possible with a 2 hour interval between doses
- $FiO_2 \geq 25\%$ to qualify, >21% for repeat dosing to allow infants to receive more treatments
- Key Measures:
  - CPAP failure
  - Next Gen ADS Device performance
  - Safety and tolerability
- Bridge Study not powered for significance, however we would like to show magnitude of effect >20%

WINDTREE THERAPEUTICS

Program Evolution and Changes Intended to Increase the Probability of Technical Success and Continue to Strengthened Data

- We have reproduced positive results in our Phase 2a and Phase 2b
- Utilize the Phase 3 / Go to Market Next Gen ADS which is designed to mitigate the risk of filter related treatment interruptions
- Phase 3 Next Gen device features may support clinical outcomes:
  - Faster set up may decrease time to treatment (time is important)
  - Easier to use
- Given safety profile we are continually seeking to optimize dosing with more intensive dosing:
  - Initial 100 min. dose for all
  - Decreasing interval from 2 hours to 20 min. between doses with additional repeat dosing possibilities
  - FiO_2 at 25% for inclusion, >21% for repeat allows more infants to receive clinically needed repeat dosing before RDS becomes severe
- Executing in our best sites

Other Potential Development Activities

- Lyophilized Lucinactant (LS)
- Preclinical Activities

WINDTREE THERAPEUTICS

Potential Opportunity to Become RDS Market Leader with Both Non-Invasive and Invasive KL4 Surfactant

~40%

Today's Treatment Pathways:

~60%

Surfactant Therapy + Mechanical ventilation (MV)	nCPAP Support until presumptive endogenous surfactant production
Animal derived surfactants delivered invasively	No Aerosolized surfactant available

nCPAP Failures

Future Treatment Pathways:

(Illustrative)

~20%

~80%

Surfactant Therapy + Mechanical ventilation (MV)	nCPAP Support until presumptive endogenous surfactant production
Competitor surfactant–or– ***Lucinactant LS (Windtree)***	***with AEROSURF® (Windtree)***

Failures

Lucinactant LS (Windtree)

Source: Windtree and third-party market research; Windtree forecast

WINDTREE THERAPEUTICS

Intended Future Value Proposition and Positioning

Windtree assets can span both treatment pathways – with one surfactant for all

AEROSURF®

Lucinactant LS

- **AEROSURF + nCPAP vs. nCPAP alone:**
  - More efficacious than nCPAP alone
  - Safety benefit – noninvasive surfactant therapy reduces nCPAP failures and resulting intubation and MV thus lowering patient exposure to known complications of invasive therapy and intervention
  - Opportunity to lower costs by avoiding MV and level of respiratory support
- Easier administration by non-specialized staff provides opportunity to bring surfactant therapy to untreated RDS infants outside the current market (sites certified for invasive)
- Pricing on drug, cartridges, device fee and disposables captures more value / patient
- Possibility to lower the rate of BPD? (TBD)

- **Lucinactant LS vs. other surfactants:**
  - Synthetic vs. animal-derived
  - More convenient and faster to use
    - expected to require no warming
    - may be stored at room temperature in the NICU or used during transport
- Improvements vs. previous formulations include lower viscosity and stability currently at 4 years (vs. 1)
- Synergistic and complementary with AEROSURF – can be aerosolized
- Improved formulation to bridge from our previously FDA approved product
- LS for bolus administration gives Windtree a platform for other non-RDS, non-aerosolized applications

WINDTREE THERAPEUTICS

Leverage our Innovative Technology to Advance Acute Pulmonary Disease Care and Outcomes Beyond RDS




		Program Focus	Potential Application
RDS	Phase 2b		
Eleison-ILC	Preclinical (Phase 2 drug)	ADS delivery of liposomal cisplatin	Non-small cell lung cancer, Metastatic osteosarcoma
ALI - Radiation	Preclinical (7 studies)	Prevention of acute & chronic changes (fibrotic)	Metastatic Breast & Lung Rad.Onc; Biodefense
ALI - Viral	Preclinical (4 studies)	Mitigate lung injury, prevent vent. / ECMO	SARS, H1N1, MERS, Viral pneumo (peds), etc.
ALI - Chemical	Preclinical (3 studies)	Mitigate lung injury, prevent vent. / ECMO	Defense, industrial
Drug Delivery	Preclinical	Better delivery of drugs to lungs / higher concentration	Antivirals, Antibiotics, chemo agents, anti-fibrotic…

Planned Assessment & Prioritization in 2018

Acute Asthma | Severe Pneumonia | Post Surgical Adhesion | Cystic Fibrosis

Lung Transplant | ECMO Liberation | Chronic Sinusitis | COPD

+ Others?

Platform Exclusivities

Broad Multi-Faceted Exclusivity Portfolio

Regulatory

- **Orphan Drug Designation** in RDS for the U.S. and EU
- **AEROSURF® FDA Fast-Track Designation**

Patents

- Lyophilized KL4 Surfactant Portfolio - to 2033
- Aerosol Delivery System Portfolio - through 2031+

Trade Secrets/Know-How

- Methods of Manufacture
- Non-USP Analytical Processes

Potential Challenges to Generic Entry

- Conventional bioequivalence studies are not relevant as Surfactants are Non-Receptor Based

2018 Objectives

1. 

Complete Device Development delivering an **extremely consistent, high performing** Phase 3 / "go to market" **drug delivery platform**

2. 

Solid execution of the **Bridge Study**

3. FDA
EUROPEAN MEDICINES AGENCY

AEROSURF and Lyo Lucinactant LS **Global Regulatory Clarity** and employed in development

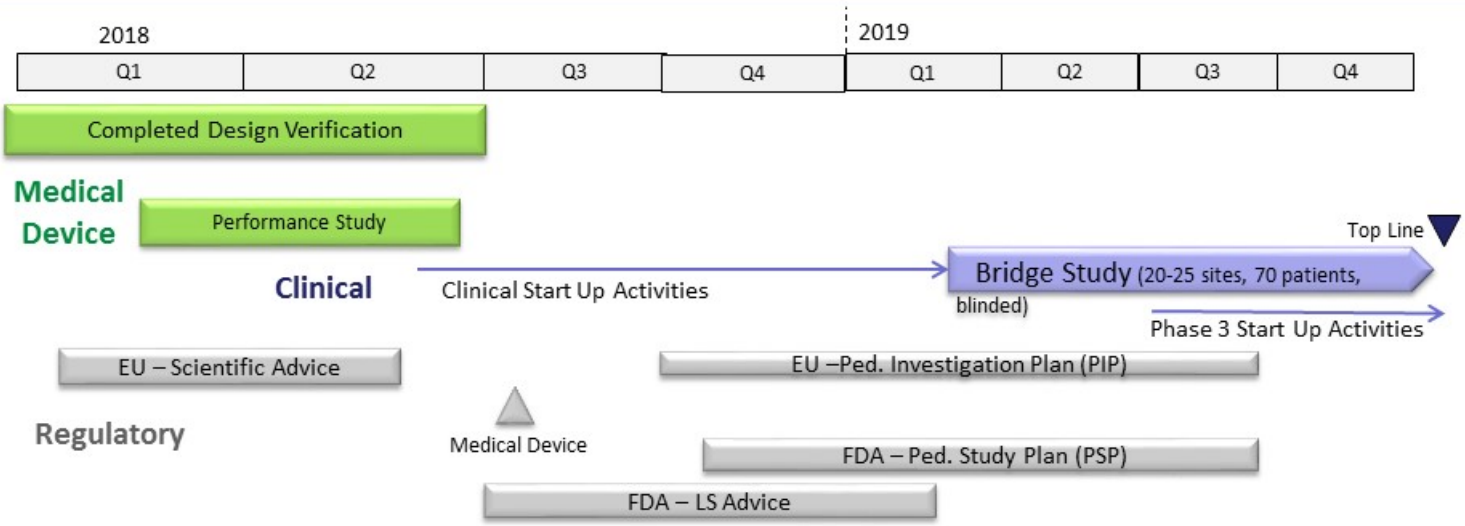
4. 

Successful funding supporting a **financially healthy organization**

5. 

Investment / Portfolio **Diversification** by potentially accessing assets within the Lee's Pharm organization and Lyo Lucinactant LS

AEROSURF® Development and Deliverables Overview



1H 2018

- ✓ Next Gen Device DV
- ✓ Device Performance Study - results
- ✓ Regulatory Milestones:
  - EMA Scientific Advice
  - FDA Device
  - FDA Lyo Lucinactant LS

2H 2018 through 2019

- ➢ AEROSURF Bridge Study
- ➢ AEROSURF Phase 3 Start-Up Activities
- ➢ EU PIP
- ➢ FDA PSP
- ➢ Other Studies
  - ➢ LS,
  - ➢ Eleison Collaboration, etc.

WINDTREE THERAPEUTICS

Note: The above schematic represents Windtree's current business planning, execution and intent as of 6/18/18. Start and completion timing for many activities are dependent upon the timely completion of other tasks (i.e. study start dependent on device availability) and sufficient available funds.

Highly Experienced Management Team

Craig Fraser CEO	Centocor, Johnson & Johnson, Wyeth, Pfizer, 3M Health Care, Aegerion Pharmaceuticals, Boehringer Mannheim
Steve Simonson, MD Chief Medical Officer	AstraZeneca, Duke Medicine, COVANCE
John Tattory CFO	Ernst & Young, Bristol-Myers Squibb
Mary Templeton General Counsel	charles SCHWAB
Kathy Cole Human Resources	CytoGen, SAVIENT Pharmaceuticals, Inc.
George Cox Manufacturing & Supply	MedImmune, RHÔNE-POULENC RORER, AUXILIUM
Ron Dundore Regulatory and Quality	FDA, AstraZeneca, PAREXEL
Larry Weinstein Medical Device	Cordis, PARI

Value Creating Potential

- **Potentially transformative therapy** addressing both the unmet efficacy and safety needs in the important, acute neonatology market
- Multiple **phase 2 clinical trials reproducing efficacy** while continuing to build a very favorable **safety and tolerability data** base
- **Developing positive health economic position** as well as opportunity to **expand the use of surfactants** due to easier, less specialized administration
- **Broad IP** with potential to more broadly **leverage the KL4 platform and ADS device** with Lucinactant LS and other pipeline studies
- **Fast Track and Orphan designations**

Windtree Therapeutics

"Striving to deliver Hope for a Lifetime!"

WINDTREE THERAPEUTICS