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): November 16, 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 2.02 Results of Operations and Financial Condition

On November 16, 2020, Windtree Therapeutics, Inc. (the "***Company***") issued a press release announcing its financial results for the quarter ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

On November 16, 2020, 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 99.2.

The information contained in each of Item 2.02 (including Exhibit 99.1) and Item 7.01 (including Exhibit 99.2) is being furnished and shall not be deemed "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 and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Document
99.1	Press Release of Windtree Therapeutics, Inc., dated November 16, 2020, announcing financial results for the quarter ended September 30, 2020, furnished herewith.
99.2	Windtree Therapeutics, Inc. Investor Presentation

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, thereunto duly authorized.

Windtree Therapeutics, Inc.

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

Date: November 16, 2020

Windtree Therapeutics Reports Third Quarter 2020 Financial Results and Provides Key Business Updates

WARRINGTON, PA – November 16, 2020 – Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology and medical device company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today reported financial results for the third quarter ended September 30, 2020 and provided key business updates.

Key Business and Financial Updates

- Announced the dosing of the first patient in the Company's Phase 2 study of istaroxime for the acute treatment of early cardiogenic shock. The Phase 2 study is an international, randomized, double blind, placebo controlled study to assess the effect of istaroxime in patients with early cardiogenic shock due to heart failure. This study will include 60 patients (30 assigned to istaroxime and 30 assigned to placebo) receiving study drug infusion over 24 hours. The primary endpoint is the change in systolic blood pressure over six hours after initiating the infusion. Secondary endpoints will include characterization of blood pressure changes over 24 hours, the number of patients requiring rescue therapy (vasopressors, inotropes or mechanical devices), assessment of renal function and measures associated with safety and tolerability.

- Announced U.S. Food and Drug Administration (FDA) acceptance of an Investigational New Drug application for a Phase 2 clinical trial studying lyophilized lucinactant, its synthetic KL4 surfactant, in COVID-19 associated lung injury and acute respiratory distress syndrome (ARDS) patients. The initial study will evaluate changes in physiological parameters in patients who are intubated and mechanically ventilated for COVID-19 associated lung injury and ARDS. The study will evaluate the dosing regimen, tolerability, and functional changes in gas exchange and lung compliance after KL4 surfactant administration. The Company plans to enroll up to 20 patients with COVID-19 and ARDS who are on mechanical ventilation, from 4 to 5 U.S. sites beginning in the fourth quarter with results expected in one to two quarters.

- With Windtree focused on KL4 surfactant development in COVID-19 lung Injury, it has been decided Lee's Pharmaceutical (HK) (the license partner for KL4 surfactant in Asia) will execute the AEROSURF bridge study in premature infants with respiratory distress syndrome (RDS) within its licensed territory. Lee's will continue to fund clinical development of Aerosurf with Windtree providing technical support.

- Presented a corporate overview at the virtual H.C. Wainwright 22nd Annual Global Investment Conference in September.

"Windtree has made significant progress on advancing our clinical and regulatory goals over the past quarter," said Craig Fraser, president, and chief executive officer of Windtree. "With the IND acceptance by the FDA, we expect to start our clinical trial for the treatment of COVID-19 associated lung injury in the next several weeks. We are working with top insitutions and investigators and both interest and urgency for the study has only increased given the recent surge in COVID-19 rates and the further understanding of the harmful impact of the virus on these patients' lungs. In the third quarter we were also pleased to start dosing in our Phase 2 trial of istaroxime for the treatment of early cardiogenic shock in heart failure patients and will continue to work to expand sites to ramp enrollment for this trial globally. We continue to focus on the successful execution of our planned upcoming milestones this quarter, and anticipate 2021 to be another meaningful year with important milestones and pipeline progress including the planned start of the next acute heart failure study with istaroxime."

Select Financial Results for the Third Quarter ended September 30, 2020

For the third quarter ended September 30, 2020, the Company reported an operating loss of $8.7 million, compared to an operating loss of $7.2 million in the third quarter of 2019.

Research and development expenses were $3.9 million for the third quarter of 2020, compared to $3.8 million for the third quarter of 2019. The increase in research and development expenses is primarily due to increases in clinical program costs.

General and administrative expenses for the third quarter of 2020 were $4.8 million, compared to $3.4 million for the third quarter of 2019. The increase in general and administrative expenses is primarily due to an increase in professional fees and $0.9 million in severance costs associated with the departure of two exectuives during the third quarter of 2020.

The Company reported a net loss of $9.0 million ($0.54 per basic share) on 16.6 million weighted-average common shares outstanding for the quarter ended September 30, 2020, compared to a net loss of $7.1 million ($0.66 per basic share) on 10.7 million weighted average common shares outstanding for the comparable period in 2019.

As of September 30, 2020, the Company reported cash and cash equivalents of $22.4 million which is expected to be sufficient to fund operations through at least the next twelve months.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, which will be filed with the Securities and Exchange Commission on November 16, 2020, which includes detailed discussions about the Company's business plans and operations, financial condition and results of operations.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders to treat patients in moments of crisis. Using new clinical approaches, Windtree is developing a multi-asset franchise anchored around compounds with an ability to activate SERCA2a, with lead candidate istaroxime being developed as a first-in-class treatment for acute heart failure and early cardiogenic shock in heart failure. Windtree has also focused on developing AEROSURF® as a non-invasive surfactant treatment for premature infants with respiratory distress syndrome, and is facilitating transfer of clinical development of AEROSURF® to its licensee in Asia, Lee's HK, while Windtree evaluates other uses for its synthetic KL4 surfactant for the treatment of acute pulmonary conditions including lung injury due to COVID-19 infection. Also in its portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

For more information, please visit the Company's website at www.windtreetx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The Company may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are based on information available to the Company as of the date of this press release and are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company's current expectations. Examples of such risks and uncertainties include: risks and uncertainties associated with the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the Company's clinical trials or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime, AEROSURF®, KL4 surfactant and the Company's other product candidates; the Company's ability to secure significant additional capital as and when needed; the Company's ability to access the debt or equity markets; the Company's ability to manage costs and execute on its operational and budget plans; the results, cost and timing of the Company's clinical development programs, including any delays to such clinical trials relating to enrollment or site initiation; risks related to technology transfers to contract manufacturers and manufacturing development activities; delays encountered by the Company, contract manufacturers or suppliers in manufacturing drug products, drug substances, aerosol delivery systems (ADS) and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the FDA or other regulatory authorities may not agree with the Company on matters raised during regulatory reviews, 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 the Company's product candidates, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals and risks related to the Company's efforts to maintain and protect the patents and licenses related to its product candidates; risks related to the size and growth potential of the markets for the Company's product candidates, and the Company's ability to service those markets; the Company's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; and the rate and degree of market acceptance of the Company's product candidates, if approved. These and other risks are described in the Company's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2020	December 31, 2019
	Unaudited	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,356	$ 22,578
Prepaid expenses and other current assets	1,692	1,283
Total current assets	24,048	23,861
Property and equipment, net	702	798
Restricted cash	154	154
Operating lease right-of-use assets	855	1,390
Intangible assets	77,090	77,090
Goodwill	15,682	15,682
Total assets	$ 118,531	$ 118,975
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 726	$ 1,708
Collaboration and device development payable, net	-	1,972
Accrued expenses	4,279	3,226
Operating lease liabilities - current portion	605	750
Loans payable - current portion	704	161
Total current liabilities	6,314	7,817
Operating lease liabilities - non-current portion	358	794
Loans payable - non-current portion	2,364	4,608
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	2,400	-
Deferred tax liabilities	16,370	15,821
Total liabilities	42,806	44,040
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value; 120,000,000 shares authorized at September 30, 2020 and December 31, 2019; 16,921,506 and 13,697,419 shares issued at September 30, 2020 and December 31, 2019, respectively; 16,921,482 and 13,697,395 shares outstanding at September 30, 2020 and December 31, 2019, respectively	17	14
Additional paid-in capital	788,996	763,097
Accumulated deficit	(710,234)	(685,122)
Treasury stock (at cost); 24 shares	(3,054)	(3,054)
Total stockholders' equity	75,725	74,935
Total liabilities & stockholders' equity	$ 118,531	$ 118,975

Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
License revenue with affiliate	$ -	$ -	$ -	$ 198
Total revenues	-	-	-	198
Expenses:				
Research and development	3,882	3,792	11,838	10,547
General and administrative	4,823	3,395	11,518	9,990
Total operating expenses	8,705	7,187	23,356	20,537
Operating loss	(8,705)	(7,187)	(23,356)	(20,339)
Other (expense) income:				
Interest income	21	25	115	124
Interest expense	(46)	(105)	(121)	(358)
Other (expense) income, net	(290)	141	(1,750)	473
Total other (expense) income, net	(315)	61	(1,756)	239
Net loss	$ (9,020)	$ (7,126)	$ (25,112)	$ (20,100)
Net loss per common share				
Basic and diluted	$ (0.54)	$ (0.66)	$ (1.65)	$ (1.87)
Weighted average number of common shares outstanding				
Basic and diluted	16,579	10,730	15,228	10,724

Windtree Therapeutics

Company Overview

November 15, 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™

- Biopharmaceutical / device company located in Pennsylvania with research operations in Milan and Taipei. NASDAQ: WINT
- Multiple clinical assets and a pipeline focused on important acute cardiovascular and acute pulmonary needs and markets
- Currently executing several clinical programs which we believe have the potential to be catalysts for growth
- Highly experienced management team and company leadership

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 mid2021
Potential for Breakthrough designation	**Istaroxime** (Cardiogenic Shock)			Phase 2		▪ Active study in ~60 patients in early cardiogenic shock; Data currently expected Q3 2021
FDA, EMA Orphan Drug for RDS	**KL4 Surfactant – COVID 19** (COVID 19 Pilot; Possible invasive Tx for RDS in neonates)			Phase 2		▪ IND Accepted; Initiate trial Q4 2020; anticipate data in late Q1 / early Q2 2021
FDA Fast Track Designation, Orphan Drug	**AEROSURF** (Non-Invasive Tx for RDS)			Phase 2b		▪ Bridge study in ~80 patients with new ADS to be funded and executed by licensee
	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

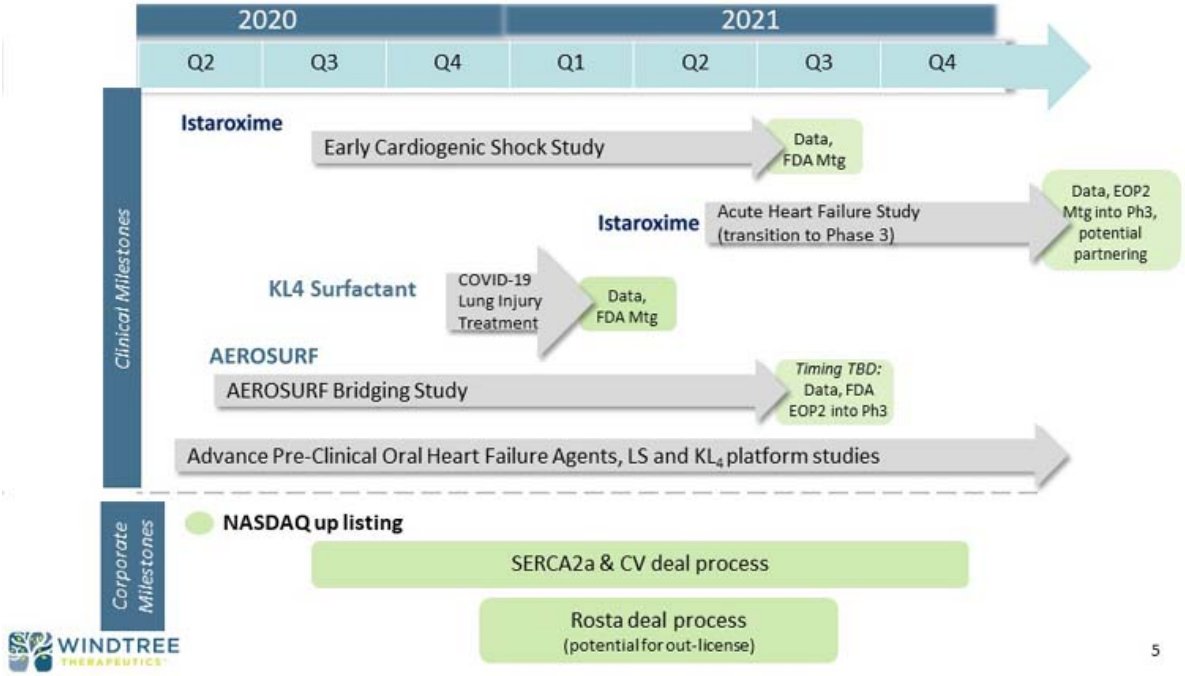
WINDTREE THERAPEUTICS

Strategy for Value Creation

Planned Milestones

To be updated once full assessment of potential COVID-19 impact to trial conduct is fully understood

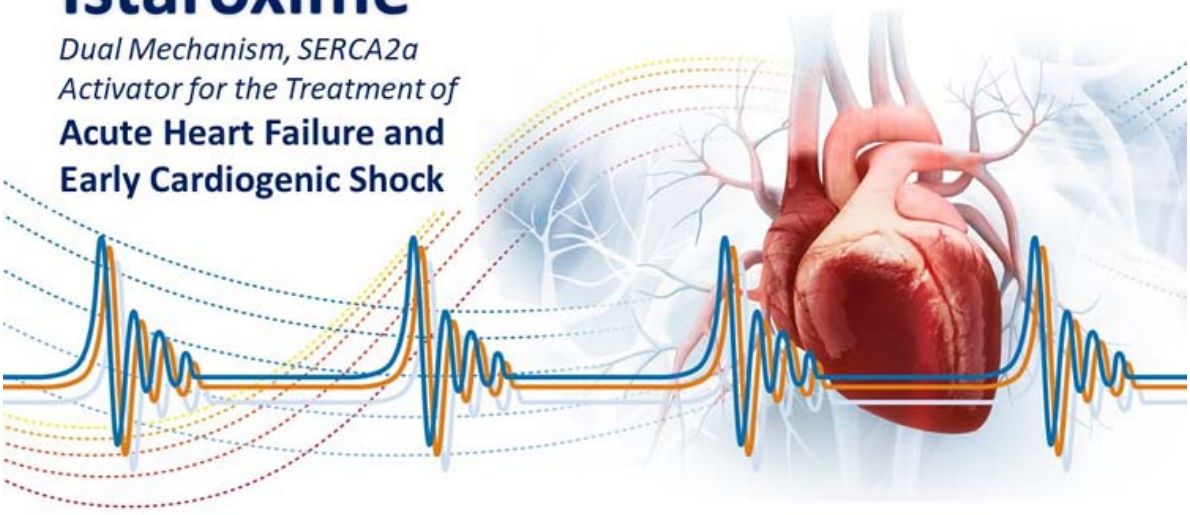
- **Four clinical programs** focused on significant markets with unmet needs
- **Multiple clinical and business milestones which may have the potential to be catalysts**



Istaroxime

Dual Mechanism, SERCA2a Activator for the Treatment of

Acute Heart Failure and Early Cardiogenic Shock



WINDTREE THERAPEUTICS

Heart Failure –
A Large Market with Significant Unmet Need

The prevalence of heart failure is high and increasing (as is mortality)

- 6M U.S., 18-20M worldwide patients
- #1 cause of U.S. hospitalization in patients > 65 years old;
  - > 1.3M admissions annually (U.S.) ~1.5M admissions annually (E.U.)
- In-patient mortality up to 7%; 30-day: can exceed 10%
- Most expensive of the Medicare diagnoses;
  U.S. hospitals spend > $18B annually

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

WINDTREE THERAPEUTICS

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 (SBP) 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]

WINDTREE THERAPEUTICS

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.**

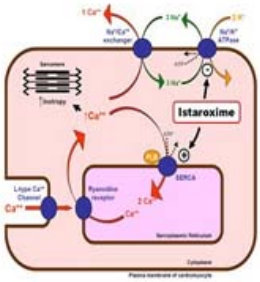
Dual Mechanism of Action

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

Istaroxime

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



WINDTREE THERAPEUTICS

Istaroxime AHF Phase 2a & 2b Studies – Summary

Multicenter, double blind, placebo-controlled, parallel group in 240 patients




Phase 2a	n=**120** ADHF Patients (dyspnea plus need for IV furosemide ≥ 40mg)	Dosing= **0.5, 1, 1.5**µg/kg/min	**6** hour Infusion	• Primary: PCWP significantly improved • Stroke Vol & SBP – significant increase • Heart Rate (HR) - lowered
Phase 2b	n=**120** ADHF Patients	Dosing= **1.0, 1.5**µg/kg/min	**24** hour Infusion	• Primary: E/e' (echocardiographic assessment of PWCP) was significantly improved by both doses • Heart rate decreased and stroke volume increased • Istaroxime maintained / increased systolic blood pressure • Renal function 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 AEs)

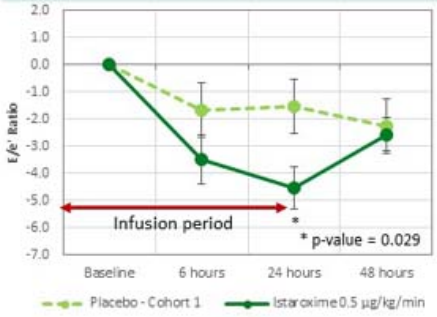
Phase 2 trial results demonstrated improved cardiac function without unwanted side effects of existing therapies

WINDTREE THERAPEUTICS

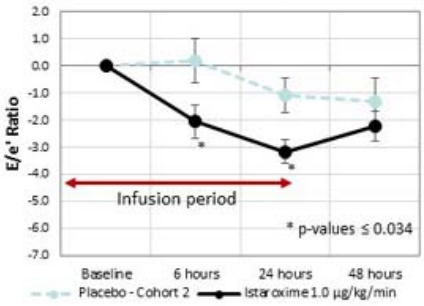
Primary Endpoint –

Significant Changes in E/e' Ratio and Stroke Volume

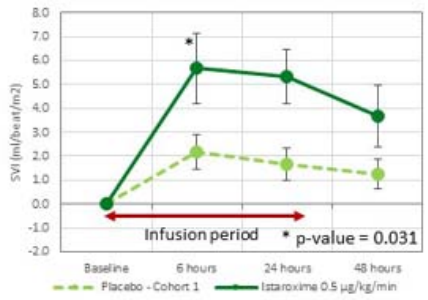
istaroxime 0.5 µg/kg/min vs. placebo



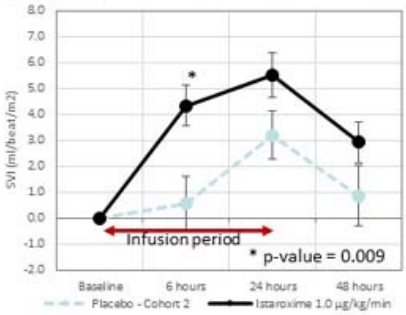
istaroxime 1.0 µg/kg/min vs. placebo



E/e'



Stroke Volume

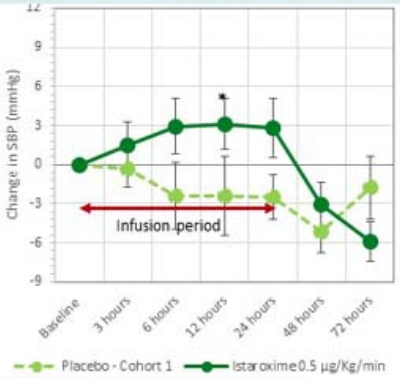


WINDTREE THERAPEUTICS

Data shown as means and standard errors

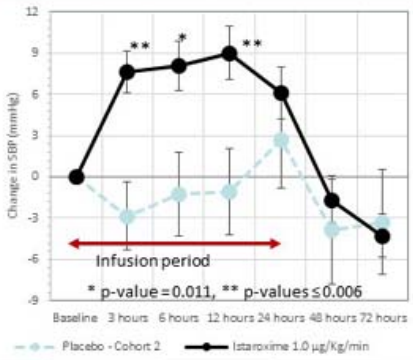
Systolic Blood Pressure Maintained or Increased During Treatment and Renal Function Tended to Improve

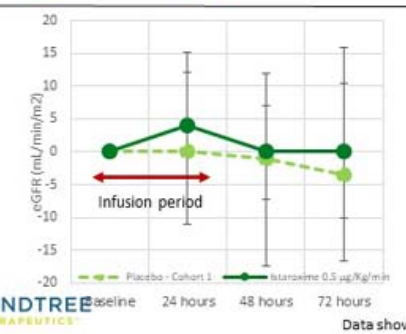
istaroxime 0.5 µg/kg/min vs. placebo



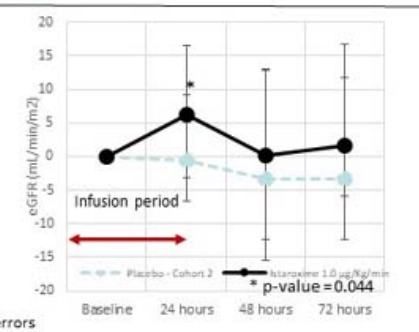
SBP

istaroxime 1.0 µg/kg/min vs. placebo





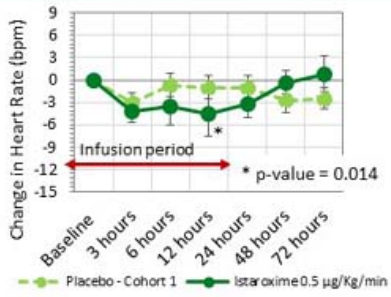
GFR



Data shown as means and standard errors

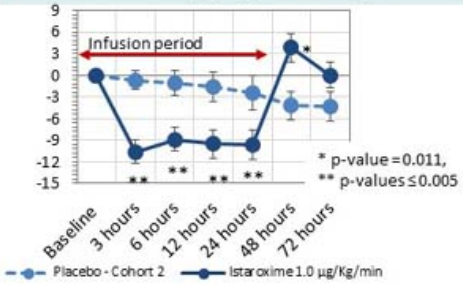
Heart Rate Decreased and No Increases in Cardiac Troponins

Istaroxime 0.5 µg/kg/min vs. placebo



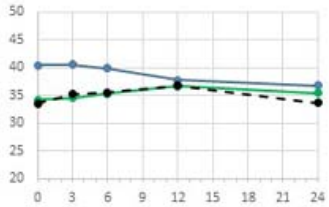
Heart Rate

Istaroxime 1.0 µg/kg/min vs. placebo

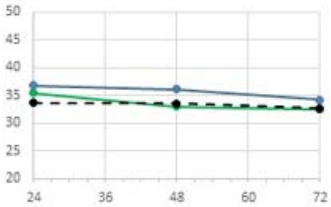


Cardiac TnT

cTnT – 0 to 24 hours



cTnT – 24 to 72 hours



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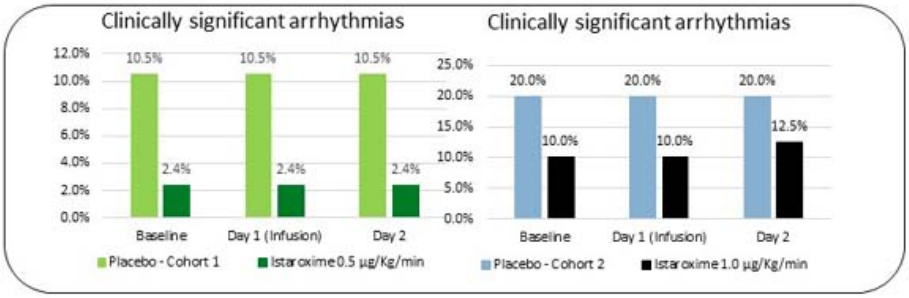
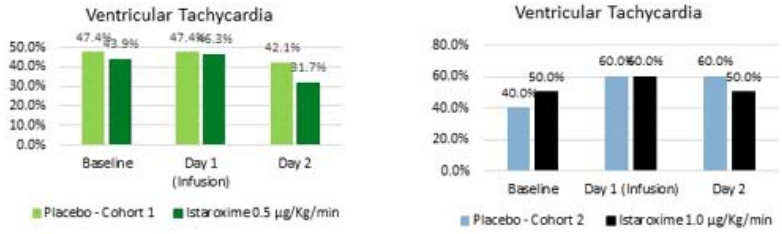
Favorable Profile Observed with 24-hour Holter Monitoring





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

Istaroxime – Acute Heart Failure
Next Steps

Objective: Create a strong phase 3 and partnership position

Execute an additional study designed to complete Phase 2 and inform Phase 3
- 300 patients, 75 centers globally (estimates)

Leverage characteristics in a target population whose needs match the unique attributes of istaroxime: **patients with low blood pressure and/or diuretic resistance**

Increase infusion time to >24 hours

Obtain data on measures that can be primary endpoints for phase 3

Planned study start up in 2H 2020 to be able to enroll in mid-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 Commentary 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]
- **Precedent lead us to believe there may be opportunities for an accelerated regulatory pathway and review**

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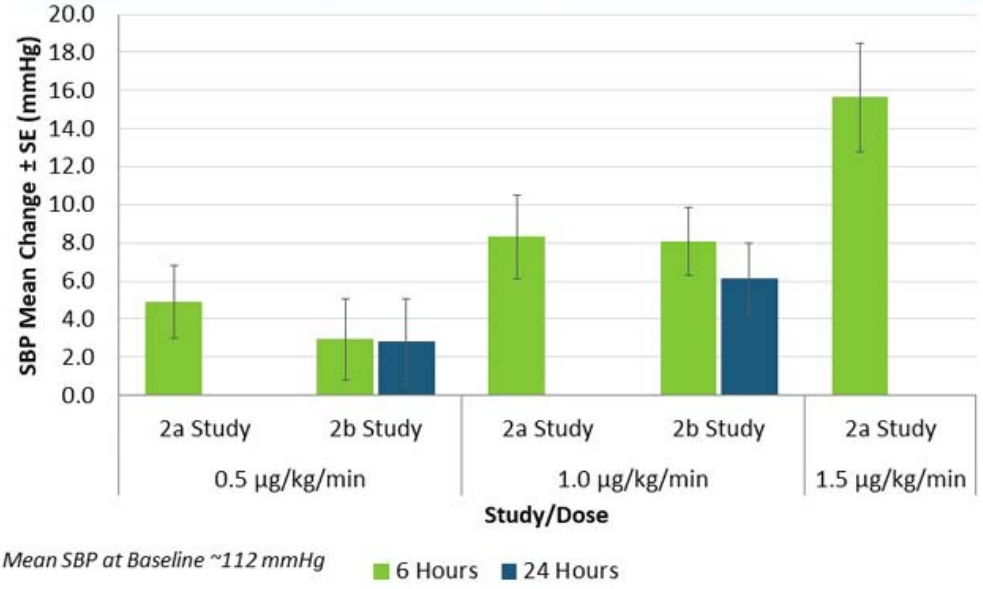
1) Kosaraju A, Hai O. Cardiogenic Shock. [Updated 2019 Jan 25]. In: https://www.ncbi.nlm.nih.gov/books/NBK482255/
CSRC Think Tank - July 24, 2019
2) Senatore et al., Am J Cardiovasc Drugs, February 2019, Volume 19, Issue 1, pp 11–20 (https://doi.org/10.1007/s40256-018-0297-9)

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

6 Hours 24 Hours

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Istaroxime –
Early Cardiogenic Shock in Severe AHF Study

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**

Ongoing early cardiogenic shock study:

(while we are preparing for the larger phase 2b acute heart failure study):

~60 patients in early cardiogenic shock (SBP 75-90mmHg) with AHF in the EU and US

1.5µg/kg/min target dose for 24 hours

- Primary endpoint is SBP AUC at 6 hours
- Other measures include: arrythmias, SBP AUC at 24 hours, echo measures, etc.

Started Q3-2020 with data expected in Q3 2021

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

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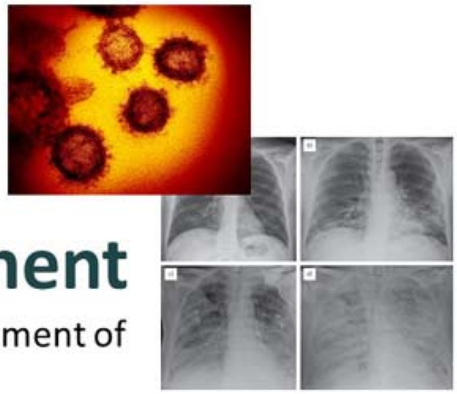
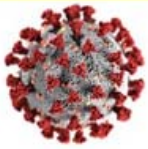
COVID-19
Lung Injury Treatment

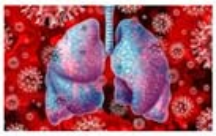
Synthetic KL4 Surfactant for the Treatment of Lung Injury in COVID-19 Patients



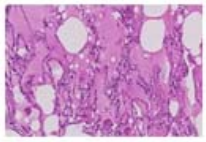
COVID-19 and ARDS Have A Significant Negative Impact On Surfactant Related Lung Function



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



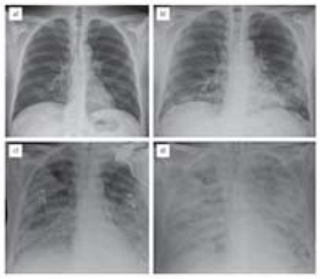
ACE2 is a surface molecule on alveolar Type 2 cells of lungs, the source of surfactant in the lung



Damaged Type 2 cells results in impaired surfactant production

Increased likelihood of mechanical ventilation

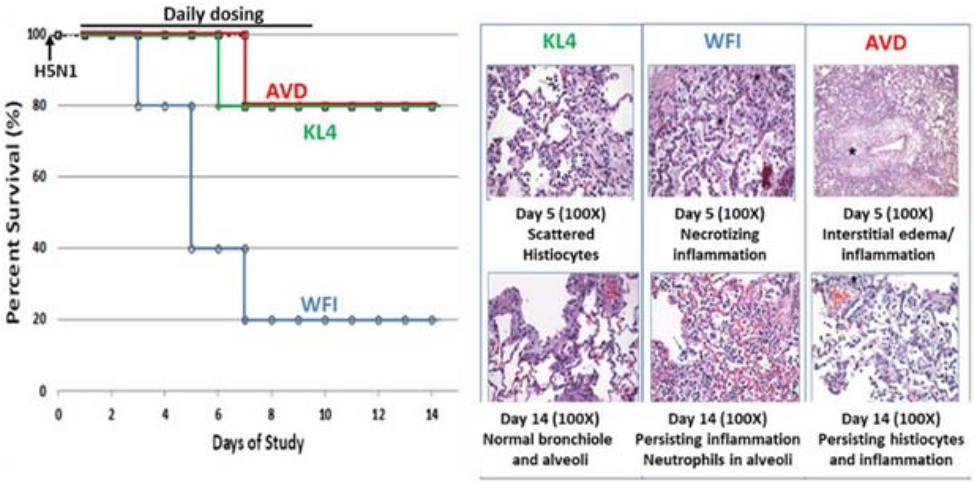
- COVID-19 infection can cause serious lung injury resulting in acute respiratory distress syndrome (ARDS) – a condition with high mortality and no approved drug therapies and where surfactant abnormalities are an important factor.
- Recent publications suggest that lung fibrosis and severe interstitial 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

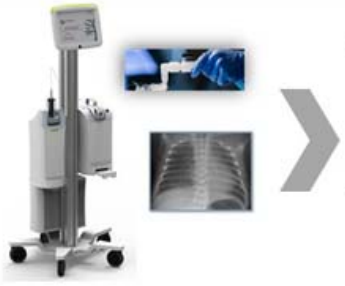
KL4 Surfactant Significantly Reduced Mortality in a Pre-Clinical H5N1 Study – *With and Without Anti-Viral Agent*

- 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

WINDTREE THERAPEUTICS

References in appendix

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

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

- Up to 20 patients from 4-5 US sites
  - led by investigators at Brigham & Women's and Duke Medical Center

- Dosing through the endotracheal tube, target 80 mg TPL/kg. Repeat dosing based on improvement in oxygenation

- Outcome measures include:
  - Physiologic response: Oxygenation Index (OI)
  - Lung compliance on the ventilator
  - Clinical parameters (time on MV, days in ICU, mortality)

Q4 2020 start; expected recruitment in approximately 3 - 6 months of time
(depending on COVID-19 rates)

If study outcomes are favorable, plan can be to initiate 2 expanded trials:

1. Expanded study in ventilated patients to establish outcomes
2. 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*

We have been evaluating the applicability of KL4 surfactant for multiple etiologies of lung injury as well as pandemic influenza long before the COVID-19 pandemic

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	▪ ~$10M of NIH support for clinical and non-clinical programs including lung protection studies involving viral infections with H1N1 and RDS ▪ CEO testified before congressional committee regarding KL4 for the treatment of SARS
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 damage and improved overall survival

WINDTREE THERAPEUTICS

AEROSURF®

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

Respiratory Distress Syndrome (RDS)
Current Treatment Pathways

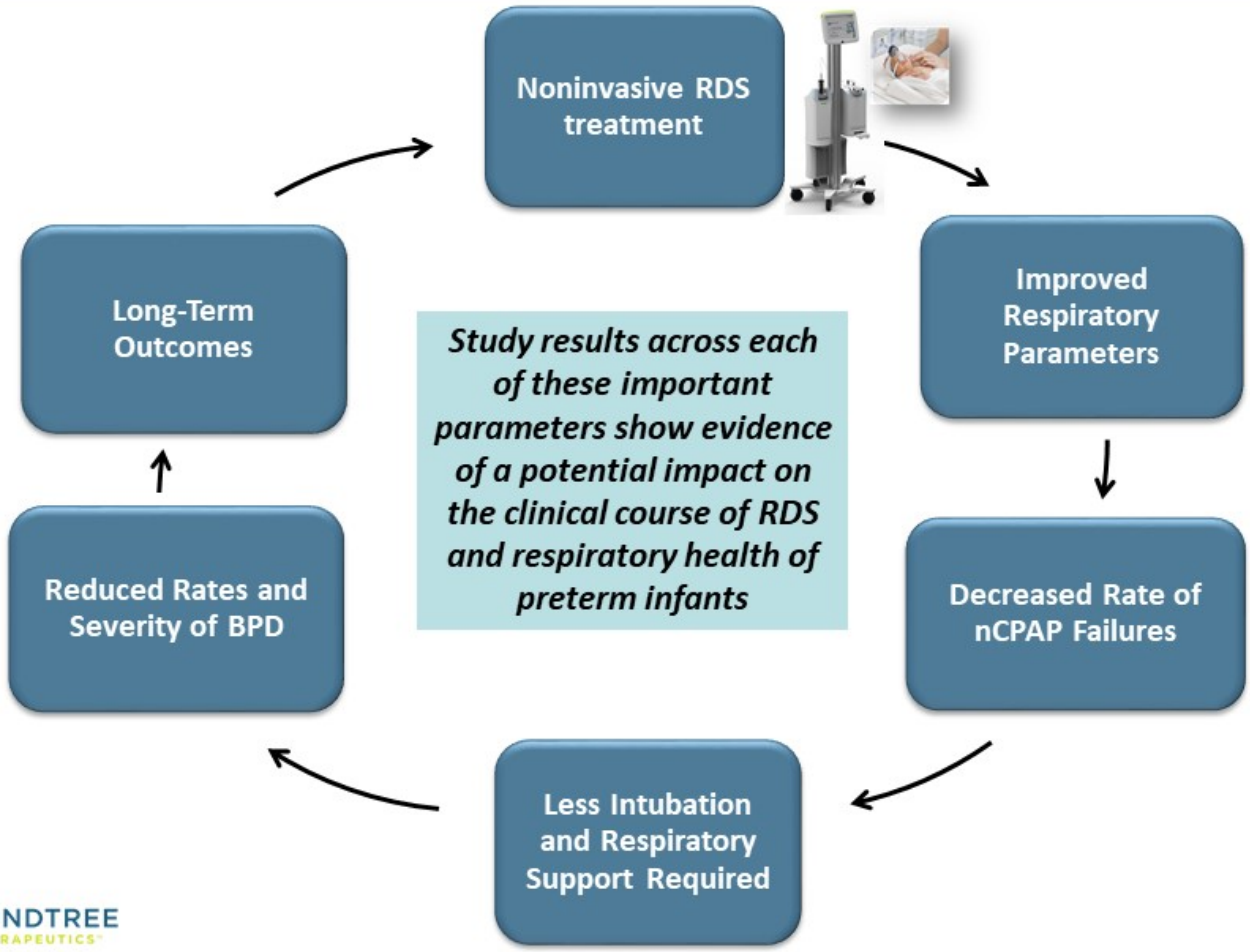
- Premature infants experience respiratory distress syndrome ("RDS") due to lungs lacking endogenous surfactant. Surfactant helps keep lungs open between breaths and gas exchange
- Physicians must choose between invasive surfactant delivery with known, significant complications or non-invasive nasal 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	▪ Animal derived	▪ None
Method of Delivery	▪ Proprietary aerosol delivery system (ADS) with nCPAP	▪ Intubation usually in combination with mechanical ventilation	▪ Nasal prongs
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**

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

✓ Demonstrated efficacy in reducing nCPAP failure, need for intubation and BPD with a generally positive safety profile

✓ Transitioned to the newly-developed ADS

Program Strategy

1. 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
2. Leveraging the partnership with Lee's to execute in Asia (the largest market) and fund the above study in a non-dilutive manner
   - We believe this allows Windtree to do more investment across adult applications (i.e. Lung Injury) and with acute cardiovascular programs)
3. Continue business development for potential additional partnerships and licensing ex-Asia

WINDTREE THERAPEUTICS

Summary

Financial Summary & Capitalization as of Sept. 30, 2020

- Cash & Equivalents of ~$22.4 million
- Bank Debt: ~$2.4M credit facility due in March 2022

Securities	Common Equivalents
Common Stock	16,921,482
Options (WAEP $15.76)	1,906,878
Warrants (WAEP $16.40)	7,896,150
Fully Diluted Equivalents	26,724,510

Strategy for Value Generation

- **Strong Clinical Execution to Deliver Milestones**: Execute well our several important, late-stage clinical programs for news flow and achievement of milestones that may be catalysts for growth
- **Transactions**:
  - Secure focused BD transactions for deal revenue and non-dilutive financial support of clinical development.
  - Progress the heart failure platform to an attractive and valuable position for global partnership (while retaining US co-promotion rights)
- **Optimization**: Leverage our highly experienced team in execution and in portfolio optimization efforts that may bring in new, well suited development opportunities / transactions

Windtree Therapeutics

"Striving to deliver Hope for a Lifetime!"

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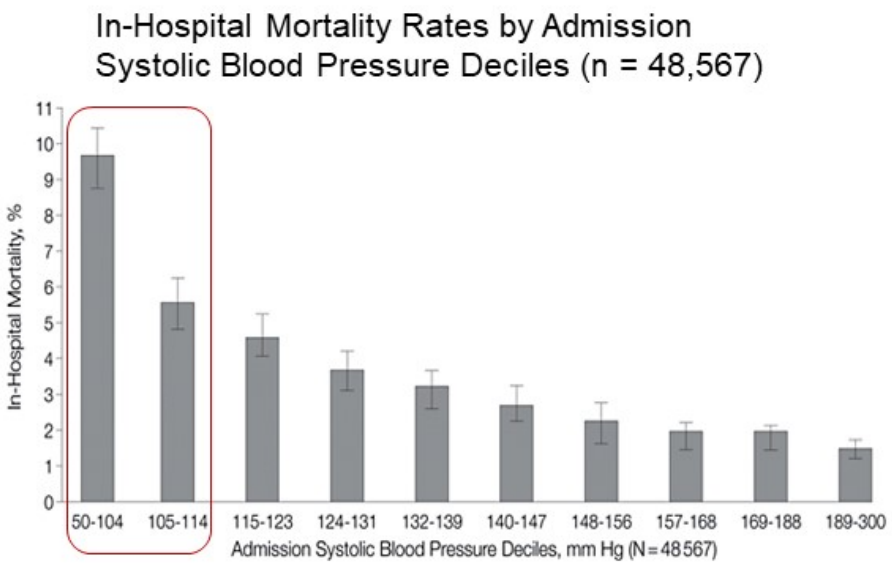
Appendix

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

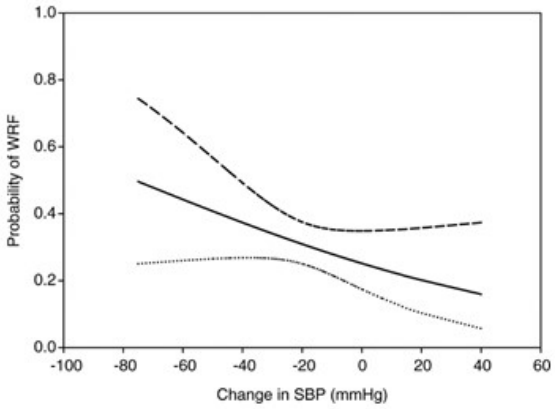


Gheorghiade, M. et al. JAMA 2006;296:2217-2226.

European Journal of Heart Failure (2011) 13, 961–967
doi:10.1093/eurjhf/hfr060

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



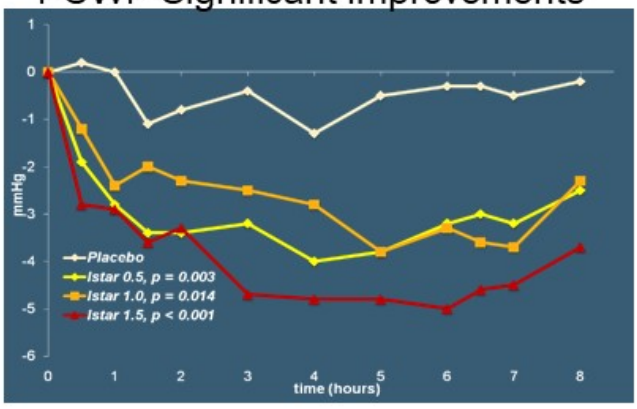
WINDTREE THERAPEUTICS

Istaroxime Phase 2a (HORIZON-HF) Study

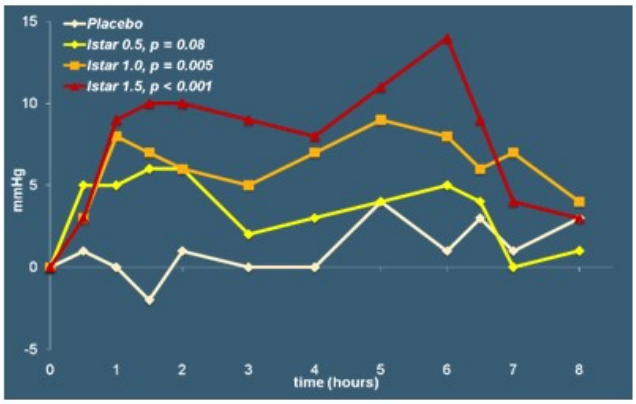
- Multicenter, double blind, placebo-controlled, doses 6-hour infusion of istaroxime 0.5, 1.0, 1.5 ug/kg/min, conducted in the EU
- Hospitalized with AHF, with criteria including:
  - LVEF ≤ 35%
  - SBP 90-150 mmHg
- N=120 (30/group)
- Significant improvement in PCWP, SBP, heart rate was lower. Istaroxime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

Primary Endpoint:

PCWP Significant Improvements



Dose-dependent Increase in SBP



WINDTREE THERAPEUTICS

Istaroxime Phase 2b 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

References Supporting Utilization of KL_4 Surfactant for the Treatment of Lung Injury

1. Hoffmann, M., H. Kleine-Weber, et al. (2020). "The novel coronavirus 2019 (2019-nCoV) uses the SARS-coronavirus receptor ACE2 and the cellular protease TMPRSS2 for entry into target cells10.1101/2020.01.31.929042." bioRxiv: 2020.01.31.929042.
2. Bernheim, A., X. Mei, et al. (2020). "Chest CT Findings in Coronavirus Disease-19 (COVID-19): Relationship to Duration of Infection." Radiology: 200463.
3. 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.
4. Song, F., N. Shi, et al. (0). "Emerging 2019 Novel Coronavirus (2019-nCoV) Pneumonia10.1148/radiol.2020200274." Radiology **0**(0): 200274
5. Gregory TJ, Steinberg KP, Spragg R, Gadek JE, Hyers TM, Longmore WJ, et al. Bovine surfactant therapy for patients with acute respiratory distress syndrome. Am J Respir Crit Care Med. 1997;155:1309-1315.
6. Bernard GR, Artigas A, Brigham KL, Carlet J, Falke K, Hudson L, et al. The American-European consensus conference on ARDS. Definitions, mechanisms, relevant outcomes, and clinical trial coordination. Am J Respir Crit Care Med. 1994;149:818-824.
7. Nicholas TE, Doyle IR, Bersten AD. Surfactant replacement therapy in ARDS. White knight or noise in the system? Thorax. 1997;52:195-197.
8. Brandstetter RD, Sharma KC, DellaBadia M, Cabreros LJ, Kabinoff GS. Adult respiratory distress syndrome: A disorder in need of improved outcome. Heart & Lung. 1997;26:3-14.
9. Wiedemann HP, Tai DY. Adult respiratory distress syndrome (ARDS): Current management, future directions. Cleve Clin J Med. 1997;64:365-372.
10. Fulkerson WJ, MacIntyre N, Stamler J, Crapo JD. Pathogenesis and treatment of the adult respiratory distress syndrome. Arch Intern Med. 1996;156:29-38.
11. Schuster DP, Kollef MH. Acute respiratory distress syndrome. Disease A Month. 1996;42:267-326.
12. Schuster DP, Kollef MH. The acute respiratory distress syndrome. New Engl J Med. 1995;332:27-37.
13. Sachdeva RC, Guntupalli KK. Acute respiratory distress syndrome. Crit Care Clin. 1997;13:503-521.
14. Ashbaugh DG, Bigelow DB, Petty TL, Levine BE. Acute respiratory distress in adults. Lancet. 1967;2:319-323.
15. Petty TL, Reiss OK, Paul GW, et al., Characteristics of pulmonary surfactant in adult respiratory distress syndrome associated with trauma and shock. Am Rev Respir Dis. 1977;115:531-536.
16. Petty TL, Silvers, Paul GW, Stanford RE. Abnormalities on lung properties and surfactant function in adult respiratory distress syndrome. Chest. 1979;75:571-574.
17. Hallman M, Spragg RG, Harrell JH, Moser KM, Gluck L. Evidence of lung surfactant abnormality in respiratory failure: Study of bronchoalveolar lavage phospholipids, surface activity, phospholipase activity, and plasma myoinositol. J Clin Invest. 1982;70:673-683.
18. Pison U, Seeger W, Buchhorn R, Joka T, Brand M, Obertacke U, et al. Surfactant abnormalities in patients with respiratory failure after multiple trauma. Am Rev Respir Dis. 1989;140:1033-1039.
19. Pison U, Overtacke U, Brand M, Seeger W, Joka T, Bruch J, et al. Altered pulmonary surfactant in uncomplicated and septicemia-complicated courses of acute respiratory failure. J Trauma. 1990;30:19-26.
20. Gregory TJ, Longmore WJ, Moxley MA, Whitsett JA, Reed CR, Fowler AI, et al. Surfactant chemical composition and biophysical activity in acute respiratory distress syndrome. J Clin Invest. 1991;88:1976-1981.
21. Greene KE, Wright JR, Steinburg KP, et al., Serial changes in surfactant-associated proteins in lung and serum before and after onset of ARDS. Am J Respir Crit Care Med. 1999;160:1843-1850

Surfactant in ARDS References

1. Gregory TJ, Steinberg KP, Spragg R, Gadek JE, Hyers TM, Longmore WJ, et al. Bovine surfactant therapy for patients with acute respiratory distress syndrome. Am J Respir Crit Care Med. 1997;155:1309-1315.
2. Wiedemann H, Baughman R, de Boisblanc E, et al., A multi centered trail in human sepsis-induced ARDS of aerosolized synthetic surfactant (Exosurf). Am J Respir Crit Care Med. 1992; 145:A184.
3. Weg JG, Balk RA, Tharratt RS, et al., Safety and potential efficacy of an aerosolized surfactant in human sepsis-induced adult respiratory distress syndrone. JAMA 1994;272:1433-1438.
4. Anzueto A, Baughman RP, Guntapalli KK, et al., Aerosolized surfactant in adults with sepsis-induced acute respiratory distress syndrome. New Engl J Med. 1996;334:1417-1421.
5. Spragg RG, Gilliard N, Richman P, et al., Acute effects of a single dose of porcine surfactant on patients with the acute respiratory distress syndrome. Chest 1994;105:195-202.
6. Walmrath D, Gunther A, Ardeschir H, et al., Bronchoscopic surfactant administration in patients with severe adult respiratory distress syndrome and sepsis. Am J Respir Crit Care Med 1996;154:57-62.
7. Walmrath D, Grimminger F, Papert D, et al., Bronchoscopic administration of bovine natural surfactant in ARDS and septic shock: impact on gas exchange and haemodynamics. Eur Respir J. 2002;19:805-810.
8. Wilson DF, Zaritsky A, Bauman LA, et al., Instillation of calf lung surfactant extract (calfactant) is beneficial in pediatric acute hypoxemic respiratory failure. Crit Care Med 1999;27:188-195.
9. Willson DF, Zaritsky A, Bauman LA, Dockery K, James RL, Conrad D, Craft H, Novotny WE, Egan EA, Dalton H. Instillation of calf lung surfactant extract (calfactant) is beneficial in pediatric acute hypoxemic respiratory failure. Members of the Mid-Atlantic Pediatric Critical Care Network. Crit Care Med. 1999;27(1):188-95.
10. Willson DF, Thomas NJ, Markovitz BP, Bauman LA, DiCarlo JV, Pon S, Jacobs BR, Jefferson LS, Conaway MR, Egan EA; Pediatric Acute Lung Injury and Sepsis Investigators. Effect of exogenous surfactant (calfactant) in pediatric acute lung injury: a randomized controlled trial. JAMA. 2005;293(4):470-6.
11. Willson DF, Thomas NJ, Tamburro R, Truemper E, Truwit J, Conaway M, Traul C, Egan EE; Pediatric Acute Lung and Sepsis Investigators Network. Pediatric calfactant in acute respiratory distress syndrome trial. Pediatr Crit Care Med. 2013;14(7):657-65.
12. Willson DF, Truwit JD, Conaway MR, Traul CS, Egan EE. The Adult Calfactant in Acute Respiratory Distress Syndrome Trial. Chest. 2015;148(2):356-364.
13. Walmrath D, De Vaal JB, Bruining HA, et al. Treatment of ARDS with a recombinant SP-C (rSP-C) based synthetic surfactant. Am J Respir Crit Care Med 2000;161:A379.
14. Spragg RG, Lewis JF, Wurst W, Häfner D, Baughman RP, Wewers MD, Marsh JJ. Treatment of acute respiratory distress syndrome with recombinant surfactant protein C surfactant. Am J Respir Crit Care Med. 2003;167(11):1562-6.
15. Spragg RG, Lewis JF, Walmrath HD, Johannigman J, Bellingan G, Laterre PF, Witte MC, Richards GA, Rippin G, Rathgeb F, Häfner D, Taut FJ, Seeger W. Effect of recombinant surfactant protein C-based surfactant on the acute respiratory distress syndrome. N Engl J Med. 2004;351(9):884-92.
16. Taut FJ, Rippin G, Schenk P, Findlay G, Wurst W, Häfner D, Lewis JF, Seeger W, Günther A, Spragg RG. A Search for subgroups of patients with ARDS who may benefit from surfactant replacement therapy: a pooled analysis of five studies with recombinant surfactant protein-C surfactant (Venticute). Chest. 2008;134(4):724-32.
17. Spragg RG, Taut FJ, Lewis JF, Schenk P, Ruppert C, Dean N, Krell K, Karabinis A, Günther A. Recombinant surfactant protein C-based surfactant for patients with severe direct lung injury. Am J Respir Crit Care Med. 2011;183(8):1055-61.
18. Wiswell TE, Smith RM, Katz LB, et al., Bronchopulmonary segmental lavage with Surfaxin (KL_4-surfactant) for acute respiratory distress syndrome. Am J Respir Crit Care Med 1999;160:1188-1195.

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)	VS.	**nCPAP support until endogenous surfactant production**
• Animal-derived surfactant • Delivered via intubation, usually in combination with mechanical ventilation		• 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

WINDTREE THERAPEUTICS

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**

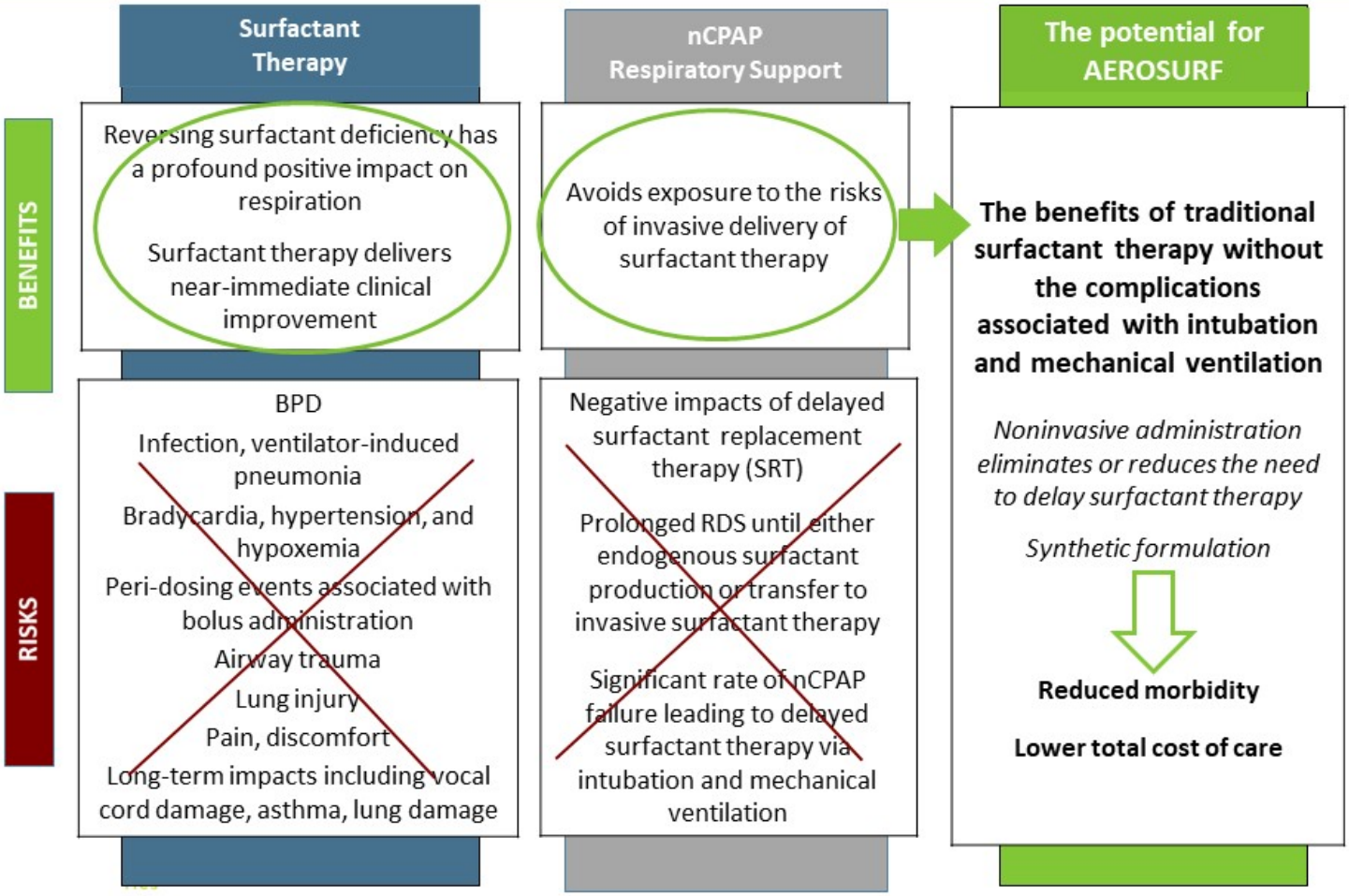
Utilizing pressure and heated capillary has demonstrated ability to **aerosolize KL4 surfactant**

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

WINDTREE THERAPEUTICS

Transformative Potential of AEROSURF®



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 Licensing ex-Asia

Mid-term (Data & EOP2)

- Heart Failure Portfolio Partner – Global
- Rosta Out-License - Global

Long-term (Strategy)

- Portfolio Optimization and Expansion
- Retained US Co-Promo Rights

WINDTREE THERAPEUTICS