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

FORM 8-K

CURRENT REPORT

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

December 11, 2019
Date of Report (Date of earliest event reported)

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

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

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

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:
☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

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

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

Item 7.01. Regulation FD Disclosure.

On December 11, 2019, executives of Windtree Therapeutics, Inc. (the "Company") held an investor conference call and discussed the Company's development programs and provided a financial update. A copy of the investor presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The information contained in the presentation is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission (SEC) and other public announcements that the Company has made and may make from time to time by press release or otherwise. The furnishing of the attached presentation is not an admission as to the materiality of any information contained therein. A playback of the full conference call and the materials presented is available at the Company's website at www.windtreetx.com.

Pursuant to General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto are 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, nor is it to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, unless the Company expressly sets forth in such future filings that such information is to be considered "filed" or incorporated by reference therein, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

As noted above, On December 11, 2019, executives of the Company held an investor conference call and discussed the Company's development programs and provided a financial update. As of December 10, 2019, the Company has $24.5 million in cash and cash equivalents. Based on current planning, the Company anticipates that, before any additional financings, it will have sufficient cash and cash equivalents to fund its development activities, business operations and debt service through the first quarter of 2021.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits:

99.1 Windtree Therapeutics, Inc. Presentation dated December 11, 2019.

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, cash flows, future revenues, the timing of planned clinical trials or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement made by us in this Current Report on Form 8-K is based only on information currently available to us and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

SIGNATURES

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

Windtree Therapeutics, Inc.

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

Date: December 11, 2019

Investor Call Presentation
December 11, 2019

OTCQB: WINT

WINDTREE THERAPEUTICS™

Forward-looking Statements

To the extent that statements in this presentation are not strictly historical, including statements about the Company's clinical development programs, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this presentation are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made, including risks relating to the Company's recent merger with CVie Therapeutics. These risks are further described in the Company's periodic filings with the Securities and Exchange Commission (SEC), including the most recent reports on Forms 10-K, 8-K and 10-Q, and any amendments thereto ("Company Filings")

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

Windtree Therapeutics Highlights

- **Late-stage pipeline of novel cardiovascular and pulmonary programs**
  - Three clinical programs with phase 2 data and pre-clinical pipeline candidates in both cardiovascular and pulmonary indications
- **Lead program, istaroxime (Ista), is a first-in-class SERCA2a activator being developed for acute heart failure (AHF) and cardiogenic shock**
  - Completed phase 2 trials demonstrated significant improvement in diastolic and systolic function
  - FDA Fast Track Designation granted in July 2019
  - Potential accelerated pathway opportunity in cardiogenic shock patients
- **Lead pulmonary program, AEROSURF®, provides noninvasive delivery of aerosolized KL4 surfactant to improve the management of respiratory distress syndrome (RDS) in premature infants**
  - Reduced nCPAP failure and need for intubation in phase 2 program when dosed as intended
  - Bridge study planned for transition to phase 3, leveraging partner financial resources
  - FDA Fast Track Designation granted in September 2016
- **Strong news flow opportunities with data readouts for both Ista and AEROSURF as well as potential business development activities in next 12 – 18 months**
- **Public biopharma company (OTCQB:WINT) with market cap ~$150 million**

$26.4 Million Private Placement Overview

- Private placement of 8.7 million shares of common stock at a per share purchase price equal to $3.02 (10% discount from the 30-day average closing price through November 29, 2019) for gross proceeds of $26.4 million
  - Proceeds include $2.95 million in non-cash consideration in the form of conversion of existing debt obligations with Lee's Pharmaceuticals
  - Net cash proceeds, after deducting estimated fees and expenses related to the offering, are expected to be approximately $23.0 million.
- For each share of common stock purchased, the purchaser received a five-year Series I warrant to purchase .5 shares of common stock at an exercise price of $4.03 per share
- Both existing and new investors from Asia and the U.S. participated in the private placement
  - Includes large, China-based pharmaceutical company with significant presence in cardiovascular market; in active discussions with company regarding a potential partnership arrangement for cardiovascular assets in China

Financial Position Update

As of December 10, 2019

- Cash and cash equivalents of $24.5 million as of December 10, 2019 (net of $0.5 million in estimated transaction related fees)
- $4.5 million of debt in a bank credit facility currently due in March 2020
  - working with bank to extend maturity to June 2021 with extension application currently under review
- Fully-diluted outstanding shares of 61.0 million and 59.0 million available for future issuance.

Current Capital Summary

Common Stock	41,035,282
Warrants	
Series I ($4.03 exercise price; expiring December 2024)	4,375,002
AEROSURF Warrants (dividend warrants to legacy WINT shareholders; expiring February 2024)	2,963,167
December 2018 Private Placement - Series F ($3.68 exercise price ; expiring June 2020)	2,003,541
December 2018 Private Placement - Series G ($4.05 exercise price ; expiring December 2023)	3,889,229
Battelle December 2018 Warrants - Series E ($6.50 exercise price; expiring December 2023)	75,000
July 2018 Convertible Debt Warrants - Series D ($4.00 exercise price; expiring July 2023)	187,500
April 2018 Private Placement Warrants - Series C ($5.52 exercise price; expiring April 2025)	135,417
February 2017 Private Placement Warrants ($27.40 exercise price; expire February 2024)	352,450
All Other Warrants (exercise price >$196.00; expiring July 2022 to October 2024)	243,154
Employee Options and RSUs	
2018 Stock Options (exercise price of $4.22)	4,336,557
2019 Stock Options (exercise price range from $3.95 to $4.60)	1,146,000
Other Stock Options (exercise prices > $24.60)	75,234
Restricted Stock Units	161,250
Fully Diluted Shares Outstanding	**60,978,783**

Windtree Therapeutics Portfolio

Late-Stage Programs in Cardiovascular and Acute Pulmonary

Cardiovascular

Istaroxime
for the Treatment of Acute Heart Failure

+ Pre-Clinical Oral, Heart Failure Candidates and Programs:

CV-IST2
(Next Generation Dual Action SERCA2a)
Oral & i.v. for chronic and acute heart failure

SERCA2a
(Selective Action)
Oral & i.v. for chronic and acute heart failure

Rostafuroxin
for genetically targeted resistant hypertension and renal impairment

Acute Pulmonary

AEROSURF®
for noninvasive treatment of RDS

Lyophilized KL4 Surfactant (LS)
for RDS

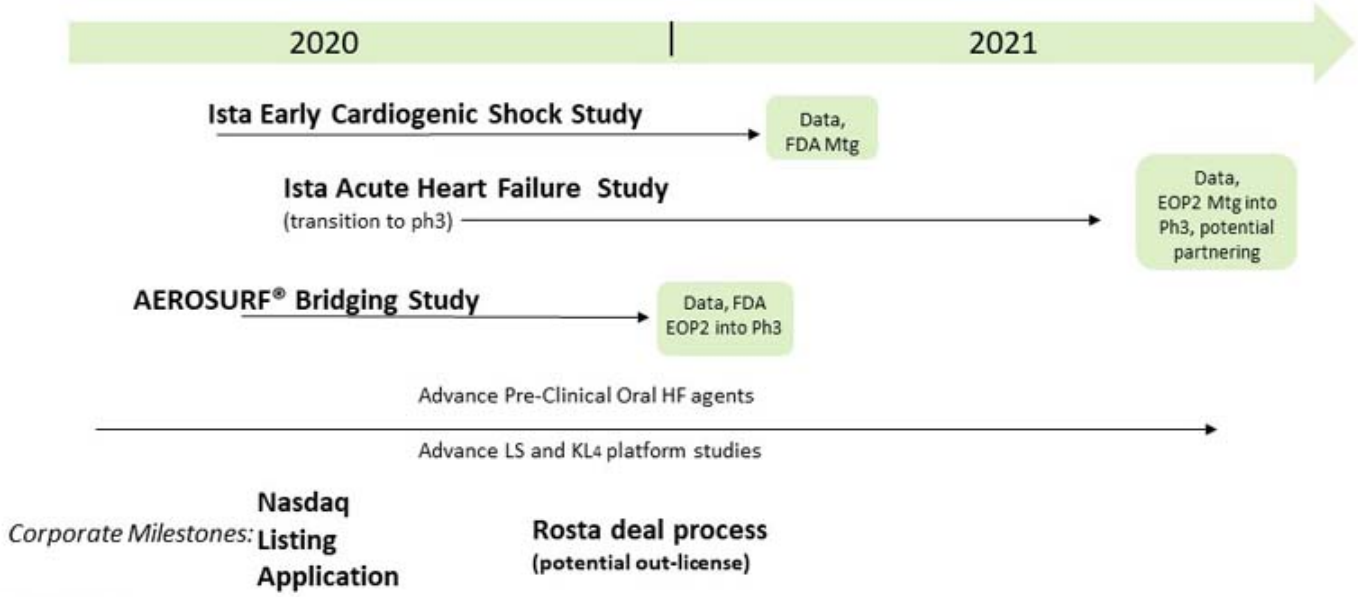
+ Pre-Clinical Programs:

Eleison
aerosol oncology collaboration

KL4 Platform
for lung protection and drug delivery

Strategy for Value Creation
Planned Milestones

- **Three late-stage programs** focused on significant markets with unmet needs
- **Multiple clinical and business milestones which have the potential to be catalysts**
- Highly-experienced management team conducting **smart, rigorous execution** and leveraging opportunities for **acceleration and non-dilutive funding** of development
- **Business development initiatives for the realization of value**



Istaroxime

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

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Heart Failure -
Significant Healthcare Issue with Significant Unmet Clinical Need

- 6 million patients in the U.S. and over 18 million worldwide. The prevalence of HF is on the rise as is mortality
- **#1 cause of hospitalizations in** patients over 65 years old **in the United States** and Western Europe with **greater than 1.3 million admissions annually in US and ~1.5 million in the EU**
- **Inpatient mortality** is ~7% and 30-day mortality can exceed 10%
- **HF has a significant cost**. Heart failure is the most expensive of the Medicare diagnoses in the U.S.
- Due to the unmet need and lack of therapeutic advances, the **FDA issued new heart failure guidance** in July 2019 reflecting greater flexibility to support development

Heart Failure -
Significant Healthcare Issue with Significant Unmet Clinical Need

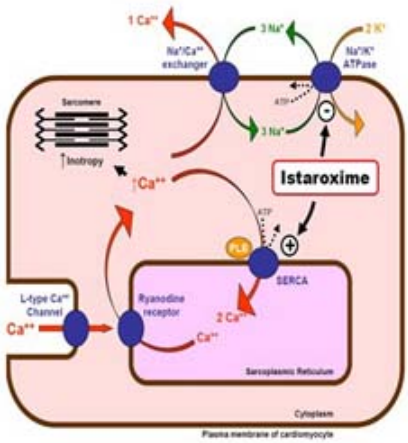
- Despite the need, **there has not been a meaningful new therapeutic advancements** in acute heart failure for decades

- **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

- **Low blood pressure and peripheral hypoperfusion are high risk**, challenging patients. They are also **generally resistant to diuretic therapy and often discharged in a sub-optimal state**

Istaroxime – Novel First-in-Class Therapy

- Novel, intravenous agent designed to improve systolic contraction and diastolic relaxation and fill function of the heart
- Unique, ***dual*** **mechanism of effect that has been shown to impact *both* systolic and diastolic dysfunction**
  - Inhibition of the sodium-potassium pump and effects on the sodium-calcium exchanger results in more calcium available for contraction (systolic effect)
  - Stimulation of SERCA2a activity **enhances calcium reuptake** improving the relaxation-contraction cycle resulting in improved diastolic ventricular function



Istaroxime Development

Leveraging the Istaroxime Profile to Produce Positive Results

Istaroxime is being developed with the objective to improve cardiac function without the unwanted side effects of existing therapies

6 studies with 3 doses in 280 patients:

Phase 2a

- **Hospitalized with AHF**; LVEF ≤ 35%, SBP 90-150 mmHg
- **6-hour infusion of 0.5, 1.0, 1.5** ug/kg/min or placebo
- **N=120** (conducted in EU)

Significant improvement in primary endpoint of pulmonary wedge pressure and blood pressure. Heart rate was lower. Istaroxime was generally well tolerated with no unexpected AEs

Phase 2b

- **Hospitalized with AHF**; LVEF ≤ 40%, **SBP 90-125** mmHg
- **24-hour infusion of 0.5 or 1.0** µg/kg/min or placebo
- **N=120** (in EU and Asia)

Istaroxime Phase 2b Study - Summary

- A 24-hour infusion of istaroxime at doses of 0.5 and 1.0 µg/kg/min was associated with **significant improvements in diastolic and systolic cardiac function** at 24 hours.
  - **The primary endpoint, E/e' at 24 hours, was significantly ($p<0.05$) improved by both doses of istaroxime**
  - **Stroke volume was substantially increased** at 24 hours

- **Uniquely, istaroxime maintained / increased systolic blood pressure; renal function also tended to improve**. Additionally, **heart rate decreased**.

- Istaroxime was generally well tolerated with no unexpected adverse events. There were **no major concerns related to arrhythmias** (as it appeared to have a favorable profile vs. placebo) **and cardiac Troponin T**; **pain at infusion site** was reported primarily with short catheters and GI symptoms primarily with high dose.

Istaroxime – Acute Heart Failure – Program Status

1. The Company has worked with top Heart Failure advisors and has had positive engagement and guidance from the FDA
   - ✓ The FDA granted Fast Track designation to the program in July 2019
2. The Company plans to transition istaroxime to phase 3-ready and partnership position by executing an additional study that is expected to complete phase 2 and inform phase 3 to:
   - ✓ leverage the characteristics of istaroxime in a target population that most particularly may benefit from the unique attributes of the drug – patients with low blood pressure and/or diuretic resistant
   - ✓ increase infusion time to greater than 24 hours (ideally 48 – 72 hours)
   - ✓ include endpoints acceptable to the agencies for approval (and that support commercial / payer messaging)
3. Study start-up activities are expected to commence in the second half 2020 and the study has the potential to be a major catalyst to the program and for the Company

Early Cardiogenic Shock Treatment

Istaroxime Potential Opportunity for Accelerated 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

- Cardiogenic shock is an area of **extreme unmet need** with no satisfactory pharmacologic interventions to reverse the condition, thus it has a **high associated mortality and morbidity**

- Because of the unmet need, there are **potential opportunities for an accelerated regulatory pathway and review**.
  - FDA outlines regulatory guidance: Sponsors are **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.** (Precedent: NDA for Giapreza® (IV Angiotensin II), approved in 2017 for increasing MAP in distributive shock)[2]

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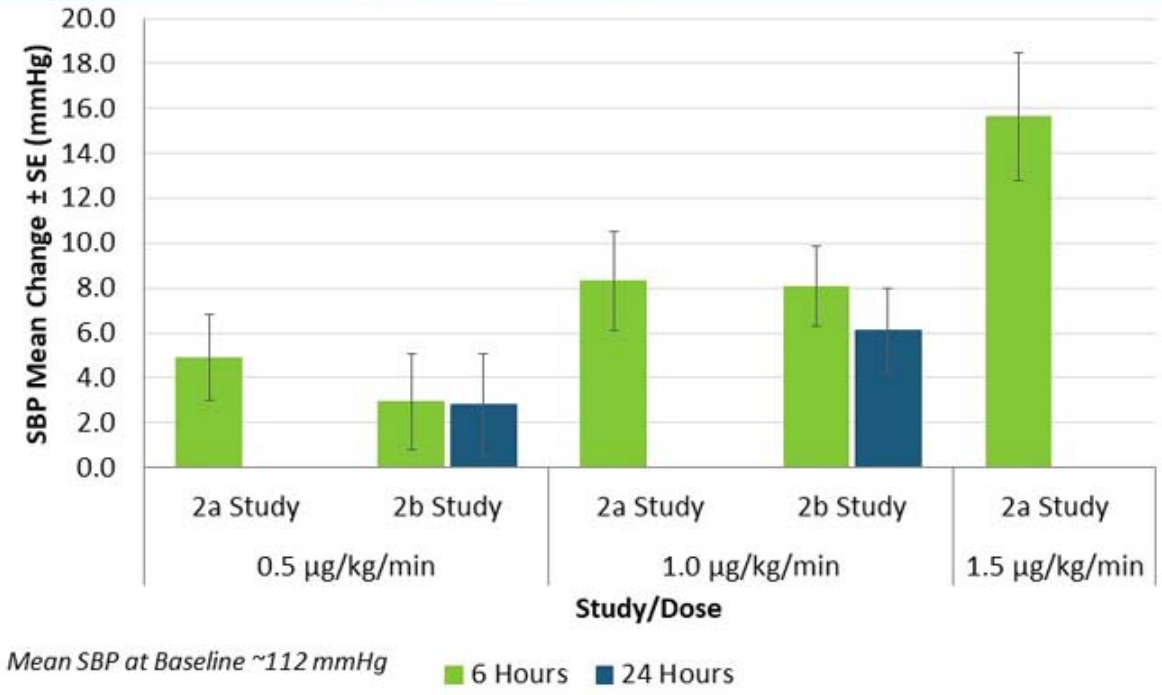
1) Kosaraju A, Hai O. Cardiogenic Shock. [Updated 2019 Jan 25]. In: https://www.ncbi.nlm.nih.gov/books/NBK482255/
CSRC Think Tank - July 24, 2019
[2] Senatore et al., Am J Cardiovasc Drugs, February 2019, Volume 19, Issue 1, pp 11–20 (https://doi.org/10.1007/s40256-018-0297-9)

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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Rationale for Istaroxime in Early Cardiogenic Shock

- Dose related changes in systolic blood pressure in the phase 2 clinical program suggest a meaningful increase in blood pressure may be achieved in early cardiogenic shock by istaroxime

- Improving systolic and diastolic cardiac function without increasing heart rate, risk for arrythmias, or myocardial oxygen demand (based on preclinical studies) would be beneficial in these patients

- The Company plans to execute a study in early cardiogenic shock while preparing to start the larger phase 2b acute heart failure study

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Novel Heart Failure Portfolio-

Oral and IV SERCA2a Activators for Chronic & Acute Heart Failure

Dual Mechanism SERCA2a Activators

- SERCA2a activators with Na^+/K^+ pump inhibitory activities
- As oral and i.v. therapies for AHF and/or chronic heart failure (CHF)

Selective SERCA2a Activators

- Selective SERCA2a Activators devoid of any Na^+/K^+ pump inhibitory activities
- As oral and i.v. therapies for AHF and/or CHF
- Select SERCA2a is an attractive approach for heart failure with preserved ejection fraction (HFpEF)

These next generation agents and platform are to be part of a complete chronic and acute portfolio opportunity for licensing / partnership

Heart Failure is a therapeutic area of focus for many large pharmaceutical companies and SERCA2a is of particular interest

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AEROSURF®

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

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

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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**

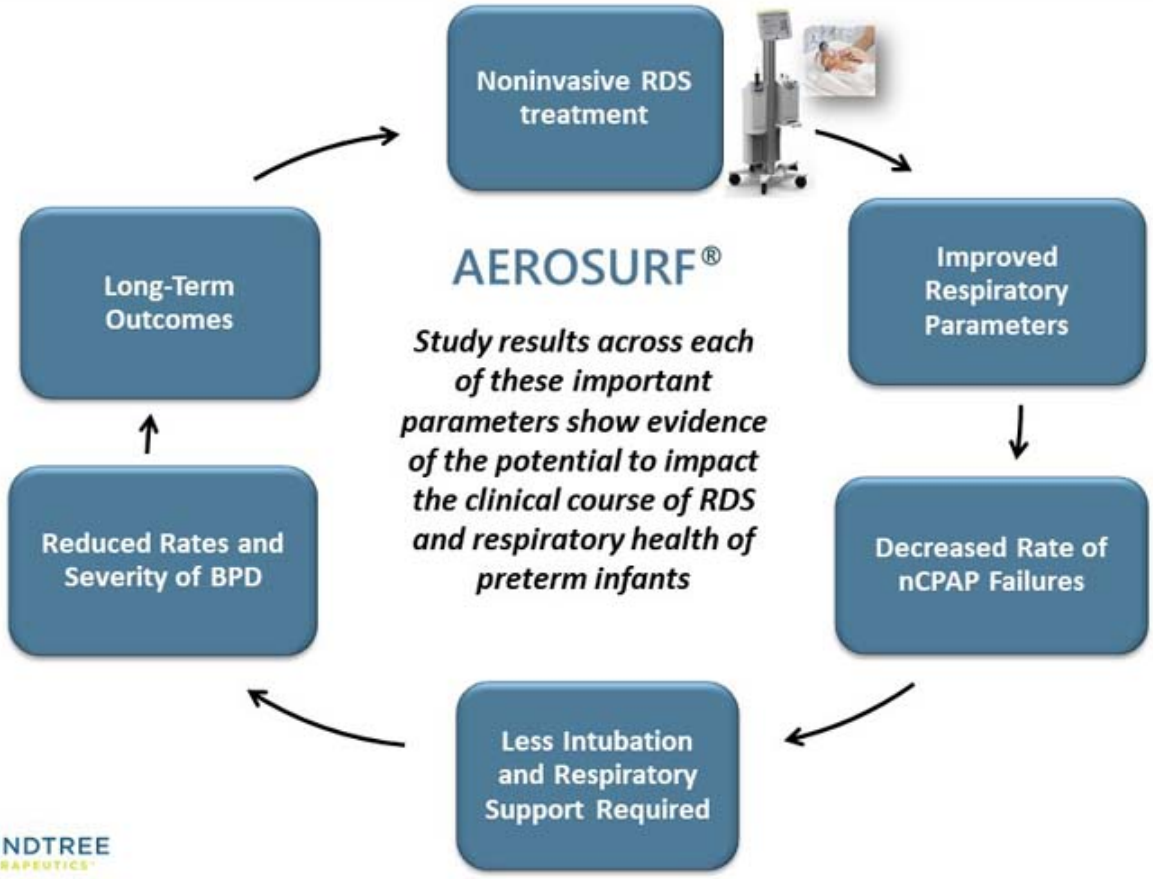
Utilizing pressure and heated capillary has demonstrated ability to **aerosolize KL4 surfactant**

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

AEROSURF® - Potential to Impact the Clinical Course of RDS

Building Evidence From 350 Patients Studied



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AEROSURF® Program Evolution and Strategy

Mitigating Risks and Strengthening Our Approach

Program Evolution

- The three phase 2a and 2b clinical trials have **reproduced efficacy in reducing nCPAP failure and the need for intubation when dosed as intended** and observed **important positive BPD data.**
  - AEROSURF has received Fast Track and Orphan designations
- The Company has transitioned to the **newly developed ADS**, which is designed for consistent performance, faster time to treatment and improved ease of use, potentially enabling better clinical outcomes
- The AEROSURF safety profile supports **employing a dosing regimen to deliver more surfactant in a shorter period of time**

Program Strategy

- **Execute a small (n=70) Bridging Study to transition to EOP2 / phase 3,** demonstrate that the new ADS works, and supplement phase 2 data with optimized dosing
- **Leverage Lee's Pharm partnership for non-dilutive** funding of clinical and participation in execution
- The Company plans to continue ongoing Business Development activities

Potential Drivers of AEROSURF® Opportunity

$1.2B+ AEROSURF® Potential [3] (see appendix)

#1
stated unmet need in RDS

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

20-30%
reduction in nCPAP failure is meaningful

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

BPD: "A trend of >20% reduction in BPD = 70+% in expected patient share"

⬆Price
(but ⬇Total Hospital Cost)

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

Market Expansion

Potential to bring surfactant therapy to new, lower skilled and less capable hospitals and geographies due to noninvasive , less specialized delivery

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

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Rostafuroxin

for genetically targeted resistant hypertension and renal impairment

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Hypertension Market –
A Unique, Genetically-Targeted Approach

- **Hypertension is a very large market with high unmet need**
  - Over 1/3 of the adult population in the U.S. has hypertension and the majority of treated patients (50-85% globally) do not reach target for control. Well known that ethnicity can impact response to different classes of agents
- **Uncontrolled/resistant hypertension has been associated with certain genetic subsets of the population**
  - Adducin polymorphisms and endogenous ouabain can trigger hypertension by enhancing renal tubular sodium reabsorption and increasing vascular tone
- **Rostafuroxin is designed to be a potent and selective antagonist of ouabain and of the mutant adducin molecule and the functional effects**
  - Phase 2a and 2b demonstrated the possibility to reduce blood pressure in a ***genetically identified subset of patients representing approximately 28%*** *of hypertensives*
  - While the blood pressure reduction in Caucasians was notable in the phase 2a and 2b trials, blood pressure response in Chinese patients was dose ordered but significantly less pronounced at the same doses. The Company is exploring the reasons for the differential response in populations.

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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 – Partner 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

Clinical and Business Strategy for Value Creation

Deliver Milestones, Execute Transactions

- **Istaroxime:** Study early cardiogenic shock to explore potential accelerated pathway for this indication. Complete Ista AHF phase 2 clinical program and develop strong phase 3 and partnership position. To create added value, advance oral (chronic) product candidates through proof of concept.
- **AEROSURF®:** transition to phase 3 with bridging study; leverage partnerships and non-dilutive funding.
- **Rostafuroxin:** out-license and use proceeds to provide non-dilutive funding of other, core programs.
- **Business Activities:** Nasdaq listing application, news flow and BD activities.

Windtree Therapeutics

"Striving to deliver Hope for a Lifetime!"