UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): August 20, 2020

Windtree Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	000-26422	94-3171943
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

2600 Kelly Road, Suite 100, Warrington, Pennsylvania	18976
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (215) 488-9300

Not Applicable
(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 (see General Instruction A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	WINT	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 7.01 **Regulation FD Disclosure.**

On August 20, 2020, Windtree Therapeutics, Inc. (the "Company") released an investor presentation to be used in presentations to investors from time to time. A copy of this investor presentation is attached hereto as Exhibit 99.1.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished solely to satisfy the requirements of Regulation FD and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit No.	Document
99.1	Windtree Therapeutics, Inc. Investor Presentation dated August 20, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Windtree Therapeutics, Inc.

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

Date: August 20, 2020

Exhibit 99.1

Windtree Therapeutics

Company Overview
August 20, 2020
(NASDAQ: WINT)

WINDTREE
THERAPEUTICS™

Forward-looking Statements

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, among other things, include 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. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will," "should," "could," "targets," "projects," "contemplates," "predicts," "potential" or "continues" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. These risks and uncertainties are further described in the Company's periodic filings with the Securities and Exchange Commission ("SEC"), including the most recent reports on Form 10-K, Form 10-Q and Form 8-K, and any amendments thereto ("Company Filings"). Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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

Windtree Therapeutics is a clinical-stage biopharmaceutical and medical device company with **multiple advanced clinical programs** spanning cardiovascular and respiratory disease states

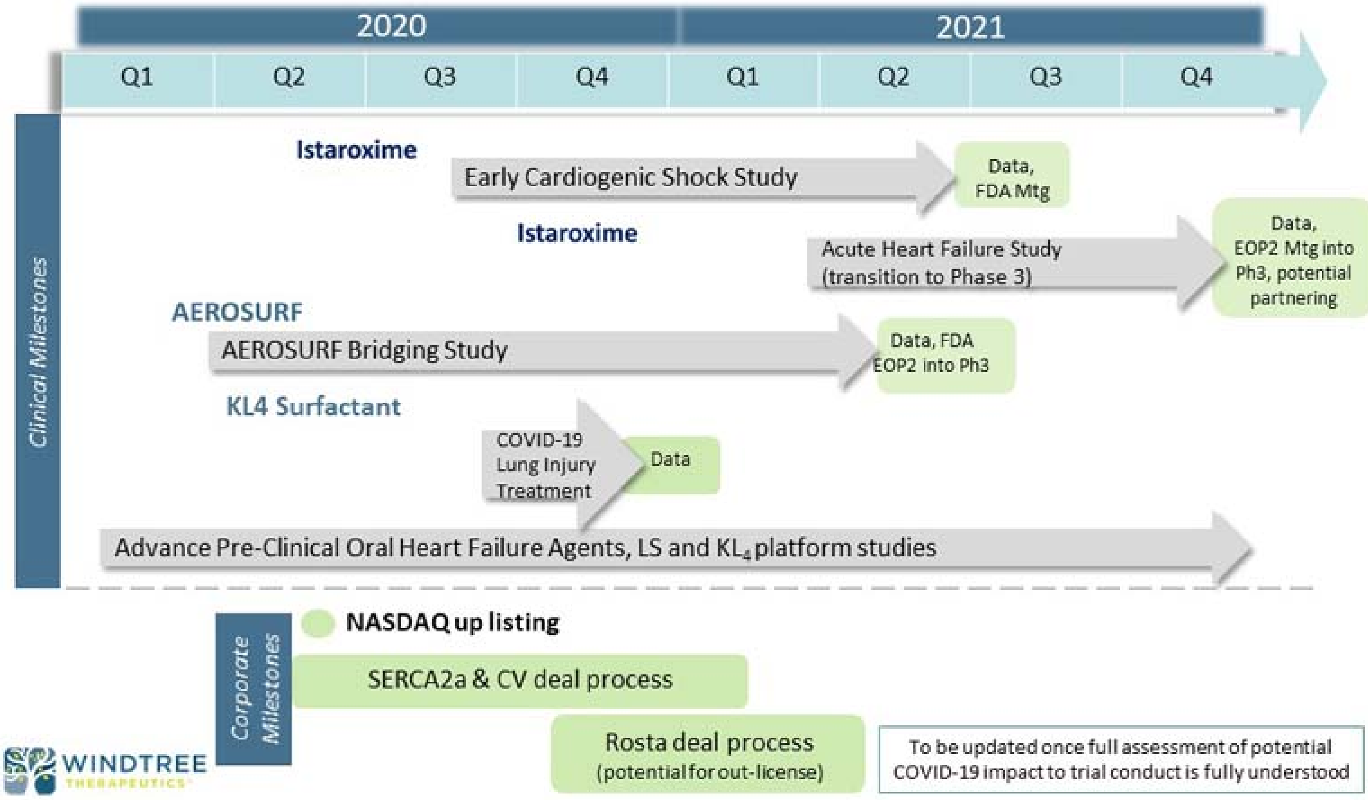
	Lead Products	Pre-	Phase I	Phase II	Phase III	Next Milestone
FDA Fast Track Designation	**Istaroxime** (Acute Heart Failure)			Phase 2b		▪ Initiate study start up in 2H 2020 for second phase 2b clinical trial in ~300 patients targeted to start in 1H 2021
Potential for Breakthrough designation	**Istaroxime** (Cardiogenic Shock)			Phase 2		▪ Q3 2020- Initiate ~60 patient study in early cardiogenic shock
FDA, EMA Orphan Drug for RDS	**KL4 Surfactant – COVID 19** (COVID 19 Pilot; Possible invasive Tx for RDS in neonates)			Phase 2		▪ Q3-2020 File IND; Initiate trial
FDA Fast Track Designation, Orphan Drug	**AEROSURF** (Non-Invasive Tx for RDS)			Phase 2b		▪ Active study in ~80 patient with new ADS supported by licensee resources
	Rostafuroxin (Genetically Associated HTN)			Phase 2b		▪ Out-licensing opportunity
	Oral SERCA2a Activators (Chronic HF; including HFpEF)					▪ High interest target for partnership ▪ Chronic and Acute Heart Failure

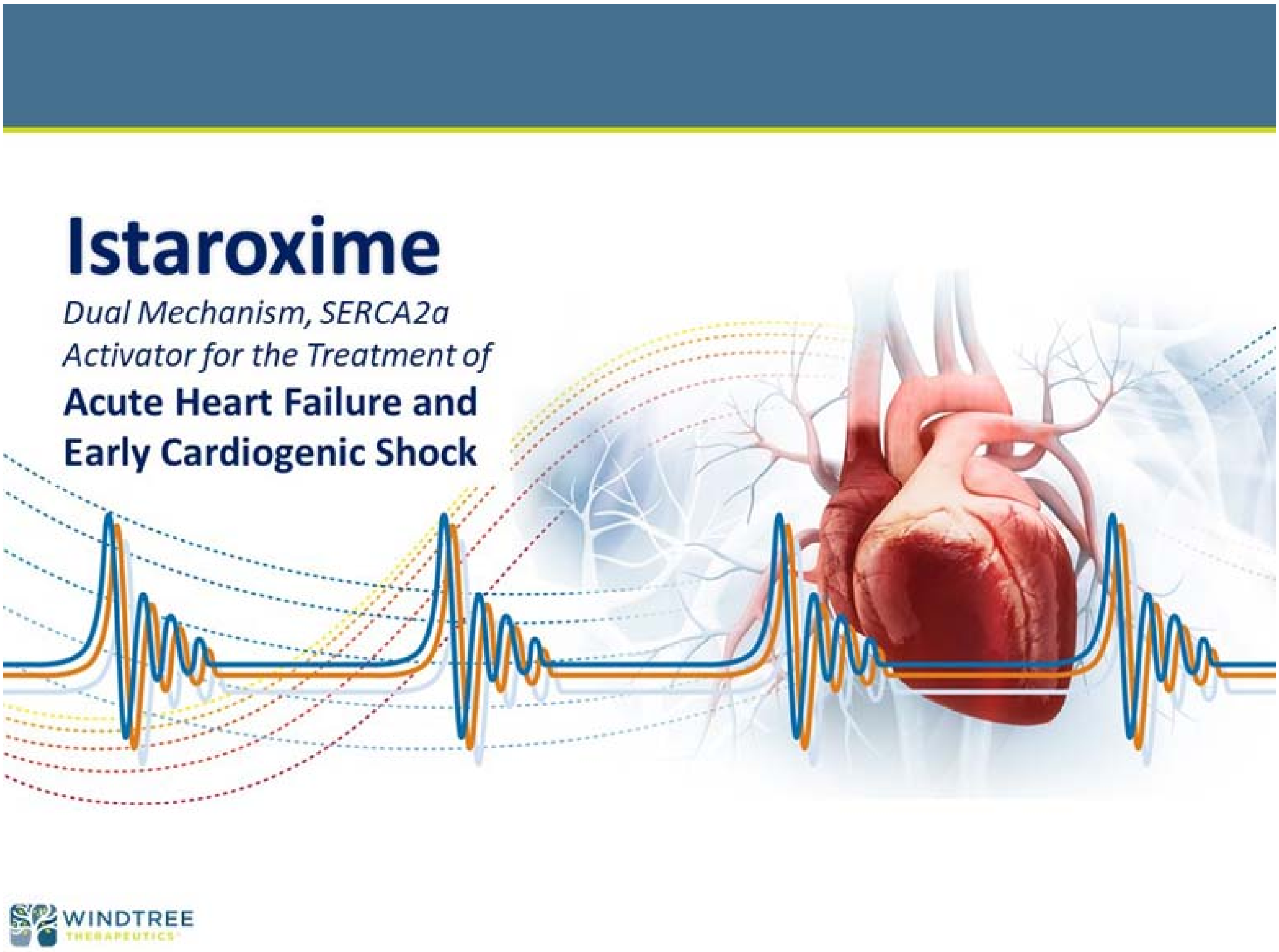
WINDTREE THERAPEUTICS

Strategy for Value Creation

Planned Milestones

- **Three clinical programs** focused on significant markets with unmet needs
- **Multiple clinical and business milestones which have the potential to be catalysts**




Istaroxime
Dual Mechanism, SERCA2a Activator for the Treatment of
Acute Heart Failure and Early Cardiogenic Shock
WINDTREE
THERAPEUTICS

Heart Failure -

The prevalence of HF is high and on the rise (as is mortality)

# of Patients:	▪ 6M (U.S.) | 18M (Worldwide)
Hospital Admissions:	▪ #1 cause of hospitalization in patients > 65 years old (U.S.) ▪ > 1.3M admissions annually (U.S.) ▪ ~1.5M admissions annually (E.U.)
Inpatient Mortality:	▪ Up to 7% ▪ 30-day: can exceed 10%
Estimated Costs:	▪ U.S. Hospitals: > $18B annually ▪ Most expensive of the Medicare diagnoses

Lack of therapeutic advances led the FDA to issue new Heart Failure Guidance in July 2019 for greater development flexibility in acceptable endpoints, specifically acknowledging mortality is not required

Sources: American Heart Association; DRG Data

Acute Heart Failure -
Significant Healthcare Issue with Significant Unmet Clinical Need

- **There has not been meaningful new pharmacologic advancements** in acute heart failure for decades
- **Current approaches to acutely improve cardiac function are associated with unwanted effects**:
  - Heart rhythm disturbances
  - Increased heart rate and myocardial oxygen demand
  - Decreased blood pressure
  - Potential damage to the heart muscle (increased troponin)
  - Worsening renal function
  - Mortality
- **Patients with low blood pressure and peripheral hypoperfusion are high risk**, challenging patients. These patients are also **generally resistant to diuretic therapy and often discharged in a sub-optimal state**
  - Low SBP in-patient mortality approximately two-fold greater than normal / high SBP[1]
  - There is a direct relationship between early drop in SBP and worsening renal function in acute heart failure[2]

1) ADHERE Registry, n=48,567; JAMA 2006
2) European Journal of Heart Failure; Voors, PRE-RELAX AHF Study; 2011; 13

Istaroxime – Novel First-in-Class Therapy

Novel intravenous agent designed to **improve systolic contraction and diastolic relaxation of the heart.**

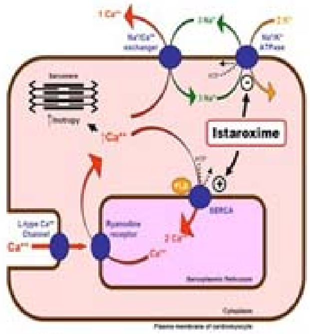
Dual Mechanism of Action

Istaroxime

1. Inhibition of the sodium-potassium pump and effects on the sodium-calcium exchanger results in increased contraction

2. Stimulation of SERCA2a activity enhances calcium reuptake resulting in improvement of the diastolic relaxation and subsequent contraction cycle

Impact on *both* systolic and diastolic dysfunction



Istaroxime AHF Phase 2b Study - Summary

Primary Endpoint:	▪ Change in E/e' at 24 hours (non-invasive estimate of PCWP) measured by echocardiography
Trial Design:	▪ Adult patients hospitalized for recurrent AHF (dyspnea plus need for IV furosemide ≥ 40mg) ▪ 120 patients ▪ Multicenter, double blind, placebo-controlled, parallel group
Dosing:	▪ 24-hour infusion of istaroxime at doses of 0.5 and 1.0 mg/kg/min
Results:	▪ **Primary endpoint was significantly improved by both doses of istaroxime** ▪ **Heart rate decreased and stroke volume increased at 24 hours** ▪ **Istaroxime maintained / increased systolic blood pressure** ▪ **Renal function also tended to improve** ▪ **No evidence for increased risk of arrythmia or increases in troponin** ▪ **Generally well tolerated (nausea and infusion site discomfort were the most common AE)**

We believe results are consistent with phase 2a and support istaroxime and SERCA2a activation for AHF

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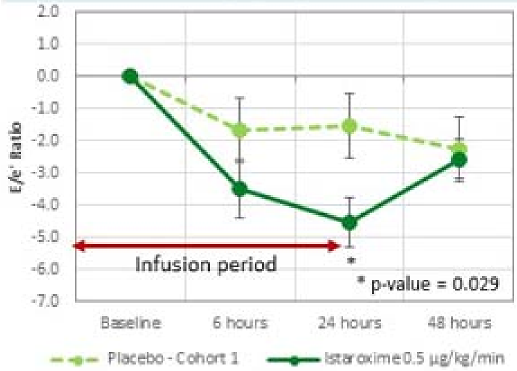
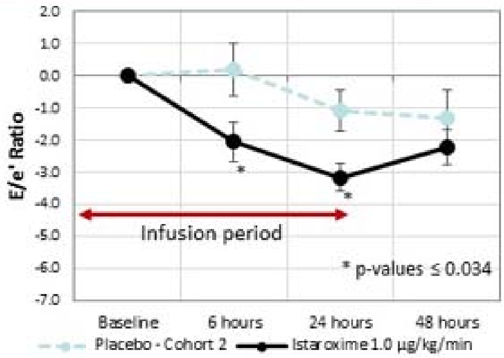
Primary Endpoint –

Significant Changes in E/e' Ratio and Stoke Volume

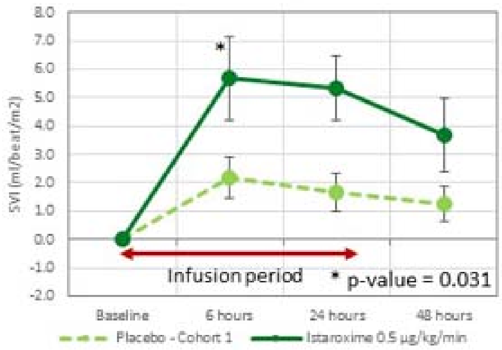
istaroxime 0.5 µg/kg/min vs. placebo



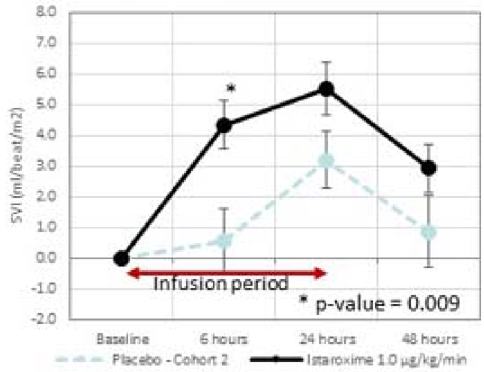
istaroxime 1.0 µg/kg/min vs. placebo



E/e'

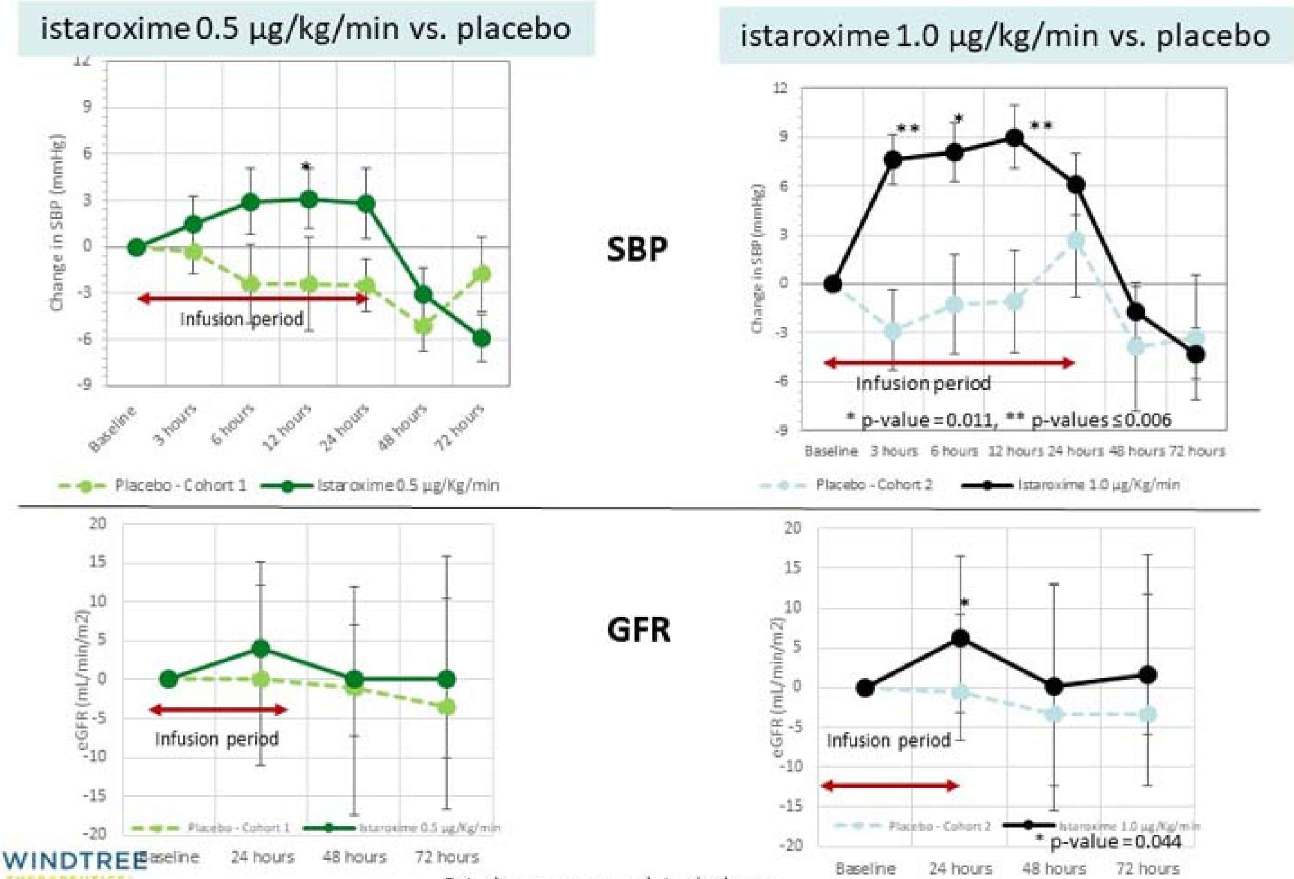


Stroke Volume



Data shown as means and standard errors

Systolic Blood Pressure Maintained or Increased During Treatment and Renal Function Tended to Improve



Data shown as means and standard errors

Istaroxime – Acute Heart Failure
Next Steps

Objective: Create a strong phase 3 and partnership position -

AHF Next Steps

- Execute an additional study that is expected to complete Phase 2 and inform Phase 3
  - 300 patients, 75 centers globally (estimates)
- Leverage characteristics in a target population that most particularly benefit from the unique attributes of the drug: low blood pressure and/or diuretic resistance
- Increase infusion time to >24 hours (ideally 48-96 hours)
- Include measures that can be pivotal for phase 3

Planned study start up in 2H 2020 to be in a position to commence in early 2021 with resourcing

Early Cardiogenic Shock Treatment

Istaroxime Potential Opportunity for Accelerated Approval Pathway

Cardiogenic shock is a **severe presentation of heart failure** characterized by **very low blood pressure and hypoperfusion** accompanied by high PCWP and decreased urine output

Challenges

- No Satisfactory Pharmacological Intervention to Reverse the Conditions
- High Associated Mortality and Morbidity

FDA Regulatory Guidance with Break-Through Therapy Designation Potential

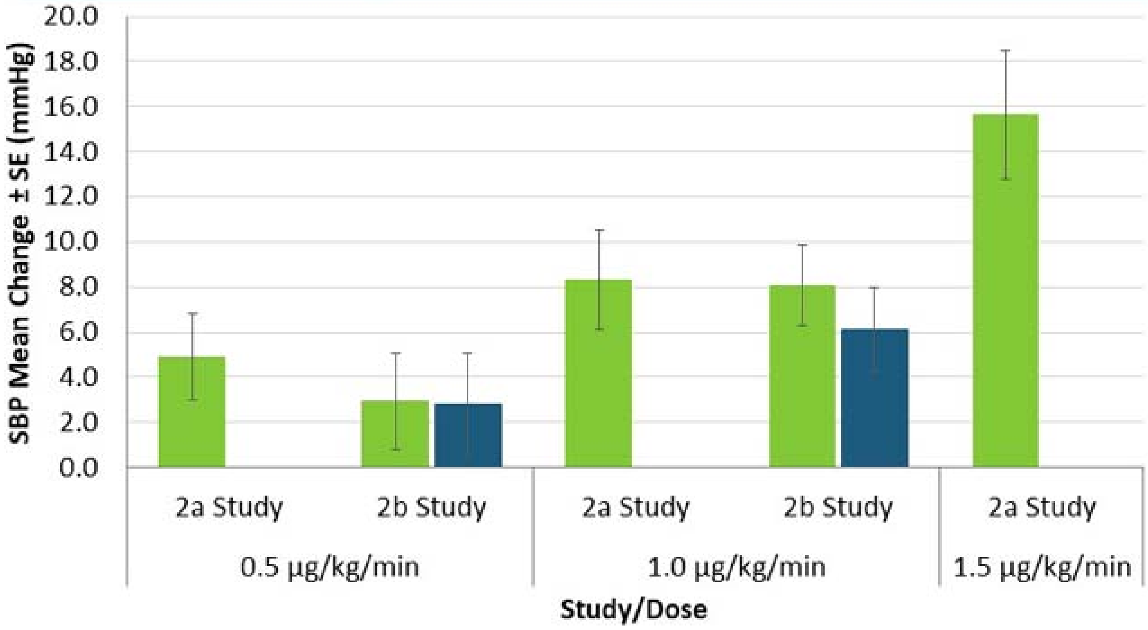
Sponsors are potentially **not required to show a benefit other than an increase in blood pressure to support approval of drugs to treat hypotension in the setting of shock[1].** (Precedent: NDA for Giapreza® (IV Angiotensin II), approved in 2017 for increasing MAP in distributive shock)[2]

Guidance and precedent lead us to believe there may be opportunities for an accelerated regulatory pathway and review

1) Kosaraju A, Hai O. Cardiogenic Shock. [Updated 2019 Jan 25]. In: https://www.ncbi.nlm.nih.gov/books/NBK482255/
CSRC Think Tank - July 24, 2019
2) Senatore et al., Am J Cardiovasc Drugs, February 2019, Volume 19, Issue 1, pp 11–20 (https://doi.org/10.1007/s40256-018-0297-9)

Istaroxime SBP Change from Baseline to 6 or 24 Hours from the Phase 2a and 2b Dose Groups

Istaroxime has the potential to improve blood pressure and organ perfusion in patients with AHF



Mean SBP at Baseline ~112 mmHg

Istaroxime – Early Cardiogenic Shock – Next Steps

Next Steps

- Initiate a study in early cardiogenic shock while we are preparing for the larger phase 2b acute heart failure study
  - ~60 patients conducted in the Europe and US
  - Start Q3-2020 with data expected in mid-2021
- Phase 2 clinical program suggests a meaningful increase in blood pressure may be achieved in early cardiogenic shock by istaroxime

Goal:

- Improve SBP with acceptable safety profile
  - Increased systolic and diastolic cardiac function without increasing heart rate, risk for arrythmias or myocardial oxygen demand
- Support a breakthrough therapy regulatory application

WINDTREE THERAPEUTICS

Pre-Clinical Programs

Novel Oral SERCA2a Activators for HF + Acute Pulmonary Platform

The Company also has early exploratory research programs to identify potential product candidates including:

Cardiovascular

Selective SERCA2a Activators

- Oral & i.v. therapies for chronic heart failure (CHF) and AHF
- Attractive approach for heart failure with preserved ejection fraction (HFpEF)

Dual Mechanism Compounds for Heart Failure

- Oral & i.v. therapies for CHF, AHF

These next generation agents and platform are part of a complete chronic and acute portfolio for licensing / partnership and the market

Acute Pulmonary

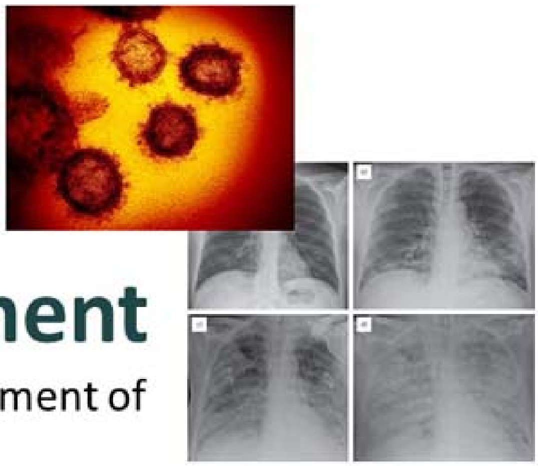
KL4 Platform

for lung protection and drug delivery

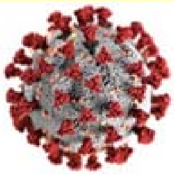
COVID-19

Lung Injury Treatment

Synthetic KL4 Surfactant for the Treatment of Lung Injury in COVID-19 Patients

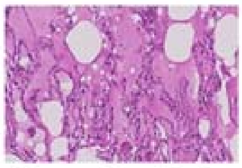


COVID-19 and ARDS Have A Significant Negative Impact On Surfactant Related Lung Function



Uses angiosten-converting enzyme 2 (ACE2) for entry into host cells

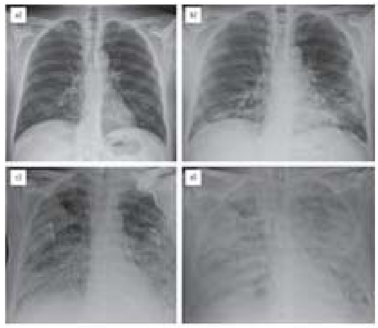
ACE2 is a surface molecule on alveolar Type 2 cells of lungs, the source of surfactant in the lung



Damaged Type 2 cells results in impaired surfactant production

Increased likelihood of mechanical ventilation

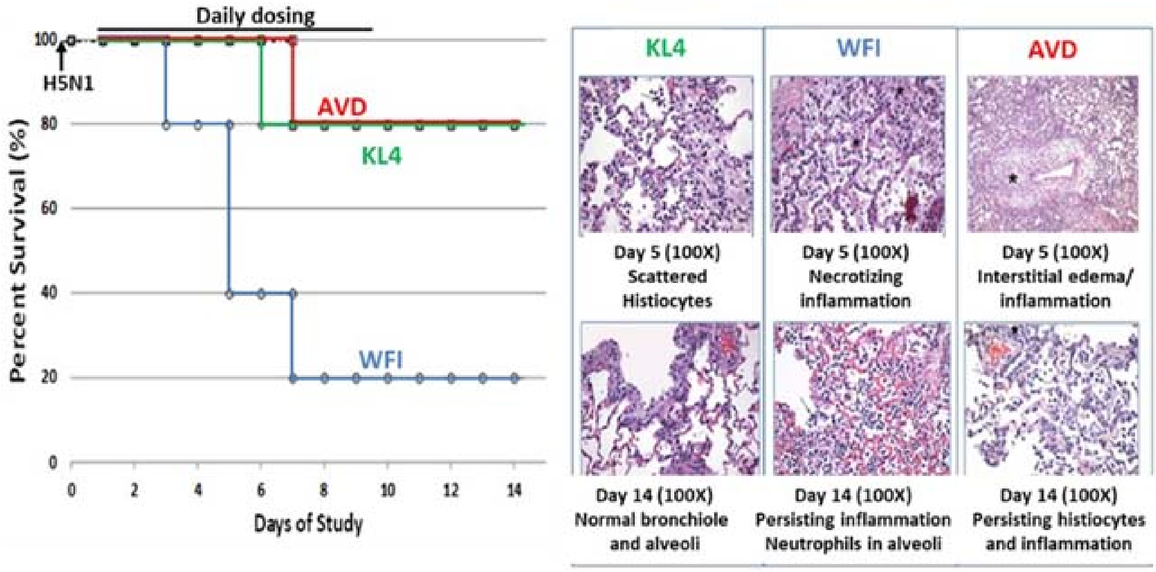
- COVID-19 infection can cause serious lung injury resulting in acute respiratory distress syndrome (ARDS) – a condition with high mortality and no approved drug therapies and where surfactant abnormalities are an important factor.
- Recent publications suggest that lung fibrosis and severe interstitial changes occur in COVID-19 patients who developed ARDS[1, 2, 3].
  - These changes resemble those seen in premature infants who are initially ventilated due to RDS and later develop bronchopulmonary dysplasia (BPD).
  - These observations support the rationale for use of exogenous surfactant in the treatment of ARDS caused by COVID-19.



1) Bernheim, A., X. Mei, et al. (2020). "Chest CT Findings in Coronavirus Disease-19 (COVID-19): Relationship to Duration of Infection." Radiology: 200463.
2) Hosseiny, M., S. Kooraki, et al. (2020). "Radiology Perspective of Coronavirus Disease 2019 (COVID-19): Lessons From Severe Acute Respiratory Syndrome and Middle East Respiratory Syndrome." American Journal of Roentgenology: 1-5.
3) Song, F., N. Shi, et al. (0). "Emerging 2019 Novel Coronavirus (2019-nCoV) Pneumonia10.1148/radiol.2020200274." Radiology 0(0): 200274

KL4 Surfactant Significantly Reduced Mortality in a Pre-Clinical H5N1 Study – *With and Without Anti-Viral Agent*

- Ferrets Infected with highly pathogenic avian (H5N1) influenza
- Results in significant viral and inflammation related lung damage that is substantially ameliorated by KL4 surfactant treatment



KL4 = aerosolize KL4 surfactant, WFI = aerosolized water (control), AVD = aerosolized KL4 surfactant + antiviral

Surfactant Administration In Severe COVID-19 Lung Injury May Have Potential to Provide Significant Benefits

- We believe our synthetic KL4 surfactant may have the potential to mitigate surfactant deficiency and resist the widespread surfactant destruction that can occur as a result of COVID-19
- Synthetic KL4 surfactant removes any immunological concerns and has manufacturing scalability versus animal-derived surfactants

Pre-clinical and clinical evidence shows surfactant replacement therapy has the potential to:

Improve

- Lung function
- Gas exchange and oxygenation
- Lung compliance

Decrease

- Inflammation in the lung
- Which may decrease lung damage, facilitate recovery and decrease mechanical ventilation

References in appendix

Clinical Proposal:
Lucinactant (KL4 Surfactant) For The Treatment of COVID-19

Initial phase 2 study will be to demonstrate changes in physiological parameters in COVID-19 associated lung injury and ARDS

- Up to 20 patients from 4-5 US sites (lead by institutions in Boston & Durham, NC)
- Dosing through the endotracheal tube, target 80 mg TPL/kg. Repeat dosing based on improvement in oxygenation
- Planned outcome measures (TBD):
  - Physiologic response: Oxygenation Index (OI)
  - Lung compliance on the ventilator
  - Clinical parameters (time on MV, days in ICU, mortality)

Expected recruitment in approximately 3 - 6 months of time
(once completed of approval process and trial initiated - depending on COVID-19 rates)

- If study outcomes are favorable, plan would be to initiate 2 expanded trials to assess:
  - Expanded study in ventilated patients to establish outcomes
  - Aerosolized delivery to avoid mechanical ventilation (similar to our respiratory distress syndrome studies)

WINDTREE THERAPEUTICS

Evidence of KL4 Surfactant Potential Utility in COVID-19 – *Demonstrated Utility Across Various Respiratory Distress*

Demonstrated Utility of KL4	
Extensive Studies in Acute Lung Conditions:	▪ 13 studies for intratracheal administration including RDS, BPD, acute hypoxemic respiratory failure and adults with ARDS ▪ 2,148 patients enrolled | 1,028 treated ▪ Aerosolized KL4 surfactant studied in 366 subjects enrolled, 223 subjects treated
SARS and Subsequent Support for Acute Lung Injury Studies	▪ CEO testified before congressional committee regarding KL4 for the treatment of SARS ▪ ~$10M of NIH support for clinical and non-clinical programs including lung protection studies involving viral infections with H1N1 and RDS
American Thoracic Society Presentation	▪ KL4 surfactant has to the potential to be employed to protect the lung and reduce mortality in patients exposed to highly pathogenic influenza as well as against pandemic strains

In May 2018 data from a preclinical animal model of a **highly pathogenic H5N1 viral** pneumonia was presented showing aerosolized KL4 surfactant reduced lung inflammation and improved overall survival

We have been evaluating the applicability of KL4 surfactant for respiratory distress as well as influenza long before the COVID-19 pandemic

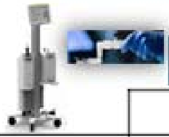
WINDTREE THERAPEUTICS

AEROSURF®

Synthetic KL4 Surfactant with
Proprietary Aerosol Delivery System
for the Treatment of RDS

Respiratory Distress Syndrome (RDS)
Current Treatment Pathways

- Premature infants experience respiratory distress syndrome ("RDS") due to lungs lacking endogenous surfactant. Surfactant helps keep lungs open between breaths and gas exchange
- Physicians have to choose between invasive surfactant delivery with known, significant complications or non-invasive nasal continuous positive airway pressure (nCPAP) alone (that often fails without surfactant)



	AEROSURF	Current Treatment	
	Non-Invasive Synthetic Surfactant	Invasive Surfactant (~40%)	nCPAP Only (~60%)
Surfactant	▪ Proprietary Synthetic KL4 surfactant[1]: – Structurally similar to human lung surfactant – shown to improve lung function in premature infants	 ▪ Animal derived	 ▪ None
Method of Delivery	▪ Proprietary aerosol delivery system (ADS) with nCPAP	▪ Intubation usually in combination with mechanical ventilation	▪ nCPAP
The AEROSURF Difference	▪ **Timely surfactant therapy delivered non-invasively to avoid potential complications** ▪ **Improves respiratory parameters** ▪ **Potential for decreased nCPAP failures and decreased need for invasive intubation and decreased rates of bronchopulmonary dysplasia (BPD)**	▪ **Timely therapy, but exposure to known significant complications associated with invasive intubation**	▪ **Avoid exposure to significant complications** ▪ **Foregoing surfactant treatment results in notable nCPAP failure rate and intubations**

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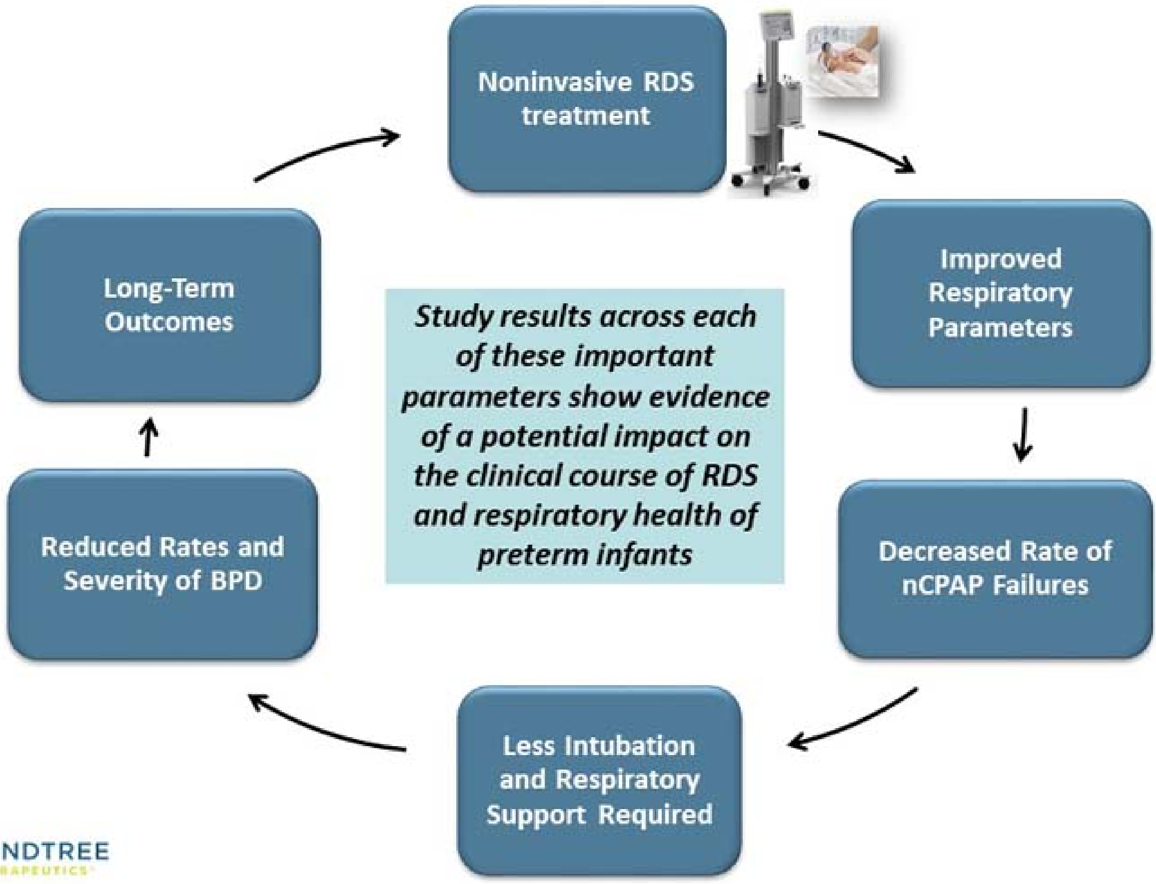
1. Liquid KL4 surfactant for RDS approved by the FDA. Lyophilized KL4 currently being developed for AEROSURF

AEROSURF® - Potential to Impact the Clinical Course of RDS

Building Evidence From Nearly 400 Patients Studied



WINDTREE THERAPEUTICS

AEROSURF® Program Evolution and Strategy

Mitigating Risks and Strengthening Our Approach

Program Evolution

- Completed three phase 2a and 2b trials
- Efficacy in reducing nCPAP failure and the need for intubation
- Transitioned to the newly-developed ADS
- Safety profile supports employing a dosing regimen to deliver more aerosolized surfactant in a shorter time period

Program Strategy

- Execute a small (n=~80 - 90) Bridging Study to transition to EOP2 / Phase 3
- Demonstrate the new ADS works and supplement phase 2 data
- Optimize dosing with more drug and shorter repeat intervals
- Leverage China, the largest market for RDS and surfactants, and use the partnership with Lee's to help fund study in a non-dilutive manner

Summary

Business Development Focus

We are actively engaged in discussions with multiple companies with a proactive focus as follows:

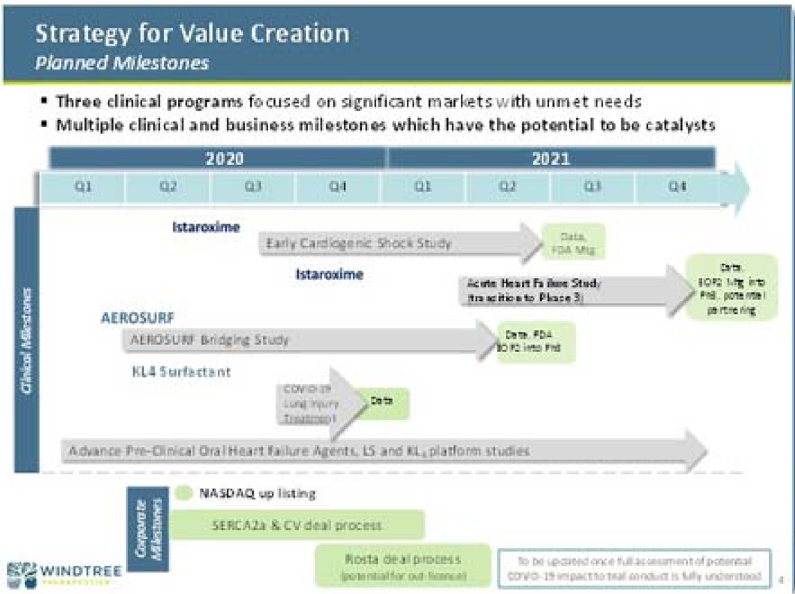
Short-term	Cardiovascular Partner – China Pure SERCA2a Pharma Partner – Global AEROSURF® / KL4 – Project Financing Model
Mid-term (Data & EOP2)	Heart Failure Portfolio Partner – Global Rosta Out-License - Global AEROSURF / KL4 – Regional or Global
Long-term (Strategy)	Portfolio Optimization and Expansion Retained US Co-Promo Rights

Financial Summary & Capitalization as of June 30, 2020

- Cash & Equivalents of $31.5 million
- Debt: ~$2.4M bank credit facility as of August 13, 2020 due in March 2022

Securities	Common Equivalents
Common Stock	16,868,732
Options (WAEP $17.41)	1,761,949
RSUs	35,000
Warrants (WAEP $16.38)	7,913,900
Fully Diluted	26,579,581

Multiple Development and Business Activities Create a Robust Outlook of Potential Milestones



2020 / 1H 2021 Planned Events

- AEROSURF bridge study start, and final data
- Nasdaq Listing (and raise)
- Istaroxime Cardiogenic Shock study start, data read out
- COVID-19 KL4 surfactant study (IND, study start, data read out as well as government engagement for possible funding)
- Heart Failure BD deliverables
- AHF study start up
- Pre-Clinical Studies

WINDTREE THERAPEUTICS

Windtree Therapeutics

"Striving to deliver Hope for a Lifetime!"

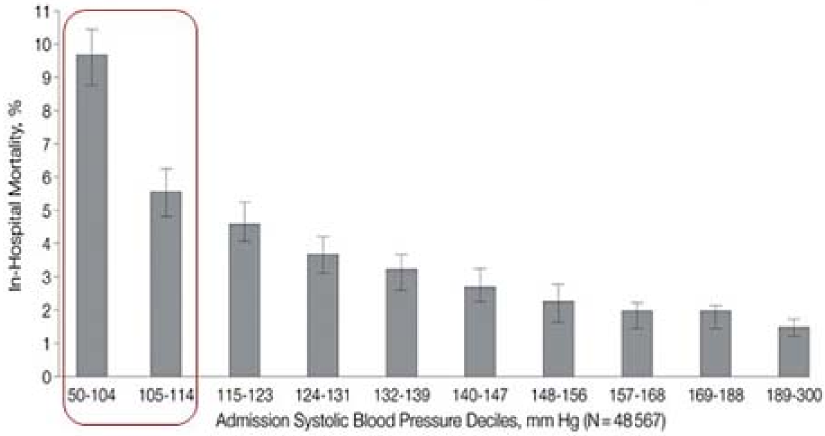
WINDTREE THERAPEUTICS

Appendix

WINDTREE THERAPEUTICS

Cardiac Output, Blood Pressure and Renal Function are Critical Factors in Managing AHF Patients and Their Outcomes

In-Hospital Mortality Rates by Admission Systolic Blood Pressure Deciles (n = 48,567)

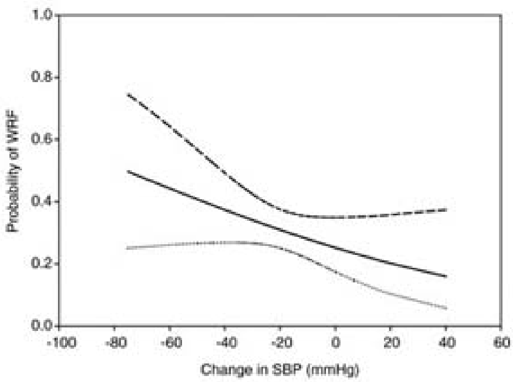


Gheorghiade, M. et al. JAMA 2006;296:2217-2226.

European Journal of Heart Failure (2011) 13, 961–967

Early drop in systolic blood pressure and worsening renal function in acute heart failure: renal results of Pre-RELAX-AHF

Adriaan A. Voors[1*], Beth A. Davison[2], G. Michael Felker[3], Piotr Ponikowski[4], Elaine Unemori[5], Gadi Cotter[2], John R. Teerlink[6], Barry H. Greenberg[7], Gerasimos Filippatos[8], Sam L. Teichman[5], and Marco Metra[9] on behalf of the Pre-RELAX-AHF study group



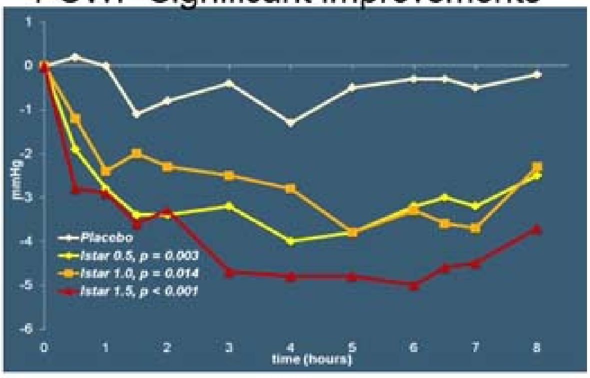
WINDTREE THERAPEUTICS

Istaroxime Phase 2a (HORIZON-HF) Study

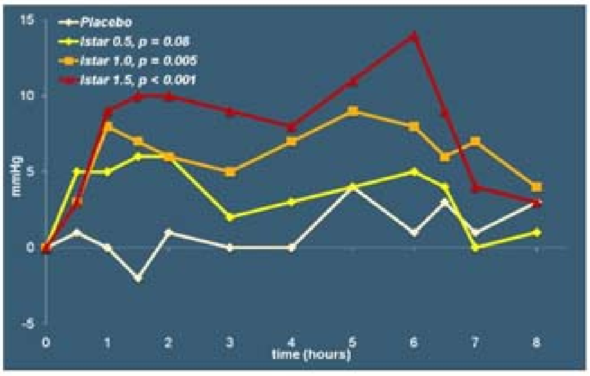
- Multicenter, double blind, placebo-controlled, doses 6-hour infusion of istaroxime 0.5, 1.0, 1.5 ug/kg/min, conducted in the EU
- Hospitalized with AHF, with criteria including:
  - LVEF ≤ 35%
  - SBP 90-150 mmHg
- N=120 (30/group)
- Significant improvement in PCWP, SBP, heart rate was lower. Istaroxime was generally well tolerated with no unexpected adverse events

Primary Endpoint:

PCWP Significant Improvements



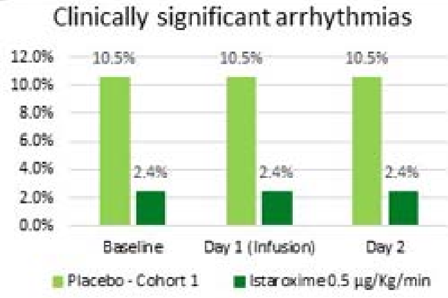
Dose-dependent Increase in SBP

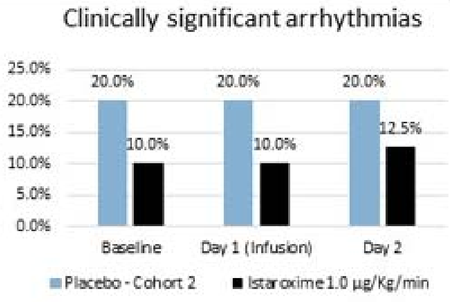


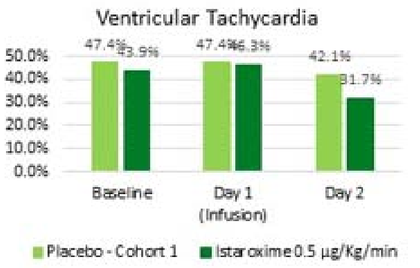
WINDTREE THERAPEUTICS

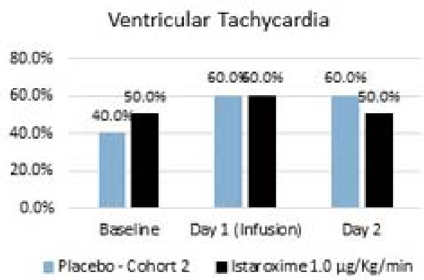
Istaroxime Phase 2b Study

Favorable Profile Observed with 24-hour Holter Monitoring









PVCs (n°/24 hours) shown as median, ventricular tachycardia and clinically significant arrhythmias shown as percentage of patients

WINDTREE THERAPEUTICS

Istaroxime Phase 2b Adverse Events

Event	Pooled placebo (n=39)	istaroxime 0.5 mg/Kg/min (n=41)	istaroxime 1.0 mg/Kg/min (n=40)
All adverse events	23 (59.0%)	31 (75.6%)	33 (82.5%)
Adverse events leading to discontinuation	1 (2.6%)	-	4 (10.0%)
Serious adverse events	2 (5.1%)	2 (4.9%)	6 (15.0%)
Cardiac death	-	-	1 (2.5%)
Cardiogenic shock	-	-	1 (2.5%)*
Cardiac failure	1 (2.6%)	2 (4.9%)	3 (7.5%)
Renal embolism	-	-	1 (2.5%)
Transient ischemic attack	1 (2.6%)	-	-
Hyperventilation	1 (2.6%)	-	-
Hypotension	1 (2.6%)	-	-
Adverse Drug Reactions†	10 (25.6%)	23 (56.1%)	25 (62.5%)
Cardiovascular††	**9 (23.1%)**	**4 (9.8%)**	**7 (17.5%)**
Gastrointestinal‡	2 (5.1%)	4 (9.8%)	14 (35.0%)
Infusion site pain/inflammation	-	20 (48.8%)	13 (32.5%)

Note: data shown as n° patients (%) - patients can have more than one event during the 30-day follow up period
* Same patient who then died, and 1 additional death occurred at Day 31 (cardiac death) outside the 30 day window
† Adverse Drug Reactions are AEs related to study drug
††Most common - arrhythmia, atrial fibrillation, cardiac failure, ventricular tachycardia
‡ Most common - abdominal pain, nausea, vomiting, diarrhoea

WINDTREE THERAPEUTICS

Respiratory Distress Syndrome (RDS)
Current Treatment Pathways

Premature infants experience RDS due to underdeveloped lungs lacking endogenous surfactant. Surfactant helps keep lungs open between breaths and proper gas exchange

Initial treatment options include invasive and noninvasive methods:

Surfactant therapy + Invasive mechanical ventilation (IMV)

- Animal-derived surfactant
- Delivered via intubation, usually in combination with mechanical ventilation

VS.

nCPAP support until endogenous surfactant production

- Noninvasive nasal delivery of continuous positive airway pressure (nCPAP)
- Supports breathing

TRADE-OFFS

Timely therapy delivery
vs.
Exposure to known significant complications

Avoid exposure to significant complications
vs.
Foregoing surfactant treatment results in notable nCPAP failure rate

Ultimately, more than 50% of RDS infants are intubated and ventilated

Source: Windtree and third-party market research

Windtree Technology Platform - AEROSURF®

Proprietary Synthetic KL4 Surfactant + **Proprietary Innovative Aerosol Delivery System (ADS)**

Structurally similar to human lung surfactant

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

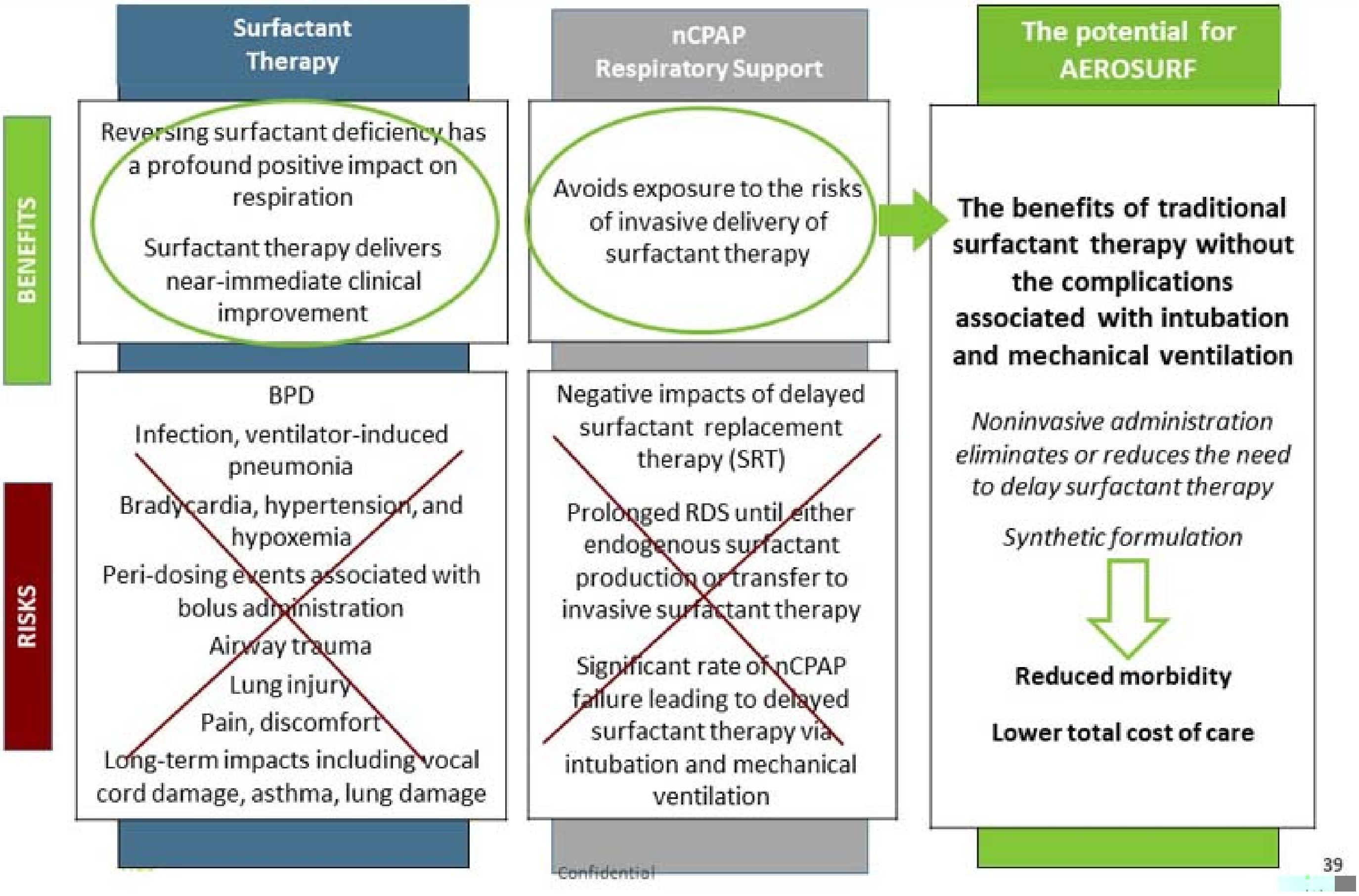
Lyophilized KL4 surfactant currently being developed for **AEROSURF**

Utilizing pressure and heated capillary has demonstrated ability to **aerosolize KL4 surfactant**

Controlled, effective and reproducible performance validated in studies

- KL4 surfactant has been shown to improve lung function in premature infants, resulting in decreased nCPAP failures and need for invasive intubation
- KL4 surfactant also has anti-inflammatory and other potentially positive attributes

Transformative Potential of AEROSURF®



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